A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

Mapa Mudiyaselage Prabhath Nishantha Piyasena

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Department of Clinical Research

Faculty of Infectious and Tropical Diseases

London School of Hygiene and Tropical Medicine

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Declaration

I, Mapa Mudiyanselage Prabhath Nishantha Piyasena confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been appropriately indicated in the thesis.

Sign -

Date - 16th April 2019

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Local Collaborator

Association of Vitreo-Retina Specialists of Sri Lanka at the National Eye Hospital - Colombo - Sri Lanka.

The funder and local collaborator are not involved in the study design, data collection, analysis or manuscript preparation.

Main Supervisor

Professor GVS Murthy

Co-Supervisor

Associate Professor Jennifer Yip

Advisory Panel

Professor Clare Gilbert

Professor Tunde Peto

Associate Professor David MacLeod

Mrs.Maria Zuurmond

List of abbreviations

CI - Confidence interval

DCCT - Diabetes control and complications trial

DM - Diabetes mellitus

DNA - Did not attend

DR - Diabetic retinopathy

DRS - Diabetic retinopathy screening

DRSP - Diabetic retinopathy screening program

DRSS - Diabetic retinopathy screening services

DTA - Dignostic test accuracy

ETDRS - Early treatment diabetic retinopathy study

F - Female

FGD - Focus group discussion

FN - False negative

FP - False positive

Gr 1 - Grader one

Gr 2 - Grader two

HbA1c - Haemoglobin A1 C

HE - Health education

HEI - Health educational intervention

HIC - High income countries

HR - Human resources

HSROC - Hierachial summary receiver operating characteristic

ICO - International council of ophthalmology

IDF - International diabetes federation

K - Kappa

LIC - Low income countries

LMIC - Low and middle-income countries

M - Male

M - Moor

MO - Medical officer

MOH - Medical officer of health

MOH - Ministry of Health

NCD - Non-communicable diseases

NICE - National institute of healthcare excellence

NO - Nuclear opalescence

NPDR - Non-proliferative diabetic retinopathy

NPV - Negative predictive value

OR - Odds ratio

PCO - Posterior capsular opacity

PDR - proliferative diabetic retinopathy

PEMAT - Patient education materials assessment tool

PICOC - Population, intervention, comparison, outcome and context

PwDM - People with diabetes mellitus

PPV - Positive predictive value

PRISMA - Preferred reporting items for systematic reviews and meta-analysis

QUADAS - Quality assessment tool for diagnostic accuracy studies

ROC - Receiver operating characteristic

S - Sinhala

SSI - Semi-structured interviews

STDR - Sight threatening diabetic retinopathy

T - Tamil

TN - True negative

TP - True positive

TRD - Tractional retinal detachment

UKPDS - United Kingdom prospective diabetes study

UMIC - Upper middle-income countries

WESDR - Wisconsin epidemiologic study of diabetic retinopathy

WHO - World health organization

ABSTRACT

Background

Diabetic retinopathy (DR) is a common microvascular complication of diabetes mellitus which can lead to sight loss, if not detected and treated in time.

Objectives

This study aimed to assess the feasibility of integrating DR screening (DRS) services into free public sector health care in Sri Lanka. The objectives were to identify barriers to access DRS, to determine the most appropriate DRS modality and to assess acceptability of a health educational intervention (HEI).

Methods

The study was conducted using mixed methods. The barriers were assessed through systematic literature search and qualitative studies. A systematic literature review and meta-analysis was conducted to assess the diagnostic accuracy of DRS using digital retinal imaging. Based on the results of the formative stages, a local context specific DRS modality was defined and validated at a tertiary level medical clinic by trained physician graders. Finally, a HEI was adapted and acceptability was assessed using participatory approach.

Results

The formative studies revealed that lack of knowledge and awareness on DR, lack of skilled human resources and DRS imaging infrastructure as the main barriers. In the meta-analysis, highest sensitivity was observed in mydriatic more than two field strategy (92%, 95% CI 90-94%). In the validation study, sensitivity of the defined referable DR was 88.7% for grader 1 and 92.5% for grader 2, using mydriatic imaging. The specificity was 94.9% for grader 1 and 96.4% for grader 2. The overall acceptability of the HEI material was satisfactory.

Conclusions

Knowing the barriers to access DRS is a pre-requisite in development of a DRS program. Non-mydriatic 2-field strategy is a more pragmatic approach in implementing DRS programs in low income non-ophthalmic settings, with dilatation of pupils of those who have ungradable images. The process of adapting HEI was not simply translation into local language, instead a tailored approach for the local context.

Preface

Format of the thesis

The present PhD thesis is in the 'research paper' format. It includes a number of research articles, published, or submitted / formatted for submission to peer reviewed indexed journals. The listed chapters are therefore formatted this way and include publication details in a cover sheet, which includes acknowledgment of the contributions of other people I worked with locally in Sri Lanka and at the London School of Hygiene and Tropical Medicine - United Kingdom. The information, data and interpretations that are not presented or included in the published articles / submitted manuscripts have been included as linking chapters.

I, Mapa Mudiyanselage Prabhath Nishantha Piyasena wrote the published articles, submitted manuscripts and the linking chapters.

Sign -

Date - 16th April 2019

CONTENT

List of Publications

Publication details	Status of publication
1.Piyasena MMPN, Gudlavalleti VSM, Gilbert C, Yip JL, Peto T, MacLeod D, Fonseka C, Kulatunga A, Bandutilake B, Dhanapala M, Pathirana L, Dissanayake H. Development and Validation of a Diabetic Retinopathy Screening Modality Using a Hand-Held Nonmydriatic Digital Retinal Camera by Physician Graders at a Tertiary-Level Medical Clinic: Protocol for a Validation Study. JMIR Res Protoc 2018;7(12): e10900. DOI: 10.2196/10900. PMID: 30530458. PMCID: 6305894	Published
2.Piyasena MMPN, Murthy GVS, Yip JYL, Gilbert C, Zuurmond M, Peto T, Gordon I, Hewage S, Kamalakannan S. Systematic Review on Barriers and Facilitators for Access to Diabetic Retinopathy Screening Services in Different Income Settings. PLoS ONE. 2019;14(4): e0198979. https://doi.org/10.1371/journal.pone.0198979	Published
3.Piyasena MMPN, Murthy GVS, Yip JYL, Gilbert C, Peto T, Premarathne M, Zuurmond M. A Qualitative Study on Barriers and Enablers to Uptake of Diabetic Retinopathy Screening by People with Diabetes in the Western Province of Sri Lanka. Trop Med Health. 2019 May 17;47:34. doi: 10.1186/s41182-019-0160-y. PMID: 31139011	Published
4.Piyasena MMPN, Murthy GVS, Yip JYL, Gilbert C, Zuurmond M. Service Providers' Perspectives on Barriers and Enablers to Provision of Diabetic Retinopathy Screening Services in the Western Province of Sri Lanka. Submitted and Reviewed - BMC-Health Services Research.	Submitted and reviewed.

5.Piyasena MMPN, Murthy GVS, Yip JYL, Gilbert C, Peto T, Gordon I, Hewage S, Kamalakannan S. Systematic review and meta-analysis of diagnostic accuracy of detection of any level of diabetic retinopathy using digital retinal imaging. BMC Systematic Reviews 2018;7(1):182 PMID: 30404665 PMCID: PMC6222985 DOI: 10.1186/s13643-018-0846-y	Published
6.Piyasena MMPN, Yip JYL, MacLeod D, Kim M, Murthy GVS. Diagnostic Test Accuracy of Diabetic Retinopathy Screening by Physician Graders Using a Hand Held Non-Mydriatic Retinal Camera at a Tertiary Level Medical Clinic. BMC-Ophthalmology. 2019;19(1):89 PMID: 30961576 PMCID: PMC6454614 DOI: 10.1186/s12886-019-1092-3	Published
7.Piyasena MMPN, Zuurmond M, Yip JYL, Murthy GVS. Process of adaptation, development and assessment of acceptability of a health educational intervention to improve referral uptake by people with diabetes in Sri Lanka. BMC Public Health (2019) 19:614. doi: 10.1186/s12889-019-6880-4. PMID: 31113393	Published

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Health educational intervention videos and leaflets contain in a CD-ROM in the back cover.

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ACKNOWLEDGEMENTS

This work is dedicated to my mentor, Professor GVS Murthy who has guided and supported me this journey in public health for eye care, where it was totally a darkness in my country. As the very first research degree student from Sri Lanka in this field, I had many difficulties in sailing through this project. I have been very lucky to have a supervisor who cared so much about my work as well as other matters in a difficult life of a research degree student. I am deeply indebted to Professor GV for the encouragement, constant supervision and advices provided throughout my time as his student starting from my master's degree in the year 2013. Professor GV's inimitable and exuberant style of inspiration was the driving force me to follow this path. In fact, I think that this is just a beginning considering the need of my community and for my country, where I would expect to continue working with him in future endeavours.

I must express my sincere gratitude to my wife Suvini, my parents and my father-in-law for their continued support and encouragement. I will remember forever, the caring given by them without any hesitation, tolerating all the ups and downs during past few years. Without their support I would not be able to achieve any of these milestones in my life. I would immensely thankful to my elder sister for looking after our house bound father with many chronic illnesses and for my elder sister-in-law and brother-in-law for providing their valuable house for my own use in Colombo. As I was on non-paid leave for this studentship from my former employment, continuing with the research degree would be nearly impossible without the family support.

I would also immensely thankful to my co-supervisor Associate Professor Jennifer Yip for the constant support provided to me starting from preparation of this project proposal and funding application in the year 2015. I would express my sincere thanks to Associate Professor Jennifer Yip for the encouragement and supervision provided throughout this research degree.

A special thanks to my advisers Professor Clare Gilbert, Professor Tunde Peto, Associate Professor David MacLeod and Maria Zuurmond for their constant support in my academic work. Their patience and dedication, especially when things went wrong were very much appreciated.

I would also very much thankful to the my former supervising consultant ophthalmologists Dr.Charith Fonseka, Dr.Kapila Banduthilaka and Dr.Mangala Dhanapala at the National Eye Hospital - Colombo - Sri Lanka and the consultant physician at the National Hospital of Sri Lanka - Dr.Aruna Kulatunaga for their constant support in conducting the field work in Sri Lanka. I would also thankful to the office bearers of the Association of Vitreo-Retina Spcialists of Sri Lanka for the logistical and administrative support provided in conducting this project.

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I wish to express my great appreciation to the statisticians who supported me in this project Dr. Suwin Hewage from Sri Lanka and research fellow Min Kim at the London School. They were always there for me to help day and night.

I also record my sincere thank to the physician graders Dr. Heshani Dissanayake and Dr. Lalani Pathirana who conducted the validation study at the medical clinic of National Hospital of Sri Lanka. Further, I extend my thanks to all the members of the research team, pre-intern medical graduates and sociologists at the National Eye Hospital of Sri Lanka. I greatly appreciate their dedicated work, to make this project a success in Sri Lanka.

Completing this research degree would have been more difficult without the support and friendships provided by all the staff members of the International Centre for Eye Health and International Centre for Evidence in Disability at the London School of Hygiene and Tropical Medicine - United Kingdom. Every time I visit there for my academic work, all were encouraged me achieving this target.

CONTRIBUTORS OF THE PROJECT WORK

The following table describes the contributors to the project other than supervisors or advisers at the London School of Hygiene and Tropical Medicine - United Kingdom.

Role	Name of the person	Position	Contribution
Upgrading Panel	Prof. Allen Foster Prof.Sanjay Kinra	Professor of International Eye Health - LSHTM Professor in Clinical Epidemiology - LSHTM	PhD upgrading examiner PhD upgrading 2nd examiner
Department Research Degrees Coordinator	Associate Professor Sarah Polack	Associate professor at the International Centre for Evidence in Disability	Department research degrees coordinator
Principal Investigator in the local institution	Dr. Charith Fonseka	Consultant Ophthalmologists - National Eye Hospital - Sri Lanka	Supervision of the project work in Sri Lanka
Sri Lanka Project Team - Reference test grader	Dr. Kapila Banduthilaka	Consultant Vitreo-Retinal Surgeon - National Eye Hospital - Sri Lanka	Conducting the reference standard test of the validation study
Sri Lanka Project Team	Dr. Mangala Dhanapala	Consultant Vitreo-Retinal Surgeon - National Eye Hospital - Sri Lanka	Management of the screened people with diabetes at the validation study
Sri Lanka Project Team	Dr.Aruna Kulatunga	Consultant Physician - Professorial Medical Unit - National Hospital of Sri Lanka - Colombo	Supervised the project work at the medical clinic
Sri Lanka Project Team	Dr.Udaya Dissanayaka	Consultant Physician - Out-patient medical clinic - District General Hospital - Gampaha	Supported in formative research work at the medical clinic

Sri Lanka Project Team - Physician graders	Dr. Heshani Dissanayaka Dr. Lalani Pathirana	Senior house officers in internal medicine - National Hospital of Sri Lanka	Screening the people with diabetes at the medical clinic, index test graders of the validation study
Co-reviewers	Dr. Suresh Kamalakannan Dr. Suwin Hewage	Assistant Professor - Indian Institute of Public Health - Hyderabad Freelance research consultant - Sri Lanka	Co-reviewers in conducting the systematic literature reviews
Statistician	Dr. Suwin Hewage Min Kim	Freelance research consultant - Sri Lanka LSHTM - UK	Supported in statistical analysis
Information Specialist	Irish Gordon	LSHTM - UK, Cochrane Eye and Vision Group	Preparation of data bases search terms and guided in conducting the systematic reviews
Sri Lanka - Research Team - Sociologist	Mahesh Premarathne	Lecturer and PhD candidate - Department of Sociology - University of Colombo	Guided in conducting the qualitative research and data analysis in local languages (Sinhala Medium)
Sri Lanka - Research Team - Sociologist	Kathirgamathamby Krishnaraj	Lecturer and PhD candidate - Department of Sociology - University of Colombo	Guided in conducting the qualitative research and data analysis in local languages (Tamil Medium)
Sociologist and Tri-lingual Translator	Rameeza Khan	Translator at National Institute of Social	Translations in health educational intervention

		Development - Colombo - Sri Lanka	development, conducting participatory workshops in Tamil medium, conducting health educational intervention assessment in Tamil medium
Sri Lanka - Research Team - Sociologist	Chandima Abewickrama	Program coordinator at PLAM Foundation - Nuwara-Eliya - Sri Lanka	Translations in health educational intervention development, conducting participatory workshops in Sinhala medium, conducting health educational intervention assessment in Sinhala medium
Sri Lanka - Research Team - Research Assistants	Dr.Subhash Pathirana Dr.Rukman Bandara	Pre-internship medical graduates	Assisting conducting the formative - qualitative research components
Sri Lanka - Research Team - Research Assistants	Dr.Renuha Bal-asubramaniyam Dr.Abdul Quadir Dr. Asanka Gunatunga Dr. Ruwanthi Samara-singhe Dr.Chathurangi Konara Dr.Anjali Umayangana Dr.Haritha Murage Dr.Sankika Mahanama	Pre-internship medical graduates	Assisting conducting the screening intervention validation study and health educational intervention study

Sri Lanka - Research Team - Research Assistants	Dr.Missaka Banadara	Pre-internship medical graduates	Designing the leaflet in local languages and conducting the pre-shootings of the video intervention
Sri Lanka - Research Team - Research Assistants	Dr.Varagini Varatha-rajah	Pre-internship medical graduates	Performed as an ophthalmologist in the video intervention in Tamil medium Conducting health educational intervention assessment in Tamil medium

Preamble

Backgorund of the research student and how ideas for the thesis developed

I started working as an ophthalmic medical officer at the National Eye Hospital - Colombo, starting from the year 2010 after selection through a competitive examination conducted by Post Graduate Institute of Medicine of the University of Colombo. Following which, I underwent training in general ophthalmology for 1 year and in vitreo-retina sub-specialty for 2 years. The lead retinologists of the retinal department at the National eye Hospital - Colombo, assigned me with the task of handling issues related to patients awaiting trans pars plana vitrectomy (TPPV), as he observed a particular rise in the number of patients requiring the surgery. This was the only functioning retinal unit in the country at that time. With the opportunity, I conducted a cross sectional survey of the patients who were referred for treatment. In which, I was able to reveal that the majority (>90%) of the patients who were awaiting TPPV surgery had diabetes mellitus (DM) and significant proportion had advanced diabetic retinopathy (DR) and tractional retinal detachments.

It also found that a major cause of delayed presentation was lack of knowledge and awareness on DR. This led to my preliminary work on prevention of blindness and visual impairment on DR, leading to a master's dissertation on situational analysis of availability of services for DR in the Western province of Sri Lanka. This foundation helped me to design the present study, leading to an application for a research degree at London School of Hygiene and Tropical Medicine-UK and a grant application to the Queen Elizabeth Diamond Jubilee Trust through the Commonwealth Eye Health Consortium-UK. My experience with relevant clinical work, identification of the local community need, evidence from the master's dissertation and guidance from the supervisor were helpful in developing a strong research question for this PhD project.

Chapter 1

INTRODUCTION

1.1 Global burden of diabetes mellitus

Diabetes mellitus (DM) is one of the most prevalent non-communicable diseases. DM imposes a significant impact on global health systems. In the latest estimations of International Diabetes Federation (IDF), there were 425 million people with DM (PwDM) (2017) and this will increase to 629 million by 2045 [1.1] (Figure 1.1). Other estimates representing 130 countries indicate an increase to 592 million by the year 2035 [1.2]. DM prevalence increases by 2.8-3.0% annually worldwide [1.3] and causes a significant economic impact on the health systems globally [1.4]. The increase in the prevalence of DM will be much higher (69%) in low and middle income countries (LMICs) in the next decade compared to the high-income countries (HIC) (20%) [1.5]. The highest number of PwDM are aged 40-59 years currently and this will shift to those aged 60-79 years by 2030 [1.5] (Figure 1.2). No country has shown a significant reduction in the prevalence of DM from 1980 to 2014 [1.6]. This suggests that DM is a major public health problem and will remain so in the future too.

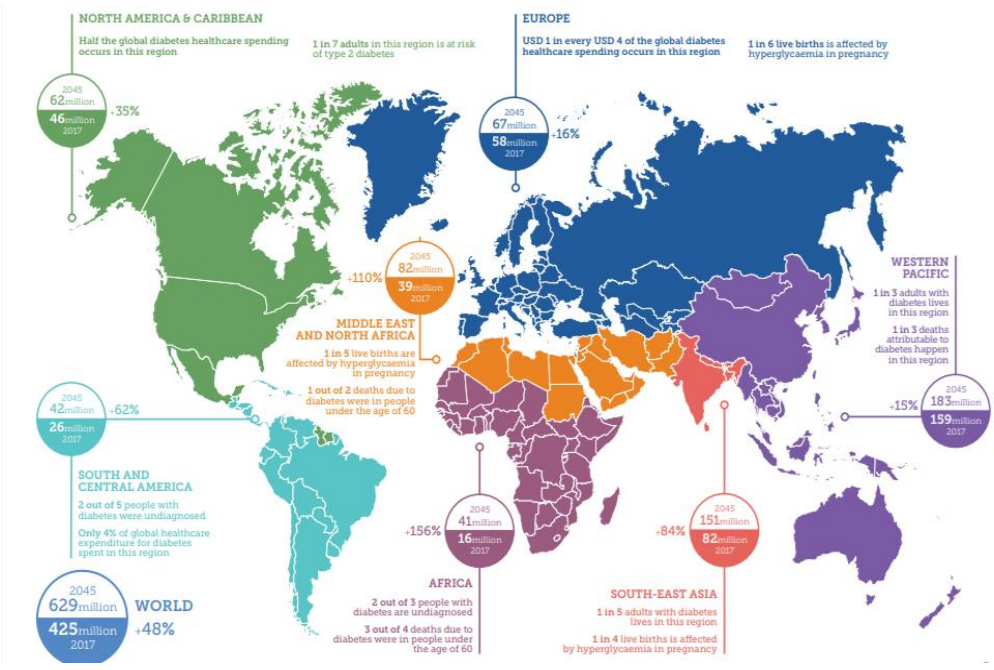


Figure 1.1 - Regional estimates of diabetes prevalence in 2017 and prediction for year 2045 [Developed by International Diabetes Federation] [1.1].

Most of the reviews concluded that the burden of DM was much higher in low and middle-income countries (LMIC). This is expected to result in an increasing number of PwDM with complications [1.2,1.6,1.7]. The LMICs are facing an epidemiological transition from communicable to non-communicable diseases. The prevalence of DM is growing relatively faster even in rural LMICs compared to rural populations in HIC (1985-1989 to 2005-2011: rural LMIC 1.8% to 7.5% and rural HIC 8.2% to 14.3%) [1.8]. A rapid rise in prevalence of type 2 DM has been reported from the South East Asia region and the South Asian region. This could be due to changes in socio-economic and demographic profiles [1.9,1.10]. The percentage increase in prevalence of DM from 2010 to 2030 is 72.1% in South Asia [1.5] (Table 1). Further, there are high proportions of undiagnosed PwDM in LMICs (overall 83.8%, in South East Asia region: 35.8-69.5%, 20-79 years age group). PwDM in these countries are identified late and therefore report with more advanced complications leading to an economic burden on the health systems [1.11]. Therefore, strategies for planning of diabetic care and its complications are needed to address this key global health issue.

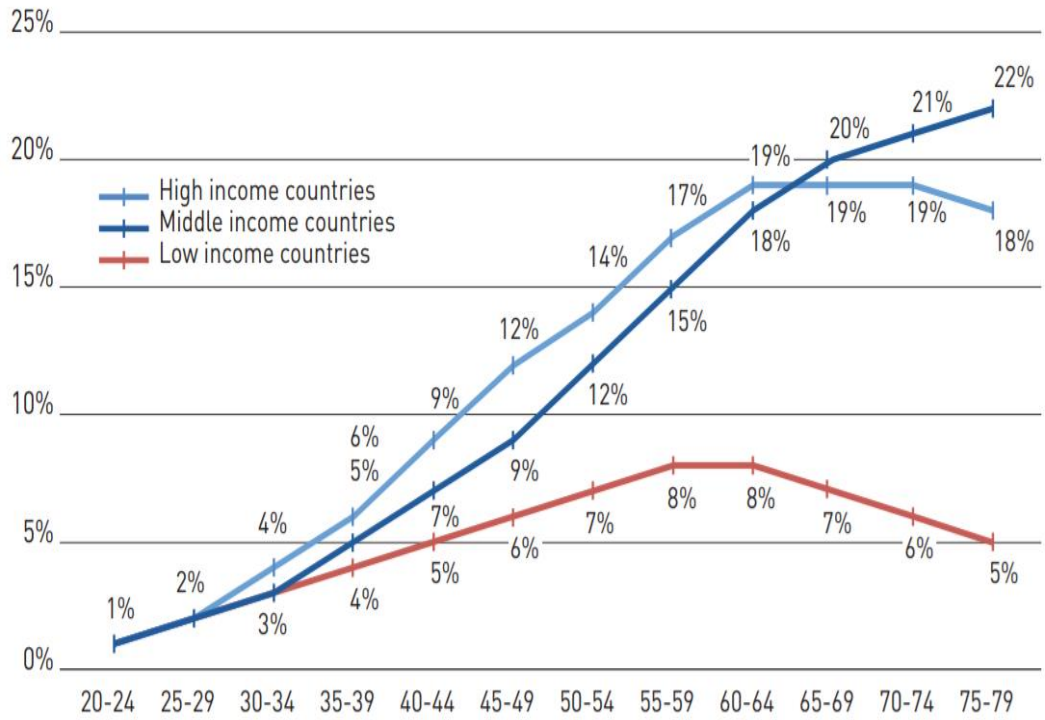


Figure 1.2 - Prevalence estimates of diabetes by income and age group [Developed by International Diabetes Federation] [1.1].

Many countries spend a significant proportion of their health budgets (5-13%) on DM, resulting in a significant burden on economy [1.12]. The situation is further aggravated by aging of the populations, complexities in disease management and rising technological costs [1.13,1.14]. Moreover, there is a significant disparity in this expenditure as 90% of available financial resources are being used for care of DM in HICs [1.12].

Table 1.1 - Regional predictions of prevalence of diabetes by 2030 – [Estimated by Shaw JE et al (2014)] [1.5].

Region	2010 Diabetes Prevalence (%)	2030 Diabetes Prevalence (%)	Percentage of Increase (%) from 2010 to 2030
Africa	3.8	4.7	98.1
Eastern Mediterranean and Middle East	9.3	10.8	93.9
Europe	6.9	8.1	20.0
North America	10.2	12.1	42.4
South & Central America	6.6	7.8	65.1
South Asia	7.6	9.1	72.1
Western Pacific	4.7	5.7	47.0
World	6.4	7.7	54.1

1.2 Diabetes mellitus epidemic in Sri Lanka

A rising trend of the DM prevalence has been observed in the South Asian countries in the recent past. One meta-analysis showed a high epidemicity index i.e., ratio of impaired glucose tolerance to total glucose intolerance, of DM in Sri Lanka (52.8% in year 2005/2006) compared to other South Asian countries [1.15]. This predicts a higher incidence of DM with time. Katulanda, P. et al. studied a population-based sample of 4388 (>20years) in the year 2011 and recorded a crude prevalence of DM of 12.6% [1.16]. In this study the highest prevalence of DM of 18.6% (95% CI 15.8-21.5) was observed in the Western province [1.16]. Ethnic Sri Lankan Tamils had the highest prevalence among

the ethnic groups (22.1%; 95% CI 15.2-29.1) [1.16]. Most of the studies done in Sri Lanka showed a higher prevalence of DM in Tamil ethnic group [1.17,1.18]. In addition, one study showed a higher rate of DM among the poorer groups and variable associations with socio-economic status [1.19]. Most of the studies from Sri Lanka showed a temporal increase in prevalence of DM over the past few decades and a recent study showed higher prevalence among urban populations (men 20.3% and women 19.8%) [1.20]. There is a dramatic increase of 966% in DM prevalence in Sri Lanka from 2002 to 2012 (Figure 1.3).

Table 1.2 - Prevalence of DM in Sri Lanka

Study	DM diagnostic criteria	Sample characteristics	Age of the sample	Prevalence of DM	Prevalence of DR	Generalisability
Katulanda P et al (2011) [1.16]	ADA* guidelines	N=4388 adults (population based, cluster sampling)	>20 years	12.6% Western province 18.6% (95% CI 15.8% - 21.5%)	Not assessed	Can be generalised
Pinidiyapathirage MJ et al (2012) [1.20]	FBS † >= 7 mmol/l IFG ‡ (5.6-6.9) mmol/l	N=2986 adults in one district (Western province / Urban) Randomly selected from the Electoral Registry	35 to 64 years	Men 20.3% Women 19.8%	Not mentioned	More generalizable to urban populations
De Silva P et al (2012) [1.17]	FBS >126 mg/dl	N=1234 adults (in one district)	35 - 64 years	Overall 14.7% Male 14.1%	Not assessed	Less (done only in Kalutara district)

				Female 15.2%		
Illangasekara U et al (2004) [1.21]	FBS	N=220 adults, random sample (rural Central province, same cohort of the previous study)	> 18 years	8.5%	Not assessed	Less (done only in a rural village in the Central province)
Illangasekara U et al (2002) [1.22]	Self-reported	N=1325	>18 years	2.1%	Not assessed	Less (Done only in a rural village in the Central province)

* American Diabetic Association, † Fasting Blood sugar, ‡ Impaired Fasting Glucose

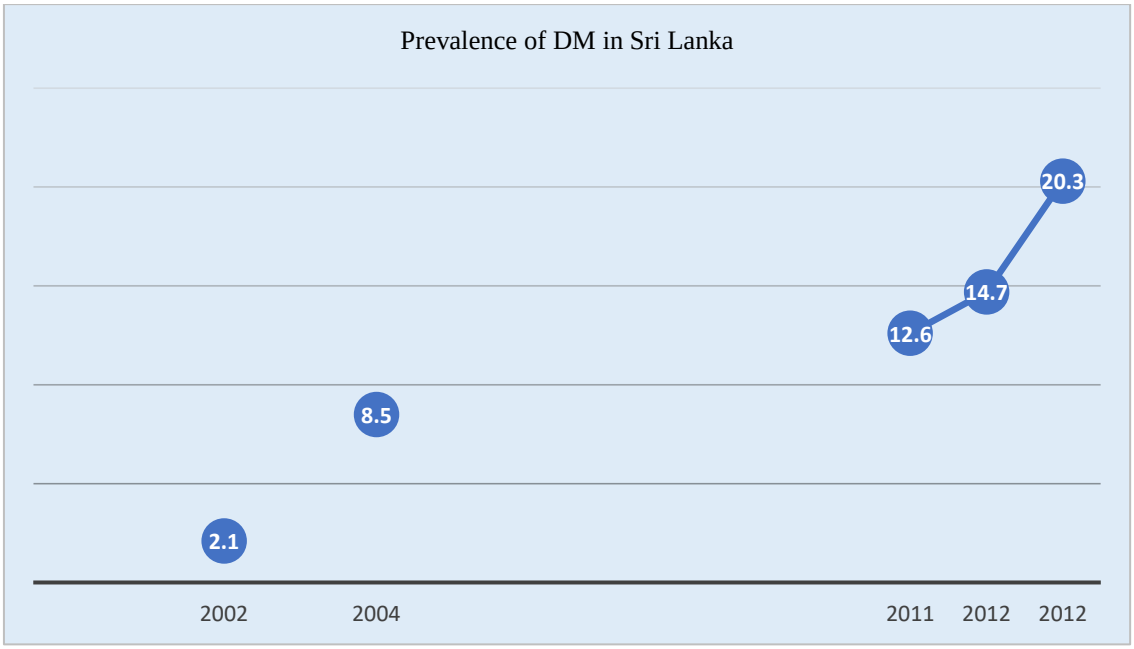


Figure 1.3 - Change of prevalence of DM in Sri Lanka over time

1.3 Epidemiology of diabetic retinopathy

1.3.1 Global magnitude of diabetic retinopathy

Diabetic retinopathy (DR) is a common microvascular complication caused by chronic hyperglycaemia [1.23]. The burden of health issues due to DR has increased globally [1.24]. It is the 5th most common cause of blindness and moderate to severe visual impairment globally [1.25] and a leading cause of blindness among the young and middle age adults of working age in HICs [1.26]. The study of global estimates of prevalence of blindness reported that DR accounted for 1% of blindness [1.27]. A recent meta-analysis showed that DR blindness could be 2.6% in 2010 affecting 0.8 million people globally [1.25]. Though the proportions are low, the visual rehabilitation of these people is a burden to any health systems and economy of a country [1.4]. Therefore, DR is of public health concern. Globally 28 million people have STDR [1.24] and 21.3 million PwDM diabetic macular oedema (DME) [1.28]. DME is expected to increase to 32.8 million by 2030 [1.28].

1.3.2 Public health significance

It is apparent that with the growing number of PwDM in the world, public health significance and attention towards DR has grown and scope for the prevention of blindness has broadened. However, we need proactive measures to overcome these issues. LMIC governments are striving for controlling the DR blindness and visual impairment in the populations, and also to achieve the goals of universal eye health coverage, mitigating inequality. Without these measures at present, we would have expected reactive responses resulting in increasing morbidity (as well as mortality). In this regard, one major requirement is availability of evidence from the local context in order to set appropriate priorities. The policy and decision makers would require evidence on burden of the condition, what works in the local context and effectiveness of those interventions. The LMICs spend very low expenditure per person in provision of diabetic care which is inadequate even for cost of the oral anti-diabetic medication per annum [1.12]. Therefore, these countries will have to adopt more innovative and cost-effective strategies to overcome DM and its complications.

1.3.3 Prevalence of diabetic retinopathy

The reported prevalence of any DR is 34.6% (95%CI 34.5-34.8%) [1.24]. Among known PwDM the prevalence of proliferative DR (PDR) is 6.96% (95% CI 6.87-7.04%) [1.24]. Available estimates suggest that the prevalence of sight threatening diabetic retinopathy (STDR) is 10.2% (95%CI 10.1-10.3%) globally [1.24]. Pooling data from 35 studies showed that the prevalence of diabetic macular oedema (DME) was 11.7% in 2010 (95% CI 11.6-11.8%) [1.28]. The prevalence of DME was high among the type 2 PwDM (Type 1: 4.2-7.9% vs Type 2: 1.4-12.8%) [1.29]. One systematic review showed that the prevalence of DR was higher among the South Asians compared to Caucasian populations [1.30]. However, another review concluded that racial differences were inconclusive due to inconsistencies in the studies [1.31].

In South India a prevalence of any DR of 18% (95% CI 16.0-20.1%) was reported and this is less than the overall global prevalence [1.32]. A meta-analysis conducted in India estimated that 14.9% (95% CI 10.7-19.0%) of the PwDM (>30 years of age) have DR which increased to 18.9% (95% CI 14.8-21.4%) when considering those aged >50 years [1.33]. Though the prevalence of any DR is low in LMICs, the proportion with STDR could be high due to different untreated risk factors affecting DR blindness [1.30]. A higher proportion of PwDM with DME was reported in LMICs, the cause of which is not known. A review stated that the prevalence of diabetic macular oedema is high in South Asian populations (6.3%-17.6%) [1.30]. The lack of evidence from population-based studies, poor reporting of diagnosis of DM and institutional bias in samples recruited from health care facilities were concerns when reviewing evidence from LMICs [1.15,1.34].

1.3.4. Incidence / Cumulative incidence of DR

The incidence of DR and DME varies by settings and there is limited evidence from LMIC settings. The incidence of STDR and DME are declining in HIC due to better control of risk factors, early screening and treatment. On the contrary, in the LMICs this is increasing due to poor availability of control measures. Comparing the evidence from Europe and United States after 4 years of follow-up, incidence of any level of DR varies from 22.5% to 50% [1.29]. In Asian countries, there is much

higher proportion of PwDM with STDR (e.g., China, 5-year cumulative incidence of DR (46.9) and 33% had STDR) [1.29].

1.3.5 Diabetic retinopathy blindness in Sri Lanka

There are no population-based DR prevalence studies from Sri Lanka. The latest national level blindness survey conducted in 2013-2014, reported a prevalence of blindness of 1.7% (>40 years of age, 95% CI 1.3-1.9) [1.35]. A study conducted in a diabetes clinic in the year 1993 stated that prevalence of DR was 31.3% (95% CI 28.0-31.6%, n=1003) and 4.1% (95% CI 2.1-6.0%) were blind due to advanced retinal disease [1.36]. In a population-based sample of 536 PwDM, researchers documented a prevalence of any DR as 27.4% in Sri Lanka (male 30.5% and females 25.6%, p=0.41) [1.37]. Another study done on a sample of young adults (mean age 37.1±5.9 years) recorded a prevalence of any degree of DR as 18.1% (mean duration of diabetes 5.2 years) [1.38]. This study found that about 50% had not undergone previous DR screening by an ophthalmologist highlighting the need of systematic DR screening program for the country [1.38]. A recent institutional study has reported a very high prevalence of DR among the PwDM (any DR prevalence 38.6%, 35.6% among males and 40.2% among females, commonest - non-proliferative DR (NPDR) prevalence 22.2%), however this study has a high institutional bias since it provides tertiary level retinal care [1.39]. In contrast another study conducted in a sample of PwDM (n=2603, duration of DM 5-15 years -72.9%) presenting at a private sector institution in Southern Sri Lanka, reported a very low prevalence of DR (7.53%), perhaps they had more access to control of DR and majority were Sinhala ethnic group (97%) [1.40]. Another study done in the Western province of Sri Lanka including a large sample of PwDM (n=6765, 95.5% type 2 DM) reported a prevalence of DR 6.8% when DM duration < 1 year and 57.8% when > 20 years [1.41]. The evidence from Sri Lanka shows that DR is an emerging public health issue.

1.4 Strategies to control diabetic retinopathy blindness

The control of risk factors is the main primary prevention strategy to prevent development of DR. The longer duration of DM, poor glycaemic control, uncontrolled systolic blood pressure and

hyperlipidaemia are major risk factors for progression of DR [1.24]. Intensive glucose control was beneficial in reducing the progression of DR by 54% as shown in the 'Diabetes Control and Complications Trial' (DCCT, 1983-1993) [1.42]. The 'United Kingdom Prospective Diabetes Study' (UKPDS, 1977-1999) highlighted that role of hypertension in development of DR and effects of elevated lipid levels in the development of retinal complications [1.43]. In addition, UKPDS showed that intensive treatment to maintain the glycaemic levels would reduce the microvascular endpoints by 25% [1.44,1.45] (Table 1.3). The genetic susceptibility of developing DR has also been postulated [1.46]. The modifiable risk factors can be targeted for control of sight loss due to DR. One epidemiological review suggests novel risk factors of DR based on inflammatory markers (e.g., interleukin-6, tumour necrosis factors) and metabolic hormones (e.g., leptin, adiponectin) which require further confirmatory research [1.29].

Table 1.3 - Risk factors for development / progression of DR

Study	Risk factor	Outcome
DCCT [1.47] UKPDS	Glycaemic level	Progression of DR
Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR) xxii [1.48]	Male gender HbA1c Body mass index	Progression of DR
WESDR ii [1.49]	Duration of diabetes	Development of DR
WESDR xvii [1.50] UKPDS	High blood pressure	Predictor of development of DR
Early Treatment Diabetic Retinopathy Study (ETDRS) Report 22 [1.51] UKPDS	Serum lipids levels	Associated with vision loss due to macular problems
	Alcohol, smoking	No enough evidence

Most of the recent reviews also showed a similar pattern of risk factors for DR. A systematic review including 35 studies concluded that longer duration of DM, poorer glycaemic control and hypertension are strongly associated with DR [1.24]. Another systematic review and meta-analysis

showed that being over-weight or obese is not a risk factors for development of DR (OR 0.89, 955% CI 0.75-1.07, p=0.21, I^2 65%) [1.52]. In contrast another review article described that higher body mass index was associated with having DR, where they did not meta-analyse the results [1.53]. A systematic review that included 8 randomised trials concluded that lipid lowering agents were protective against development of DR, however it was not protective against sight loss (worsening eye visual acuity OR 0.96, 95% CI 0.81-1.14, p=0.64) [1.54]. A meta-analysis found an inverse association of axial length and risk of STDR, concluding that having myopia is protective against STDR (risk of STDR in each millimetre increase in axial length OR 0.70, 95% CI 0.60-0.82, p=0.000) [1.55]. In addition a recent review showed that elevated homocysteine level was associated with increased risk of DR [1.56]. Confirming the conventional idea, a recent meta-analysis showed that there was no association of alcohol intake and incidence of DR [1.57]. There wasn't adequate evidence to show the association of smoking and risk of DR [1.58]. However smoking has been mentioned as a modifiable risk factor for DR in the literature in general [1.59].

A strong body of evidence exists that shows that early screening and treatment for diabetic retinal pathologies would reduce the progression to visual impairment. In these secondary prevention strategies, two land mark studies showed the benefits of early recognition and effectiveness of photocoagulation in prevention of sight loss due to DR [1.60,1.61]. The 'Diabetic Retinopathy Study' (1971-1975) showed that pan-retinal photocoagulation (scatter laser) reduced the risk of sight loss by 60% in proliferative DR (PDR) [1.62]. One main finding of 'Early Treatment Diabetic Retinopathy Study' (ETDRS) was focal laser photocoagulation reduced the moderate vision loss due to macular oedema by 50% [1.63,1.64]. The 'Diabetic Retinopathy Vitrectomy Study' (DRVS, 1987-1997, report 4) demonstrated that early vitrectomy was beneficial in restoring the vision in advanced PDR [1.65,1.66].

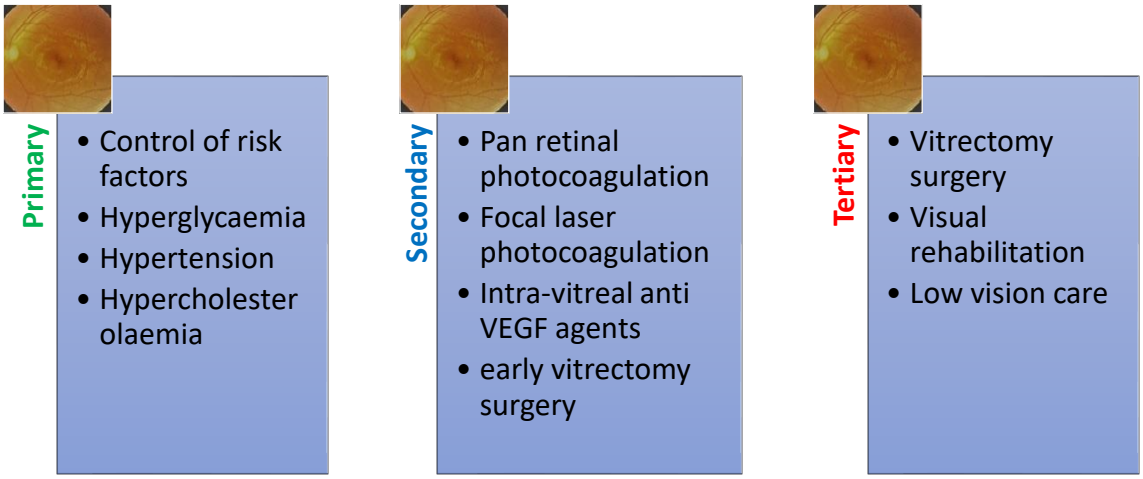


Figure 1.4 - Strategies for prevention of sight loss due to DR

Many interventions are available that can be applied at population level to control the DR blindness and visual impairment (Figure 1.4). In various populations, factors affecting DR blindness and visual impairment vary based on demographic, genetic and socio-economic characteristics. The longest duration of follow up for population-based DR screening is from Iceland (25 years). In Iceland, DR blindness reduced from 2.4% in the year 1980 to 0.5% over a 25years period following a population-based DR screening program [1.67]. The recommendations of the World Health Organization (WHO) and professional bodies are to use these effective interventions rather than development of new technologies [1.68]. However, despite availability of a strong body of evidence, these strategies are underutilised in LMICs. Therefore, as an initial approach we propose that diagnosed PwDM at institutional level should receive screening services. Therefore, it is justifiable to have DR screening program for a South Asian country like Sri Lanka at this stage despite the high prevalence of avoidable blindness due to other causes. In addition, PwDM have more likelihood of developing other conditions such as lens opacities (except nuclear sclerosis) and glaucoma compared to those who do not have DM [1.69,1.70]. Therefore, screening of PwDM for DR will facilitate and provide opportunity to identify other blinding conditions earlier as a secondary outcome [1.29].

1.5 Screening of diabetic retinopathy

The early detection of DR depends on the ability of the screening method to capture the retinal signs accurately. Currently, the minimum detectable sign is considered to be the 'micro aneurysms' and treatment starts at moderate to severe non-proliferative level or at detection of macular oedema, depending on the availability of resources in the context. The gold standard of DR screening is considered to be the ETDRS mydriatic 7-field stereoscopic retinal imaging system [1.71]. However, this method is a complex system to adopt in a resource poor setting. Therefore, various systems of classifications have been adopted according to the local requirements. Some of these classifications have been successfully used in national level DR screening programs. Various referral levels of DR are defined in these screening guidelines, in order to screen the population effectively, complying with the screening modality and skills of the primary graders (Table 1.4). A review on development of DR screening and treatment care in LMICs highlighted the necessity of DR screening guidelines for successful program implementation [1.72]. A study on assessment of screening guidelines stated that 80% of the available guidelines are from HICs while the burden for DR screening was high among the LMICs [1.73].

Table 1.4 - Table of comparison of different classification systems (as examples) based on retinal signs (extracted from Royal College of Ophthalmologists - UK guidelines) [1.74].

ETDRS Classification	UK - National Screening Committee guidelines	Scottish Guidelines	American Academy of Ophthalmology Guidelines
10 None	R0 None	R0 None	No DR
20 Micro aneurysms	R1 Background	R1 Mild BDR *	Mild NPDR †
35 Mild NPDR	-	-	Moderate NPDR
43 Moderate NPDR	R2 Pre-proliferative	R2 Moderate BDR	-
53 A-D Severe NPDR	-	R3 Severe BDR	Severe NPDR
61 Mild PDR	R3 Proliferative	R4 PDR ‡	PDR

*-Background DR, †-Non-proliferative DR, ‡-Proliferative DR

Most of the DR screening guidelines recommend screening annually and there is less evidence to propose increasing the screening interval beyond one year [1.75]. There are various methods of

examining the fundus, such as direct ophthalmoscopy, slit lamp bio-microscopy, indirect ophthalmoscopy and retinal imaging. The latest technology is digital retinal imaging. This gives an objective assessment and recording of the signs. Various countries have adopted DR screening using digital imaging according to the requirements of the local context. Here one consideration is the diagnostic test accuracy and effectiveness of the model of the DR screening at the population level.

1.6 Pathogenesis and detectable retinal signs in DR screening

There are various theories that describe the pathogenesis of DR based on the aetiology of hyperglycaemia though the exact mechanisms remain unknown. Main theories are based on aldose reductase pathway and platelet derived growth factor pathways [1.76]. The earliest pathological sign that appears in the retinal vasculature is the loss of pericytes. The loss of pericytes leads to weakening of the blood-retina barrier. In addition, glycation of the basement membrane leads to thickening and alterations in the retinal vasculature. The loss of pericytes and loss of vascular endothelial adhesions trigger endothelial cell proliferation. The earliest clinically visible sign in DR is micro-aneurysms. The derangements in the blood-retinal barrier will lead to macular oedema, where vascular endothelial growth factors play a major role. Later these changes in the internal environment will lead to increase in permeability of the vasculature leading to hard exudates and haemorrhages. Further progression of the disease will lead to loss of functional vessels hence retinal ischaemia. Retinal ischaemia escalates the new vessels growth, venous abnormalities leading to advanced STDR [1.23].

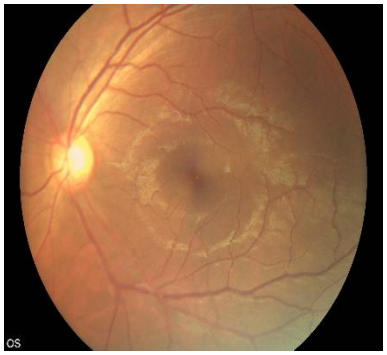


Fig 5a -Normal Fundus

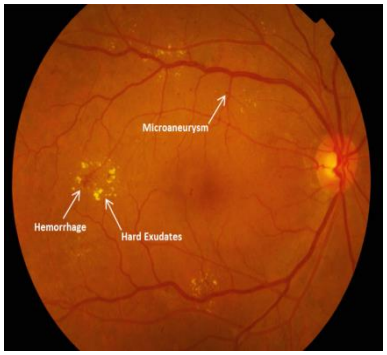


Fig 5b -Moderate NPDR

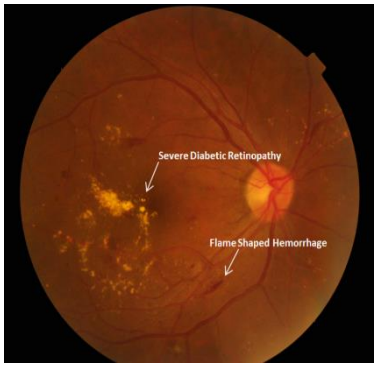


Fig 5c -Severe macular oedema

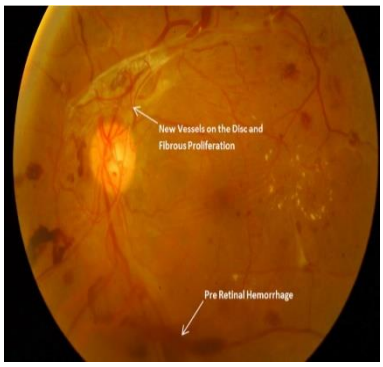


Fig 5d -Advanced DR (PDR)

Figure 1.5 - Normal fundus and fundi with signs of DR progression (Images reference International Council of Ophthalmology) [1.77].

1.7 Overview of Sri Lanka

1.7.1 Overview

Sri Lanka is a LMIC, which has a free health system available through the government sector island wide. The country has a well-developed primary care sector and achieved remarkable development in the health sector domains of the 'Millennium Development Goals' (MDG), such as maternal and child care, compared to other countries in the South Asian region [1.78,1.79]. The gross domestic product (GDP) per capita is 4,074 US $ (2017). The total health expenditure as a percentage of GDP is 1.59% [1.80]. The population is ageing very fast with an average life expectancy of 75 years and proportion of people above 60 years of age has doubled over two decades (1980 - 6.6%, 2012 - 12.4%) [1.81]. Further, disease patterns have changed from communicable to non-communicable diseases, over the past few decades, increasing the burden on the free public sector [1.82]. Sri Lanka is comprised of 25 districts and is home to a population of 20.27million in the year 2012 [1.83]. The Western province, which comprises of three districts, namely Colombo, Kalutara and Gampaha has recorded the highest population of 5.82 million (28.71%) and the capital city is in the Colombo district (Figure 1.6). The Western province has the highest population density of 3428 persons/km^2 amongst the various provinces in Sri Lanka [1.83].

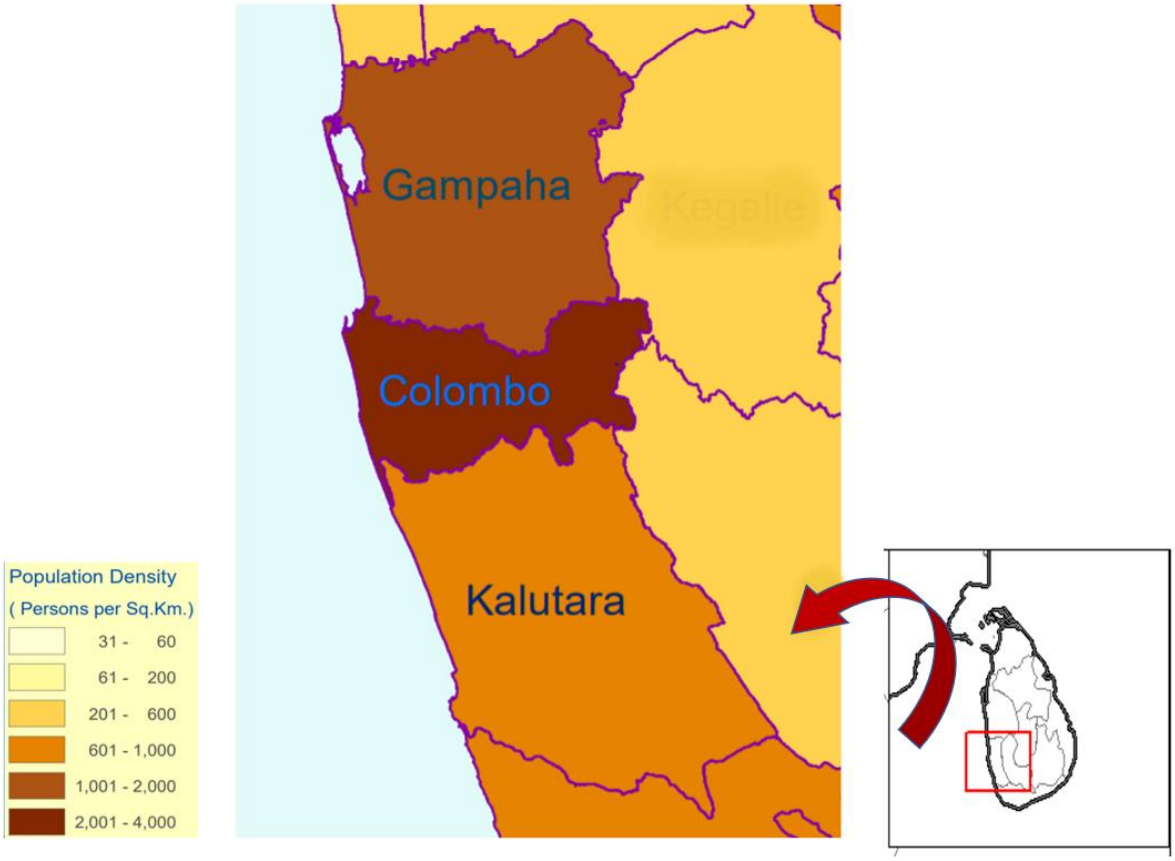


Figure 1.6 - Map of Western province - Sri Lanka (Developed from maps available from Department of Census and Statistics - Sri Lanka) [1.83].

In Sri Lanka, proportion of population 18 years and above is 70% [1.83]. The proportion of people in 15-59 years age group in the Western province is 63.9% and 13.4% of the population is 60 years and above [1.83]. The ageing population is increasing in Sri Lanka and becoming a burden on economic development [1.84]. The proportion of no schooling (aged 5 years and above) is 3.8%, very low compared to other South Asian countries and literacy rate is very high (population aged 10 years and above; overall 95.6%, male 96.8%, female 94.6%) [1.85]. The proportion of economically active is reported as 51.9% and males are engaged more (75.8%) compared to females (30%) [1.86]. The proportions of urban population in each district of the Western province is as follows: Colombo 77.6%, Gampaha 15.6% and Kalutara 8.9%. The majority of the people are Sinhala ethnic group and Buddhist by religion in the Western province (Sinhala 84.2%, Tamil 6.8%, Moor 7.9%; Buddhist

73.4%, Hindu 4.8%, Islam 8.6%, Roman Catholic 11.1%, Other 2.1%) [1.83]. The population in the Western Province has high employment rates (male 60.1%, female 39.9%) [1.83].

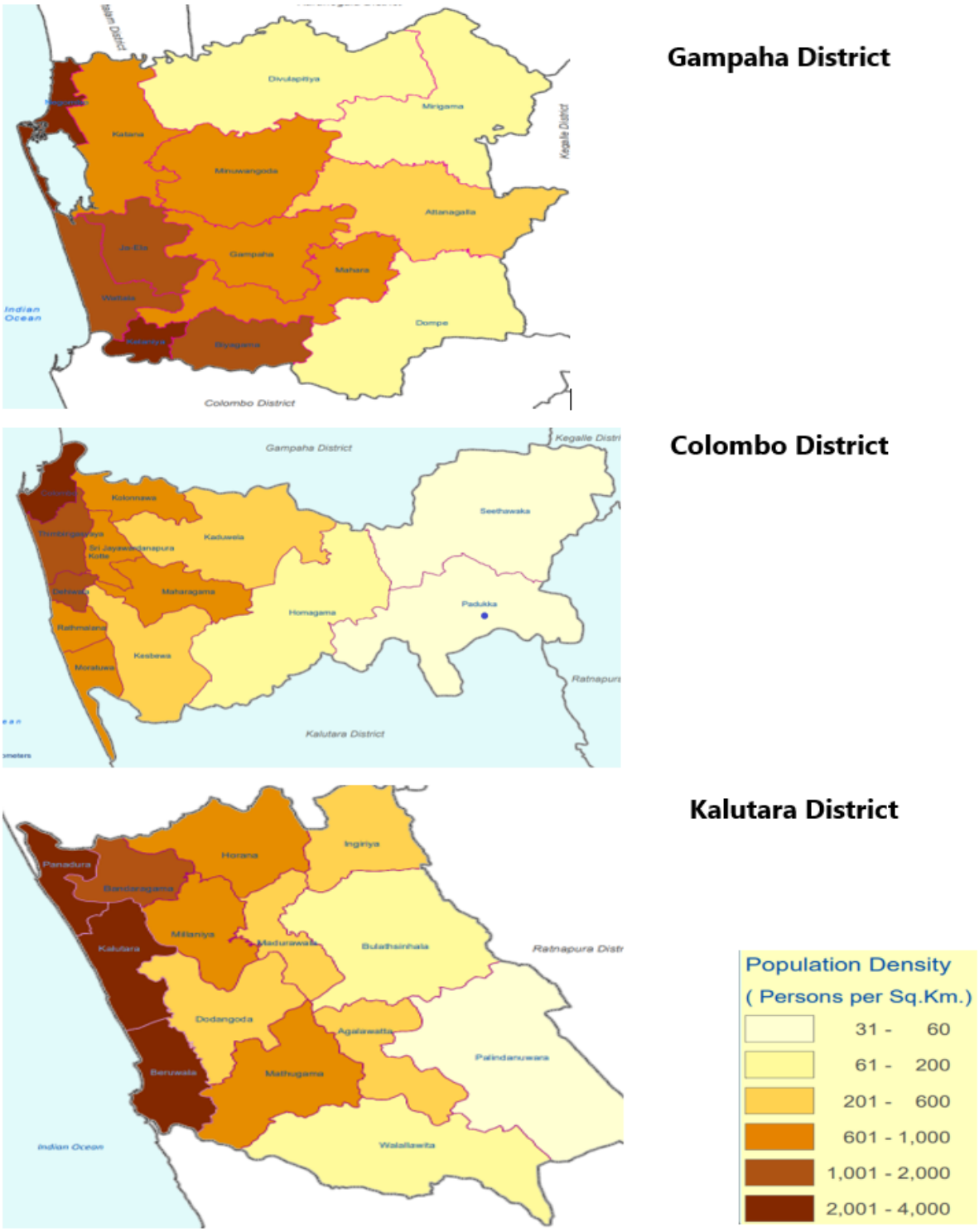


Figure 1.7 - Divisional secretariat divisions of 3 districts of the Western province of Sri Lanka (Developed from maps available from Department of Census and Statistics - Sri Lanka) [1.83].

1.7.2 Health systems in Sri Lanka

Sri Lankan health system comprises of a free public sector and a paid private sector. Public sector provides preventive care through 341 medical officer of health units and curative care through 631 institutions distributed island wide [1.87]. The health system is centrally governed by the Ministry of Health (MOH) and provincially through nine provincial directors of health services. Sri Lanka has an exemplary network of primary care units throughout the country with a special focus on maternal and child health. Private sector provides health care on a 'fee-for-service' basis. Currently primary care system is being reformed to strengthen the approach to address public health issues of non-communicable diseases (NCD) through a "shared care cluster system" [1.87] which has some implications in integrating DR screening. Sri Lanka absorbs health care related human resources through public sector funded training and post-graduate institutions, which select candidates through competitive examinations. As observed in other LMICs, one of the major challenges in provision of eye care is maldistribution of human resources [1.88]. In addition, there is a requirement of capacity building with the rapid changes in disease transitions and advancement of medical technology. Sri Lanka should adopt innovative strategies complying with these transitions, according to the needs of the population and improving the quality of care. One major consideration on improving eye care services in Sri Lanka is there is an urgent need for advocacy, using the evidence from the local context. As an example, DR blindness or blindness prevention in general had not been considered in the recent 'National Strategic Framework for Development of Health Services 2016-2025' published by the MOH-Sri Lanka.

Sri Lanka has about 21,000 medically qualified physicians (allopathic) throughout the country and 17,900 are currently employed in the public sector [1.89]. The physicians are allowed to work in both sectors and this has resulted in a ratio of 1 physician per 671 people in Sri Lanka [1.89]. It is predicted that there are an adequate number of physicians in Sri Lanka up to the year 2025 [1.89]. The eye care services provision in the public sector is mainly through secondary and tertiary levels of service delivery institutions only (Figure 1.8). Eye care services are provided by the eye care units headed by a specialist eye surgeon and a team comprised of ophthalmic residents, ophthalmic medial officers,

ophthalmic technologists (opticians / optometrists) nursing officers and assistants. There is no proper clinical ophthalmology and eye care services provision training for these cadres other than for specialist eye surgeons and ophthalmic technologists. The post-graduate diploma in ophthalmology for medical officers was terminated more than 20 years ago. Therefore, skilled human resources in eye care is highly scarce and there are only about 98 specialist eye surgeons (1 eye surgeon per 200,000 people) in the country and 40% of them are employed in the Western province. Under this health system environment, the available ophthalmologists are overburdened with people with blinding eye conditions such as cataract. Therefore, DR Screening has got a very low priority. The current system of DR screening is an opportunistic screening only.

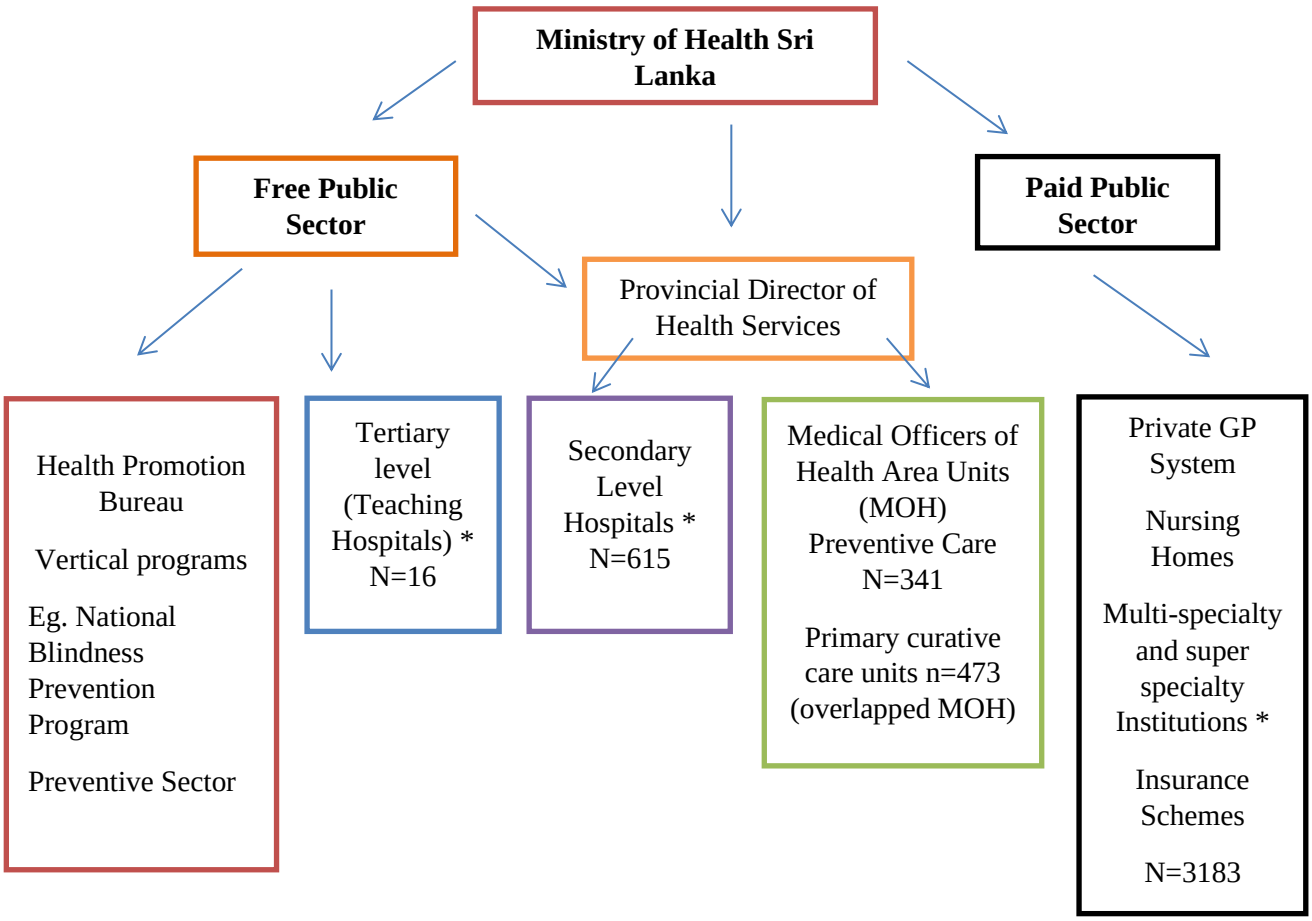


Figure 1.8 - A highly concise schematic diagram of health system of Sri Lanka (where specialist eye care available)*

1.8 Training and assessment of the primary graders in the Western province of Sri Lanka

Poor allocation of resources in LMIC generally hamper eye service delivery. The ophthalmologists are a scarce resource in low income settings [1.90]. A survey conducted in Pakistan concluded that DR screening uptake could be increased by task sharing [1.91]. In the planning process of DR screening, effective usage of available resources is recommended for low income settings [1.92]. A review stated that task shifting is a feasible option to improve efficiency and cost effectiveness of service delivery [1.93]. Most of the ophthalmic skills are vested with high cost professionals in LMIC. Skill mix and task-shifting is essential to achieve universal coverage. Therefore, delegation of primary screening to another cadre is an appropriate intervention. This meets the urgent needs of the population. A systematic review concluded that task shifting would enable cost savings in improving health of the population and in improving the efficiency of health systems. However, one concern in applying these principles is, most of the task shifting has been applied in primary care and in highly prevalent infectious disease management such as HIV/AIDS and tuberculosis. Whether task shifting would work in DR screening is debatable and it would be necessary to assess the validity of each model within the local context.

Most of the ophthalmic personnel are overburdened with other highly prevalent conditions such as cataract, uncorrected refractive errors and glaucoma. Though the ophthalmologists are scarce, there are an adequate number of physicians in Sri Lanka. The first contact for PwDM is institutional physicians in the Sri Lankan health system as there is no general practitioner (GP) based referral system. Therefore, DR screening when the PwDM present for medical care would be an efficient strategy for the provider as well as for the user. It was apparent that there is adequate capacity to deliver DR treatment services at tertiary and higher secondary level of service delivery institutions in the Western province of Sri Lanka. However, capacity to deliver DR screening services is inadequate in terms of skills of mid-level human resources.

During formative research work in Western Sri Lanka, most of the service providers acknowledged that DR screening should start at the first meeting point with the PwDM to ensure high uptake. Therefore, physicians are a suitable category to screen PwDM for stratification before referring them to the

ophthalmologist's clinic. A defined referable level will reduce the DR screening workload at ophthalmologist clinics as well. All public sector physicians in Sri Lanka are qualified medical graduates. Therefore, training of physicians on DR screening would be an appropriate intervention to provide DR screening services at medical clinic level. The long-term implication of this task shifting needs assessment in future research.

Task shifting itself would not solve the problem. There is a need for development of training curricula, clinical guidelines and continuous medical education programs [1.94]. In addition, there are barriers to task shifting such as retention of trained personnel and unavailability of resources for training. A customised training plan is needed to train the selected primary graders in the Western province of Sri Lanka. Here, we assumed that training of selected graders on DR screening imaging and grading and provision of screening infrastructure would improve the access to DR screening by PwDM at institutional level. A review reiterated that 'radical health systems re-thinking' is essential for achieving the universal coverage of eye care services in LMICs [1.95]. This will be helpful to identify the dynamic interactions of the health system building blocks and the avenues for integration of DR screening services into the public sector health system (Figure 1.9).

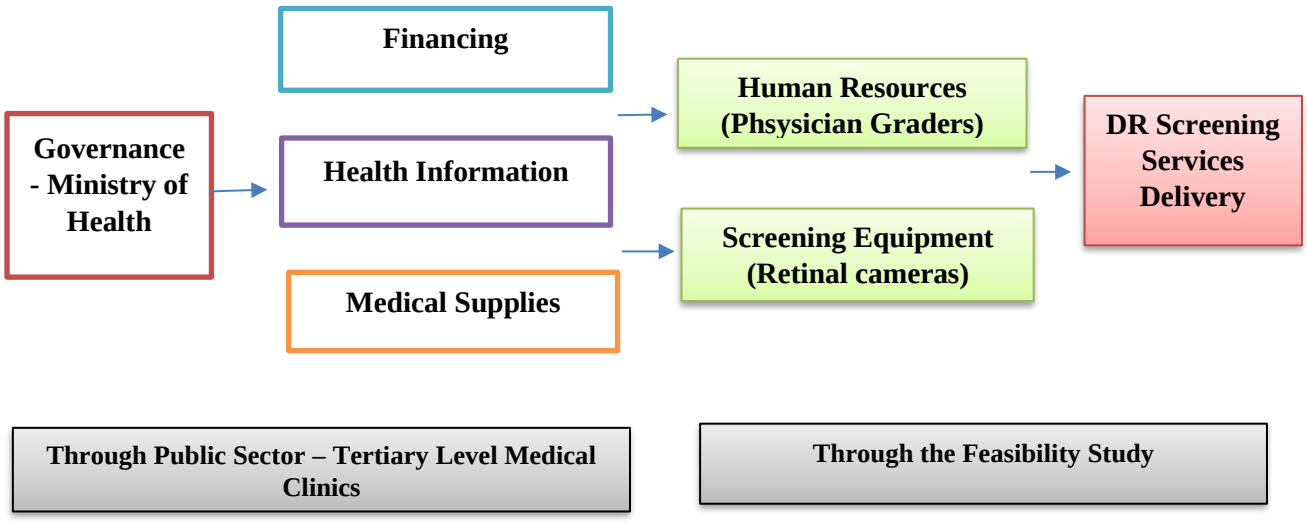


Figure 1.9 - Application of health systems to develop a DR screening model for Sri Lanka

Assuming that physician graders are the primary graders, we had to develop a relevant and less complicated training module to train the graders within a limited time-period. Therefore, we proposed to train them, using on-line training resources available from the International Council of Ophthalmology (ICO). Further, this was linked to on-line grading practicing systems developed by ICO. Two trainer retinologists from a tertiary level eye care centre in the Western proince delivered the training modules. The training program mainly consisted of knowledge and skills components and details and the results are described in chapter six (methods) and chapter 11 and 12 (results).

1.9 References: Chapter 1

1.1. IDF. International Diabetes Federation Diabetes Atlas Eighth Edition 2017 [Internet]. 2017. Available from: http://www.diabetesatlas.org/resources/2017-atlas.html. Accessed 15 Jan 2017.

1.2. Guariguata L, Whiting DR, Hambleton I, Beagley J, Linnenkamp U, Shaw JE. Global estimates of diabetes prevalence for 2013 and projections for 2035. Diabetes Res Clin Pract. 2014;103(2):137–49. PMID:24630390 DOI:10.1016/j.diabres.2013.11.002

1.3. Forouhi NG, Wareham NJ. Epidemiology of diabetes. Medicine (Abingdon). 2014 Dec;42(12):698-702. PMID:25568613 DOI:10.1016/j.mpmed.2014.09.007

1.4. da Rocha Fernandes J, Ogurtsova K, Linnenkamp U, Guariguata L, Seuring T, Zhang P, et al. IDF Diabetes Atlas estimates of 2014 global health expenditures on diabetes. Diabetes Res Clin Pract. 2016;117:48–54. PMID:27329022. DOI:10.1016/j.diabres.2016.04.016

1.5. Shaw JE, Sicree RA, Zimmet PZ . Global estimates of the prevalence of diabetes for 2010 and 2030. Diabetes Res Clin Pract. 2010;87(1):04-14. PMID:19896746. DOI:10.1016/j.diabres.2009.10.007.

1.6. NCD Risk Factor Colloboration. Worldwide trends in diabetes since 1980: A pooled analysis of 751 population-based studies with 4.4 million participants. Lancet. 2016;387(10027):1513–

30. PMID:27061677 doi:10.1016/S0140-6736(16)00618-8.

1.7. Whiting DR, Guariguata L, Weil C, Shaw J. IDF Diabetes Atlas: Global estimates of the prevalence of diabetes for 2011 and 2030. Diabetes Res Clin Pract. 2011;94(3):311–21. PMID: 22079683 DOI:10.1016/j.diabres.2011.10.029

1.8. Zabetian A, Sanchez IM, Narayan KMV, Hwang CK, Ali MK. Global rural diabetes prevalence: A systematic review and meta-analysis covering 1990-2012. Diabetes Res Clin Pract. 2014;104(2):206–12. PMID:24507869 DOI:10.1016/j.diabres.2014.01.005

1.9. Ramachandran A, Snehalatha C, Ching R, Ma W. Diabetes in South-East Asia : An update. Diabetes Res Clin Pract. 2014;103(2):231–7. PMID:24300015 DOI:10.1016/j.diabres.2013.11.011

1.10. Cheema A, Adeloye D, Sidhu S, Sridhar D, Chan KY. Urbanization and prevalence of type 2 diabetes in Southern Asia: A systematic analysis. J Glob Health.2014;4(1):010404. PMID:24976963 doi:10.7189/jogh.04.010404.

1.11. Beagley J, Guariguata L, Weil C, Motala AA. Global estimates of undiagnosed diabetes in adults. Diabetes Res Clin Pract. 2014;103(2):150–60. PMID:24300018 DOI:10.1016/j.diabres.2013.11.001

1.12. Zhang P, Zhang X, Brown J, Vistisen D, Sicree R, Shaw J, et al. Global healthcare expenditure on diabetes for 2010 and 2030. Diabetes Res Clin Pract. 2010;87(3):293–301. PMID:20171754 DOI:10.1016/j.diabres.2010.01.026

1.13. Davis K, Schoen C, Guterman S, Shih T, Schoenbaum SC. Weinbaum I. Slowing The Growth of US Health Care Expenditures : What Are The Options? The Commonwealth Fund. January 2007 [Internet]. Available from: http://people.stern.nyu.edu/wgreene/Statistics/Sicko/CommonwealthFundReport.pdf. Accessed on 15 Jan 2017.

1.14. Maruthappu M, Hasan A, Zeltner T. Enablers and Barriers in Implementing Integrated Care.

Heal Syst Reform. 2015;1(4):250–6. https://doi.org/10.1080/23288604.2015.1077301

1.15. Jayawardena R, Ranasinghe P, Byrne NM, Soares MJ, Katulanda P, Hills AP. Prevalence and trends of the diabetes epidemic in South Asia: a systematic review and meta-analysis. BMC Public Health. 2012;12(1):380. https://doi.org/10.1186/1471-2458-12-380

1.16. Katulanda P, Rathnapala D, Sheriff R, Matthews D. Province and ethnic specific prevalence of diabetes among Sri Lankan adults. Sri Lanka J Diabetes Endocrinol Metab. 2012;1(1):2–7. DOI:http://doi.org/10.4038/sjdem.v1i1.4180

1.17. De Silva AP, Hennadige S, De Silva P, Liyanage IK, Rajapakse LC, Saroj K, et al. Social, cultural and economical determinants of diabetes mellitus in Kalutara district, Sri Lanka: a cross sectional descriptive study. Int J Equity Health. 2012;11(1):76. https://doi.org/10.1186/1475-9276-11-76

1.18. Jenum AK, Diep LM, Holmboe-Ottesen G, Holme IMK, Kumar BN, Birkeland KI. Diabetes susceptibility in ethnic minority groups from Turkey, Vietnam, Sri Lanka and Pakistan compared with Norwegians - the association with adiposity is strongest for ethnic minority women. BMC Public Health. 2012;12(1):150. PMID:22380873. DOI:10.1186/1471-2458-12-150

1.19. De Silva AP, De Silva SHP, Haniffa R, Liyanage IK, Jayasinghe S, Katulanda P, et al. Inequalities in the prevalence of diabetes mellitus and its risk factors in Sri Lanka: A lower middle income country. Int J Equity Health. 2018;17(1):45. PMID:29665834. DOI:10.1186/s12939-018-0759-3

1.20. Pinidiyapathirage MJ, Kasturiratne A, Ranawaka UK, Gunasekara D, Wijekoon N, Medagoda K, et al. The burden of diabetes mellitus and impaired fasting glucose in an urban population of Sri Lanka. Diabet Med. 2013;30(3):326–32. PMID:22998091. DOI:10.1111/dme.12013

1.21. Illanasekara U, Rambodagalla S, Tennakoon S. Temporal trends in the prevalence of diabetes mellitus in a rural community in Sri Lanka. J R Soc Promot Health. 2004;124(2):92–4.

PMID:15067982

1.22. Illangasekara. u., rambadagalla.S. TS. Increasing prevalence of diabetes mellitus in a rural srilankan community. J Ceylon Coll Physicians. 2002;35:54–5.

1.23. Klein R, Klein BEK. The Epidemiology of Diabetic Retinopathy [Internet]. Fifth Edit. Vols. 2–3, Retina: Fourth Edition. Elsevier Inc.; 2005. 1503-1521 p. Available from: http://dx.doi.org/10.1016/B978-1-4557-0737-9.00045-X. Accessed on 15 Jan 2016.

1.24. Yau JWY, Rogers SL, Kawasaki R, Lamoureux EL, Kowalski JW, Bek T, et al. Global prevalence and major risk factors of diabetic retinopathy. Diabetes Care. 2012;35(3):556–64. PMID:22301125. DOI:10.2337/dc11-1909 .

1.25. Leasher JL, Bourne RRA, Flaxman SR, Jonas JB, Keeffe J, Naidoo K, et al. Global Estimates on the Number of People Blind or Visually Impaired by Diabetic Retinopathy: A Meta-analysis From 1990 to 2010. Diabetes Care. 2016;39(9):1643–9. PMID:27555623 DOI:10.2337/dc15-2171 .

1.26. Klein BE. Overview of Epidemiologic Studies of Diabetic Retinopathy. Ophthalmic Epidemiol. 2007;14(04):179–83. PMID:17896294 DOI:10.1080/09286580701396720

1.27. Pascolini D, Mariotti SP. Global estimates of visual impairment: 2010. Br J Ophthalmol. 2012;96(5):614–8. PMID:22133988 DOI:10.1136/bjophthalmol-2011-300539

1.28. Wong TY, Yau J, Rogers S, Kawasaki R, Lamoureux EL, Kowalski J. Global Prevalence of Diabetic Retinopathy: Pooled Data from Population studies from the United States, Australia, Europe and Asia. Meta Eye Gr Investig Ophthalmol Vis Sci. 2011;52(14):4818.

1.29. Lee R, Wong TY, Sabanayagam C. Epidemiology of diabetic retinopathy , diabetic macular edema and related vision loss. Eye Vis (Lond). 2015 Sep 30;2:17 PMID:26605370 DOI:10.1186/s40662-015-0026-2

1.30. Sivaprasad S, Gupta B, Crosby-Nwaobi R, Evans J. Prevalence of Diabetic Retinopathy in Various Ethnic Groups: A Worldwide Perspective. Surv Ophthalmol. 2012;57(4):347–70.

PMID:22542913 DOI:10.1016/j.survophthal.2012.01.004

1.31. Williams R, Airey M, Baxter H, Forrester J, Kennedy-Martin T, Girach A. Epidemiology of diabetic retinopathy and macular oedema : a systematic review. Eye. 2004;18(10):963–83. PMID:15232600 DOI:10.1038/sj.eye.6701476

1.32. Raman R, Rani PK, Reddi Rachepalle S, Gnanamoorthy P, Uthra S, Kumaramanickavel G, et al. Prevalence of Diabetic Retinopathy in India. Sankara Nethralaya Diabetic Retinopathy Epidemiology and Molecular Genetics Study Report 2. Ophthalmology. 2009;116(2):311–8. PMID:19084275 DOI:10.1016/j.ophtha.2008.09.010

1.33. Jotheeswaran AT, Lovakanth N, Nadiga S, Anchala R, Murthy GVS, Gilbert CE. Estimating the proportion of persons with diabetes developing diabetic retinopathy in India: A systematic review and meta-analysis. Indian J Endocrinol Metab. 2016;20(7): 51-8. PMID:27144137 DOI:10.4103/2230-8210.179774

1.34. Sabanayagam C, Banu R, Chee M, Lee R, Wang Y, Tan G, et al. Incidence and progression of diabetic retinopathy: a systematic review. Lancet Diabetes Endocrinol. 2018;S2213-8587(18):30128–1. PMID:30005958 DOI:10.1016/S2213–8587(18).

1.35. National Survey of Blindness, Visual Impairment, Ocular Morbidity and Disability in Sri Lanka [Internet]. 2015. Available from: https://www.iapb.org/resources/national-survey-of-blindness-and-vi-sri-lanka-2014-15/. Accessed on 15 Aug 2015.

1.36. Fernando DJ, Siribaddana S, Silva D SZ. Prevalence of retinopathy in a Sri Lankan diabetes clinic. Ceylon Med J. 1993;38(3):120–3. PMID:7828230

1.37. Katulanda P, Ranasinghe P, Jayawardena R. Prevalence of retinopathy among adults with self-reported diabetes mellitus: the Sri Lanka diabetes and Cardiovascular Study. BMC Ophthalmol. 2014;14(1):100. PMID:25142615. DOI:10.1186/1471-2415-14-100

1.38. Katulanda P, Waniganayake YC, Ranasinghe P, Udai WM, Wijetunga A, Jayaweera M, et al. Retinopathy among young adults with Diabetes Mellitus from a tertiary care setting in Sri

Lanka. BMC Endocr Disord. 2014;14(1):1–8. PMID:24588941. doi:10.1186/1472-6823-14-20

1.39. Nishad AAN, Silva J De, Mallawarachchi M, Amaratunge MS. Prevalence and associated factors for Development of Diabetic Retinopathy in Clinic Followed up Cohort of Diabetic Patients in a Hospital Set up in Sri Lanka. SAS J Med. 2015;1(4):172–5.

1.40. Saman W. Distribution of diabetic retinopathy among diabetics in southern province of Sri Lanka. Eur J Prev Med. 2015;3(2-1):5–8. doi:10.11648/j.ejpm.s.2015030201.12

1.41. Balasuriya BMA, Sumanatilleke MR, Jayasekera TI, Wijesuriya MA SN. Prevalence of micro and macro vascular complications of diabetes detected at single visit screening. Sri Lanka J Diabetes Endocrinol Metab. 2012;2:17–20. DOI: http://dx.doi.org/10.4038/sjdem.v2i1.4328

1.42. The Writing Team for the Diabetes Conrol and Complications Trial. Effect of Intensive Therapy on the Microvascular Complications of Type 1 Diabetes mellitus. JAMA Ophthalmol. 2002;287(19):2563–2569 PMID:12020338.

1.43. Stratton I, Kohner E, Aldington S, Turner R, Holman R, Manley S, et al. UKPDS 50. Risk factors for incidence and progression of retinopathy in type 11 diabetes over 6 years from diagnosis. Diabetologia. 2001;44(2):156–63 PMID:11270671 DOI:10.1007/s001250051594.

1.44. Kohner EM, Aldington SJ, Stratton IM, Manley SE, Holman RR, Mathews DR, Turner RC . United Kingdom Prospective Diabetes Study, 30: diabetic retinopathy at diagnosis of non-insulin-dependent diabetes mellitus and associated risk factors. Arch Ophthalmol. 1998;116(3):297–303. PMID:9514482

1.45. Robert C, Rury R, Carole A, Irene M. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. Lancet. 1998;352(9131):837–53. PMID:9742976

1.46. Rema M, Saravanan G, Deepa R, Mohan V. Familial clustering of diabetic retinopathy in

South Indian Type 2 diabetic patients. Diabet Med 2002;19(11): 910–6. PMID:12421427

1.47. The Diabetes Control and Complications Trial Research Group. The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med. 1993;329:977–86.

1.48. Klein R, Knudtson MD, Lee KE, Gangnon R, Klein BE. The Wisconsin Epidemiologic Study of Diabetic Retinopathy xxii. The Twenty-Five-Year Progression of Retinopathy in Persons with Type 1 Diabetes. Ophthalmology. 2008;115(11):1859-68. PMID:19068374. DOI:10.1016/j.ophtha.2008.08.023

1.49. Klein R, Klein BE, Moss SE, Davis MD, Demets DL. The Wisconsin Epidemiologic Study of Diabetic Retinopathy: II. Prevalence and risk of diabetic retinopathy when age at diagnosis is less than 30 years. Arch Ophthalmol. 1984;102(4):520–6. PMID:6367724

1.50. Klein R, Klein BEK, Moss SE, Cruickshanks KJ. The Wisconsin Epidemiologic Study of Diabetic Retinopathy : XVII The 14-year Incidence and Progression of Diabetic retinopathy and associated risk factors in type 1 diabetes. Ophthalmology. 1998;105(10):1801–15. PMID:9787347 DOI:10.1016/S0161-6420(98)91020-X

1.51. Chew EY, Klein ML,Ferris III LF, Remaley NA, Murphy RP, Chantry K, et al. Association of Elevated Serum Lipid Levels with Retinal Hard Exudate in Diabetic Retinopathy: Early Treatment Diabetic Retinopathy Study (ETDRS) Report 22. Arch Ophthalmol. 1996;114(9):1079–84. PMID:8790092

1.52. Zhou Y, Zhang Y, Shi K, Wang C. Body mass index and risk of diabetic retinopathy-A meta-analysis and systematic review. Medicine (Baltimore). 2017;96(22):e6754. PMID:28562529. DOI:10.1097/MD.0000000000006754

1.53. Ting D, Cheung G, Wong T. Diabetic retinopathy : global prevalence , major risk factors , screening practices and public health challenges : a review. Clin Exp Ophthalmol. 2016;44(4):260–277. PMID:26716602 doi:10.1111/ceo.12696.

1.54. Shi R, Zhao L, Wang F, Liu F, Chen Z, Li R, et al. Effects of lipid-lowering agents on diabetic retinopathy: a Meta-analysis and systematic review. Int J Ophthalmol. 2018;11(2):287–95. PMID:29487821. DOI:10.18240/ijo.2018.02.18.

1.55. Wang X, Tang L, Gao L, Yang Y, Cao D, Li Y. Myopia and diabetic retinopathy : A systematic review and meta-analysis. Diabetes Res Clin Pract. 2015;111:1–9. PMID:26531140 DOI:10.1016/j.diabres.2015.10.020

1.56. Lei X, Zeng G, Zhang Y, Li Q, Zhang J, Bai Z, et al. Association between homocysteine level and the risk of diabetic retinopathy : a systematic review and meta - analysis. Diabetol Metab Syndr. 2018;10: 61. PMID:30083252. DOI:10.1186/s13098-018-0362-1

1.57. Zhu W, Meng Y, Wu Y, Xu M, Lu J. Association of alcohol intake with risk of diabetic retinopathy : a meta- analysis of observational studies. Sci Rep. 2017 Jan 31;7(1):4. PMID: 28127054 DOI: 10.1038/s41598-017-00034-w

1.58. Nagrebetsky A, Brettell R, Roberts N, Farmer A. Smoking cessation in adults with diabetes : a systematic review and meta-analysis of data from randomised controlled trials. BMJ Open. 2014;4:e004107. doi:10.1136/bmjopen-2013-0041072014;4(3).

1.59. Scanlon PH, Aldington SJ, Stratton IM. Epidemiological Issues in Diabetic Retinopathy. Middle East Afr J Ophthalmol. 2013;20(4):293–300. PMID:24339678. doi:10.4103/0974-9233.120007

1.60. The Diabetic Retinopathy Srudy Research Group. Photocoagulation Treatment of Proliferative Diabetic Retinopathy. Clinical Application of Diabetic Retinopathy Study (DRS) Findings. DRS Report Number 8. Ophthalmology. 1981;(88)7:583-600. PMID:7196564

1.61. The Diabetic Retinopathy Srudy Research Group. Indications for photocoagulation treatment of diabetic retinopathy: Diabetic Retinopathy Study Report no. 14. Int Ophthalmol Clin.1987; (27)4:239–53. PMID:2447027

1.62. The Diabetic Retinopathy Study Research Group. Photocoagulation treatment of proliferative

diabetic retinopathy. Clinical application of Diabetic Retinopathy Study (DRS) findings, DRS Report Number 8. Ophthalmology. 1981;88(7):583–600 PMID:7196564.

1.63. Early Treatment Diabetic Retinopathy Study Group. Photocoagulation for Diabetic Macular Edema. ETDRS Report No 1. Arh Ophthalmol. 1985;103(12):1796–1806. PMID:2866759 doi:10.1001/archopht.1985.0105012003001.

1.64. Early Treatment Diabetic Retinopathy Study Group. Early Photocoagulation for Diabetic Retinopathy. ETDRS Report No 9. Ophthalmology. 1991;98(5):766–785 PMID:2062512.

1.65. The Diabetic Retinopathy Vitrectomy Study Research Group. Early Vitrectomy for Severe Vitreous Hemorrhage in Diabetic Retinopathy. Two-Year Results of a Randomized Trial-Diabetic Retinopathy Vitrectomy Study Report 2. Arch Ophthalmol. 1985;103(11):1644–1652 PMID:2865943 doi:10.1001/archopht.1985.01050110038020.

1.66. The Diabetic Retinopathy Vitrectomy Study Research Group. Early Vitrectomy for Severe Proliferative Diabetic Retinopathy in Eyes with Useful Vision. Ophthalmology. 1988;95(10):1307–20. PMID:2465517

1.67. Stefansson E. Prevention of diabetic blindness. Br J Ophthalmol. 2006;90(1):2–3. PMID:16361653 doi:10.1136/bjo.2005.082065.

1.68. World Health Organization. Prevention of blindness from diabetes mellitus. Geneva WHO [Internet]. 2005;1–48. Available from: https://www.who.int/blindness/Prevention%20of%20Blindness%20from%20Diabetes%20Mellitus-with-cover-small.pdf?ua=1. Accessed on 18 Jan 2016.

1.69. Li L, Wan X, Zhao G. Meta-analysis of the risk of cataract in type 2 diabetes. BMC Ophthalmol. 2014;14(94) PMID:25060855. doi:10.1186/1471-2415-14-94

1.70. Zhao Y, Chen X. Diabetes and risk of glaucoma: systematic review and a Meta-analysis of prospective cohort studies. Int J Ophthalmol. 2017;10(9):1430–1435 PMID:28944. doi:10.18240/ijo.2017.09.16

1.71. Grading diabetic retinopathy from stereoscopic colour fundus photographs - An extension of the modified Airlie House classification : ETDRS report number 10. Early Treatment Diabetic Retinopathy Study Group. Ophthalmology. 1991;98(5):786-806. PMID:2062513

1.72. Lin S, Ramulu P, Lamoureux EL, Sabanayagam C. Addressing risk factors, screening, and preventative treatment for diabetic retinopathy in developing countries: A review. Clin Exp Ophthalmol. 2016;44(4):300–20. PMID:26991970 DOI:10.1111/ceo.12745

1.73. Chakrabarthi R, Harper CA, Keeffe JE. Diabetic Retinopathy Management Guidelines. Expert Rev Ophthalmol. 2012;7(5):417–39. https://doi.org/10.1586/eop.12.52

1.74. The Royal College of Ophthalmologists Diabetic Retinopathy Guidelines. [Internet]. Version 2013;2012(July). Available from: https://www.rcophth.ac.uk/wp-content/uploads/2014/12/2013-SCI-301-FINAL-DR-GUIDELINES-DEC-2012-updated-July-2013.pdf. Accessed on 15 Jan 2016

1.75. Taylor-Phillips S, Mistry H, Leslie R, Todkill D, Tsertsvadze A, Connock M, et al. Extending the diabetic retinopathy screening interval beyond 1 year: systematic review. Br J Ophthalmol. 2016;100(1):105–14. PMID:25586713. DOI:10.1136/bjophthalmol-2014-305938.

1.76. Zhang K, Ferreyra HA, Grob S, Bedell M, Zhang JJ. Chapter 46 - Diabetic Retinopathy: Genetics and Etiologic Mechanisms [Internet]. Fifth Edition. Vol. 1, Retina. Elsevier Inc.; p925-939. Available from: https://www.sciencedirect.com/science/article/pii/B9781455707379000461?via%3Dihub. Accessed on 15 Jan 2017.

1.77. ICO Guidelines for Diabetic Eye Care. International Council of Ophthalmology. [Internet] 2017. Available from: http://www.icoph.org/downloads/ICOGuidelinesforDiabeticEyeCare.pdf. Accessed on 15 Jan 2018.

1.78. UNDPs role and leadership in achieving the MDG in Sri Lanka-About Sri Lanka. [Internet].

Available from: http://www.lk.undp.org/content/srilanka/en/home/countryinfo/. Accessed on 19 Aug 2014.

1.79. The World Bank- Data-Sri Lanka [Internet]. Available from: http://data.worldbank.org/country/sri-lanka. Accessed on 19 Aug 2014.

1.80. Economic and social statistics of Sri Lanka 2013. Central Bank of Sri Lanka [Internet]. Available from: http://www.cbsl.gov.lk/pics_n_docs/10_pub/_docs/statistics/other/econ_&_ss_2013_e.pdf. Accessed on 20 Oct 2014.

1.81. Sri Lanka-Addressing the Needs of an Aging Population-Document of the World Bank-May 28, 2008 [Internet]. Available from: http://siteresources.worldbank.org/INTSRILANKA/Resources/LKAgingFullRep.pdf. Accessed on 19 Aug 2014.

1.82. Marshall SJ. Developing countries face double burden of disease. Bull World Heal Organ. 2004;82(7):556. PMID:15500291

1.83. Census of Population and Housing 2012. Department of Census and Statistics of Sri Lanka [Internet]. 2012. Available from: http://www.statistics.gov.lk/PopHouSat/CPH2012Visualization/htdocs/index.php?usecase=indicator&action=Data&indId=. Accessed on 19 Aug 2016.

1.84. Semasinghe WM. Social Development of Sri Lanka: Achievement and Challenges. Sri Lanka J Soc Sci. 2009;01(03):283–309.

1.85. Literacy rates by district, sex and sector. Census of Population and Housing-Sri Lanka-2001 [Internet]. 2011. Available from: http://www.statistics.gov.lk/PopHouSat/PDF/Population/p9p10 Literacy rates by district, sex and sector.pdf. Accessed on 19 Aug 2016.

1.86. Poverty Headcount Ratio Brief : Decomposition of Consumption Poverty. Department of

Census and Statistics [Internet]. 2014. Available from: http://www.statistics.gov.lk/poverty/HIES-2012-13-News Brief.pdf. Accessed on 19 Aug 2016.

1.87. Ministry f Health Sri Lanka - Medical Statistics Unit. Annual Health Bulletin-Sri Lanka 2015 [Internet]. Available from: http://www.health.gov.lk/moh_final/english/public/elfinder/files/publications/AHB/2017/AHB 2015.pdf. Accessed on 19 Aug 2016.

1.88. Samarage SM . Migration and Human Resources for Health: From Awareness to Action-Health Care System:Sri Lanka. International Organization for Migration. [Internet] Available from: https://www.iom.int/jahia/webdav/site/myjahiasite/shared/shared/mainsite/microsites/IDM/workshops/Migration_and_HR_23240306/MHCW_final_report.pdf. Accessed on 19 Aug 2016.

1.89. Silva D De. How many doctors should we train for Sri Lanka ? System dynamics modelling of training needs. Ceylon Medical Journal. 2017;62(4):233–37. DOI:http://doi.org/10.4038/cmj.v62i4.8573

1.90. Resnikoff S, Felch W, Gauthier T, Spivey B. The number of ophthalmologists in practice and training worldwide : a growing gap despite more than 200 000 practitioners. Br J Ophthalmol 2012;96(4):783–787.

1.91. Shah M, Noor A, Ormsby G, Chakrabarti R, Harper C, Islam F, et al. Attitude and perceptions of eye care workers and health adminsitrators regarding task sharing in screening and detection for management of diabetic retinopathy in Pakistan. Ophthalmic Epidemiol. 2018;25(2):169–75. PMID:28976241 DOI:10.1080/09286586.2017.1381273

1.92. Poore S, Foster A, Zondervan M, Blanchet K. Planning and developing services for diabetic retinopathy in Sub-Saharan Africa. Int J Heal policy Manag. 2015;4(1):19–28. DOI:10.15171/IJHPM.2015.04 .

1.93. Fulton BD, Scheffler RM, Sparkes SP, Auh EY, Vujicic M, Soucat A. Health workforce skill mix and task shifting in low income countries : a review of recent evidence. BMC Hum Resour Health. 2011;9(1):1. PMID:21223546. DOI:10.1186/1478-4491-9-1.

1.94. Joshi R, Alim M, Kengne AP, Jan S, Maulik PK, Peiris D, et al. Task shifting for non-communicable disease management in low and middle income countries - A systematic review. PLoS One. 2014;9(8): e103754. PMID:25121789. DOI:10.1371/journal.pone.0103754.

1.95. Blanchet K, Gilbert C, Savigny D De. Rethinking eye health systems to achieve universal coverage : the role of research. Br J Ophthalmol. 2014;98(10):1325-8. PMID:24990874 doi:10.1136/bjophthalmol-2013–303905.

Chapter 2

REVIEW OF LITERATURE

2.1 Need for screening for DR

The World Health Organization (WHO) announced that member states should target to achieve universal eye health coverage according to the global action plan from 2014 to 2019 [2.1]. The factors affecting effective utilisation of DR screening services are unique to a health system. One review reported that there are many reasons for underutilisation of eye care. Also, the definition of 'high risk' for blindness varies with the context [2.2]. It is mentioned that evidence based cost effective strategies should be adopted to control DR blindness [2.3]. Most of the LMIC settings have some sort of DR screening services. However, these services are not available universally. The principles of universal eye health coverage are applicable to setting up DR screening as well [2.4]. DR screening is a well-established preventive strategy to control sight loss in DR. However this has not been integrated in to most of the LMIC health systems due to various barriers [2.4]. On the other hand, there are inequities in DR screening service provision even in HIC settings [2.5].

The available evidence strongly suggests that early screening and treatment prevents sight loss due to DR. In Sri Lanka, provision of DR screening services is an imperative due to the increasing prevalence of DM. Screening for DR can be opportunistic or proactive. Screening refers to application of a diagnostic test to a population, which has no symptoms of the disease. DR screening complies with 'Wilson and Jungner Screening Criteria' of implementation of a disease screening program [2.6]. However, the issue is how to deliver acceptable level of quality services, cost effectively and in an equitable manner in low income settings [2.6]. Further, tests used in DR screening should be safe, precise and validated [2.7]. DR screening models use digital imaging in many parts of the world.

2.2 Process of developing DR screening models

The development of a DR screening model is a complex process especially in resource poor LMIC settings. A systematic review conducted in India to assess the burden of DR among the PwDM stated

that preventive strategies such as early detection was not considered in blindness prevention programs [2.8]. This is the situation in most of the LMICs. In addition, there should be facilities to treat the identified pathologies. The current 'status quo' model adopted in most of the LMICs does not favour the development of a full population-based DR screening program. Therefore, in these settings, alternative screening models need consideration. Universal coverage cannot be achieved without addressing the barriers [2.9].

2.3 Assessing diagnostic test accuracy

The retinal imaging technique used in ETDRS is generally considered as the gold standard for DR screening [2.10]. However, this method is not feasible at a program level. The knowledge of diagnostic test accuracy (DTA) is an important factor to develop an effective DR screening modality. Achievement of required level of DTA is a challenge in any setting. Various factors pertaining to the imaging system, human resources involved in grading and characteristics of the PwDM affect the DTA. A systematic review showed that mydriatic imaging was an effective strategy in detection of DR [2.11]. However, one study documented that variation in pupil size did not influence the sensitivity (mydriatic 84.5% vs non-mydriatic 82.9%, OR 0.89 (95% CI 0.56-1.41, p=0.61)) or specificity (mydriatic 88.6% vs non-mydriatic 87.9%, OR 0.94 (95% CI 0.57-1.54, p=0.80)) of DR screening [2.12]. The different field strategies, pupil status and degree of view were the main technical features that determined the DTA using retinal imaging. A systematic review on using telemedicine for detecting DR, showed that sensitivity of detecting absence of DR was 80% (95% CI 75-84%) with non-mydriatic digital imaging, and this increased to 91% (95% CI 84 -94%) following mydriasis (Specificity non-mydriatic 95% (95% CI 93 -96%), mydriatic 95% (95% CI 94 -96%)) [2.13]. Most of the studies showed that >85% of sensitivity in detecting any level of DR could be achieved using mydriatic 2-field method [2.14–2.21]. This is compatible with the 'Diabetes UK' criteria for minimum sensitivity level of 80% which most of the national programs follow [2.22]. Most of the 1-field strategies could not achieve this recommended level [2.14,2.15,2.18,2.23–2.25]. Non-mydriatic methods have become popular due to the ease of use and increased image quality with advanced technology.

However, evidence on selection of a best-suited modality for a resource poor setting like Sri Lanka is still scarce.

Table 2.5- Comparison of validity of different method of DR screening (based on available systematic reviews and meta-analyses)

Method of screening	**Method of analysis**	**Measure of diagnostic accuracy (Sensitivity) (95% CI)**	**Measure of diagnostic accuracy (Specificity) (95% CI)**	**Limitations**	**Study author, year and reference number**
Retinal photography	Detecting any level of DR	Overall 82.5% (75.6-87.9) Mydriatic 84.5% (76.9-90.0) Non-mydriatic 82.9% (73.9-89.2)	Overall 88.4% (84.5-91.4) Mydriatic 88.6% (83.7-92.1) Nonmydriatic 87.9% (81.6-92.2)	Polaroid film camera, digital imaging and clinical examination accuracy levels were aggregated in to one summary estimate	Bragge P, et al. (2011) [2.12]
Tele-medicine using digital imaging	Detecting various levels of DR combining all field strategies	>70% except severe NPDR 53% (45-62)	>90% except mild NPDR 89% (88-91)	Different field strategies combined in to one estimate	Shi L, et al. (2014) [2.13]
Retinal Photography	Detecting any DR compared to 7 field imaging as a reference	1 field - range 66-87% 2 field - range 86-98% 3 field - range 66-98%	1 field - range 45-96% 2 field - range 78-95% 3 field - range 72-86%	Pupil status and type of imaging not specified	Govinda A, et al. (2011) [2.26]

Automated screening	DR vs No DR, ungradable images included in the analysis	90.5% (89.3-91.6)	67.4% (66.0-68.8)	Pupil status and type of imaging not specified	Norgaard MF, et al. (2018) [2.27]

2.4 Successful task-shifting approaches to DR screening

Human resources (HR) involved in DR grading is a key factor in development of a successful DR screening program. Sometimes it is the major limitation in implementing DR screening in many low income countries [2.28]. Due to the scarcity of ophthalmologists in low-income settings, it is not an efficient use of their time to use them for the first level DR screening. Many non-ophthalmic cadres such as endocrinologists and family physicians have been successfully validated to screen DR [2.29–2.31]. One review concluded that digital fundus photography had become the preferred method for detecting DR. This review suggested non-mydriatic retinal imaging by a trained technician as a feasible method [2.32]. However, selection of specific personnel is context specific.

2.5 Role of an enabling environment for DR screening

One systematic review showed that improving infrastructure and processes in the health system and increasing service user awareness can significantly promote DR screening [2.33]. Health system assessments mention that economic and logistic reasons hinder the provision of DR screening services [2.34]. Various geographic and cultural issues need to be addressed according to the context [2.35]. It has also been mentioned that the lack of policy or public health approach to screening could be a barrier to develop programs [2.28,2.36]. Such factors need assessment for implementing a DR screening program in Sri Lanka. The lack of scientific evidence from the local context is a major obstacle in persuading the decision makers.

2.6 Client perceptions on DR screening

Awareness of need for detecting DR at a symptomless stage is a key factor that facilitates regular follow up. State of 'symptom-less-ness' in DR may be a crucial factor in health seeking behaviour of a PwDM in any community. The most consistent barrier across most of the studies is lack of knowledge regarding DR screening among the PwDM [2.37–2.44]. Reports also state that even when PwDM had the appropriate knowledge, absence of a recommendation by the service provider may hinder access [2.45]. Culturally competent care is desirable in a diverse patient community overcoming the sociocultural barriers [2.46,2.47]. Access barriers are different for different segments of the population - e.g. for people with disabilities [2.48]. Certain high risk populations are vulnerable to sight loss due to underutilization of services [2.2]. Implementing public health interventions in general, would still have problems in accessing health care for certain communities which require further investigations [2.49]. One report mentioned that inequalities have been observed in detection and treatment of DR which require multi-sectoral engagement [2.5]. Defining the barriers will enable to implement public health strategies to improve access [2.50]. Therefore, it is necessary to understand the potential barriers in access and challenges in provision of DR screening services in Sri Lanka.

Social norms, beliefs, attitude and motivation of PwDM should be considered to overcome the barriers to accessing DR screening [2.34,2.51]. Some researchers reported that psychological reasons, attitude of the family members and limited personal mobility may also result in failure to attend [2.37,2.39,2.51–2.53]. PwDM may not like to attend screening due to the discomfort of mydriasis [2.54,2.55]. Studies have also shown that patient satisfaction on the screening modality is important in addressing the barriers [2.35]. Factors such as cost of the services, affordability and not having an insurance could be a barrier in a paid system [2.56–2.60]. Another important barrier relates to cooperation and communication problems with service providers [2.35,2.41,2.61]. When reviewing literature, it is apparent that lot more is needed in the Western province of Sri Lanka with regard to assessing the specific barriers for DR screening. There was no literature from Sri Lanka answering these research questions.

2.7 Provider perspective of DR screening

In order to understand the barriers, it is important to assess the service providers' views and system factors as well. The knowledge of DR and DR screening among the physicians and availability of training programs are important in addressing the barriers to access [2.36,2.62]. Apart from service users' knowledge, lack of provision of health education from the service provider is considered as a barrier [2.34,2.43,2.63]. In addition comprehensiveness of the given information is also important [2.44,2.58,2.64]. Service providers' attitude on performing a dilated fundoscopy on an asymptomatic patient and non-adherence to guidelines could also affect the uptake of services [2.65,2.66]. Further, unavailability of screening and cost of services have also been identified as major barriers to access [2.37,2.41,2.56,2.57]. It was shown that availability of a diabetics register and communication system would improve accessibility [2.39,2.52]. There should be a confidence/trust in the service provider by the PwDM in order to improve the access [2.35,2.45]. Factors such as waiting time, time taken to share results were also considered as barriers in accessing screening services [2.51,2.54,2.67]. Some authors found that transferring patients from one service provider to another, type of eye care provider performing the last eye examination etc. may affect uptake of screening services on follow up visits [2.53,2.68]. Referral pattern is an important aspect in addressing DR screening barriers which has implications in developing a DR screening service for the Western province [2.42,2.60].

2.8 Need for integrated service delivery

In the assessment of health care systems governance, financing, service delivery, human resources (HR), medical supplies and health information systems are the major components [2.69]. In this local setting, governance may have major implications on initiation of a DR screening program due to lack of quality evidence. There is lack of government responsiveness and less preference for DR blindness and visual impairment prevention in Sri Lanka. This despite the high burden of diabetes and DR observed by clinicians. Therefore, lobbying for DR screening programs is lacking in this context. Hence there were no policy directives until now. Integration provides solutions for most of the issues in health systems for chronic disease services delivery [2.70]. DR screening requires appropriate

integration for sustainability [2.36]. To understand the priorities of integration more systematically, assessing the need of the group of subsets concerned (e.g., PwDM at medical clinics) and analysing their utilization patterns is desirable. The need for multi-sectoral engagement for successful integration has also been emphasised. A review reported that integrated health care systems positively affect the quality of care [2.71]. Most authors mention that there is no single best mode of integration to achieve required outcomes [2.72].

It is recommended that integration should not happen in a context with low resources and services should be provided in a user friendly and cost effective manner and as a continuum [2.73]. The objective of integration is to strengthen the people centred care delivery designed according to their needs [2.74]. The integration of services can be two dimensional- vertical and horizontal. The WHO defines the typologies of integration as follows [2.74] i.e., organizational, functional, service and clinical. In most of the LMICs, services are delivered at centres/institutions developed based on a particular health issue and this has led to defragmentation of the health system [2.75]. Since it is a long-drawn process and multi-sectoral engagement is needed, it has not been popular with the providers. One school believes that integrated services will improve the access and efficiency of delivering services and it is not merely a solution for lack of resources [2.75]. Most programs developed to integrate the services at the place of delivery help in enhancing the bond between provider and the user [2.75]. However, vertical programs have shown many disadvantages, leading to reduced efficiency and multiplication of service delivery [2.76]. Further, in vertical programs, there is a possibility of shifting of scarce skilled HR from the routine services [2.76].

2.9 Models of integrated care

The models of integrated DRS care are diverse. Irrespective of the design of the model, integration aims to achieve patient satisfaction, quality of care and improved access [2.77]. However, there is less evidence on cost effectiveness of integrated models [2.78]. In terms of the outcomes, different stakeholders may have different perceptions of the outcome of the integrated care [2.77]. A review stressed

that integrated care was not a ‘panacea’ for all [2.77]. The intensity of the integration at 3 levels has been recently described [2.70,2.79,2.80] (see Figure 2.10 and 2.11). The three critical elements are linkage, coordination and full integration. The stage of full integration needs pooling resources towards an objective geared to the needs of people. Before integration, it is necessary to understand the processes, methods and tools required for delivering the intended integrated care [2.79,2.80].

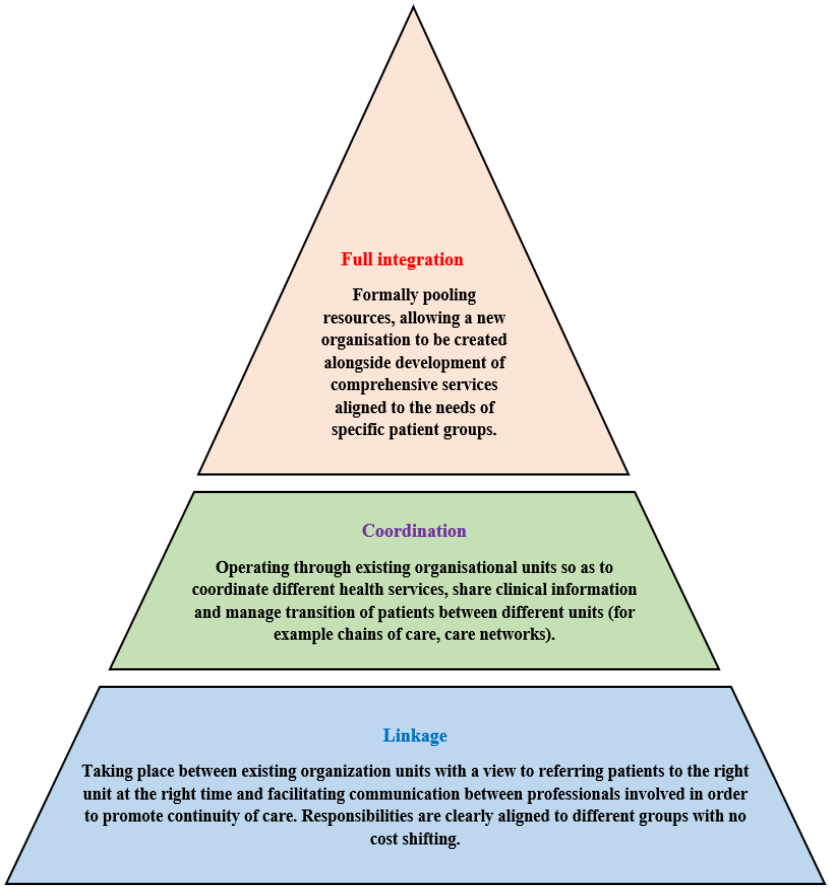


Figure 2.10- Leutz (1999) model of integration (Adapated from Leutz 1999 and further developed by Shaw S, et al 2011 - Extracted from Reference no [2.79])

2.10 Integrated DR screening

DR screening services integration can be done at various levels of service delivery. In this feasibility study, we focused on tertiary level institutions considering the requirement of availability of DR treatment facilities. We aimed to overcome the barriers to access DR screening by the PwDM and maximize the use of available resources in this model. Contextual differences should be appraised when

implementing models [2.77]. A systematic review mentioned four main elements that can be considered in integrated care, i.e., improving patient care, changes in the organisation and system, changes in human resources and finance and governance [2.77]. In our study, the focus is on training HR in DR screening to improve DR screening services delivery through the free public sector health care institutions.

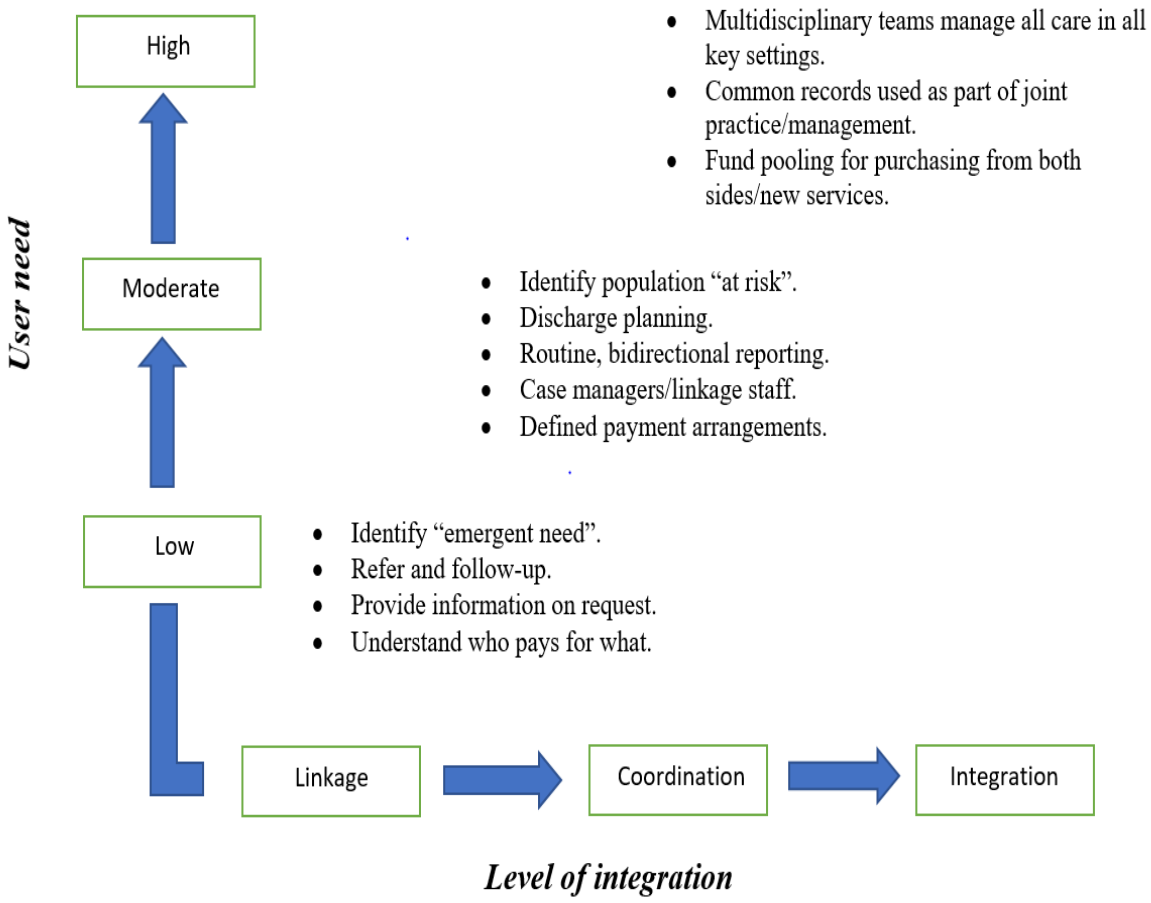


Figure 2.11 - Level of integration and user need as described by Leutz (1999) (Adapted from Leutz 1999 and further developed by Nolte E, et al 2008 - Extracted from reference no [2.80]).

2.11 References: Chapter 2

2.1. World Health Organization. Universal Eye Health-A Global Action Plan 2014-2019 [Internet]. 2013. Available from: https://www.who.int/blindness/AP2014_19_English.pdf?ua=1. Accessed on 16 Aug 2016.

2.2. Elam AR, Lee PP. High-Risk Populations for Vision Loss and Eye Care Underutilization: A Review of the Literature and Ideas on Moving Forward. Surv Ophthalmol. 2013;58(4):348–58. PMID:23664105 DOI:10.1016/j.survophthal.2012.07.005.

2.3. Leasher JL, Bourne RRA, Flaxman SR, Jonas JB, Keeffe J, Naidoo K, et al. Global Estimates on the Number of People Blind or Visually Impaired by Diabetic Retinopathy: A Meta-analysis From 1990 to 2010. Diabetes Care. 2016;39(9):1643–9. PMID:27555623 DOI:10.2337/dc15-2171.

2.4. Ellison EW. Universal eye health: Increasing access for the poorest. Community Eye Heal J. 2013;26(83):s3. PMID:24421586

2.5. Kliner M, Fell G, Gibbons C, Dhothar M, Mookhtiar M, Cassels-Brown A. Diabetic retinopathy equity profile in a multi-ethnic, deprived population in Northern England. Eye (Lond). 2012;26(5):671–7. PMID:22302063. doi:10.1038/eye.2012.3 .

2.6. Andermann A, Blancquaert I. Bulletin of the World Health Organization Revisiting Wilson and Jungner in the genomic age : a review of screening criteria over the past 40 years. Bull World Heal Organ. 2008;86(4): 317-9. PMID:18438522.

2.7. Irish College of Ophthalmologists. Framework for the Development of a Diabetic Retinopathy Screening Programme for Ireland. 2008;(October). [Internet] Available from: http://www.hse.ie/eng/services/publications/topics/Diabetes/Framework_for_a_Diabetic_Retinopathy_Screening_Programme_.pdf. Accessed on 19 Aug 2016.

2.8. Jotheeswaran AT, Lovakanth N, Nadiga S, Anchala R, Murthy GVS, Gilbert CE. Estimating

the proportion of persons with diabetes developing diabetic retinopathy in India: A systematic review and meta-analysis. Indian J Endocrinol Metab. 2016;20(7):S51-8. DOI:10.4103/2230-8210.179774 .

2.9. Jacobs B, Ir P, Bigdeli M, Annear PL, Van Damme W. Addressing access barriers to health services : an analytical framework for selecting appropriate interventions in low-income Asian countries. Health Policy Plan. 2011; 27(4):288-300. PMID:21565939. DOI:10.1093/heapol/czr038

2.10. Early Treatment Diabetic Retinopathy Study Research Group. Early photocoagulation for diabetic retinopathy. ETDRS report number 9. Ophthalmology. 1991;98(5):766–85. PMID:2062512.

2.11. Hutchinson A, McIntosh A, Peters J, Keeffe JE, Khunti K, Baker R. Effectiveness of screening and monitoring tests for diabetic retinopathy - a systematic review. Diabet Med. 2000;17(7):495–506. PMID:10972578

2.12. Bragge P, Gruen RL, Chau M, Forbes A, Taylor HR. Screening for Presence or Absence of Diabetic Retinopathy: a meta-analysis. Arch Ophthalmol. 2011;129(4):435–44. PMID:21149748 DOI: 10.1001/archophthalmol.2010.319

2.13. Shi L, Wu H, Dong J, Jiang K, Lu X, Shi J. Telemedicine for detecting diabetic retinopathy: a systematic review and meta-analysis. Br J Ophthalmol. 2015;99(6):823–31. PMID:25563767. DOI:10.1136/bjophthalmol-2014-305631.

2.14. Baeza M, Orozco-Beltrán D, Gil-Guillen VF, Pedrera V, Ribera MC, Pertusa S, et al. Screening for sight threatening diabetic retinopathy using non-mydriatic retinal camera in a primary care setting: To dilate or not to dilate? Int J Clin Pract. 2009;63(3):433–8. PMID:19222628 DOI:10.1111/j.1742-1241.2008.01921.x

2.15. Ding J, Zou Y, Liu N, Jiang L, Ren X, Jia W, et al. Strategies of digital fundus photography for screening diabetic retinopathy in a diabetic population in urban China. Ophthalmic

Epidemiol. 2012;19(6):414–9. PMID:23171212 DOI:10.3109/09286586.2012.716895

2.16. Liesenfeld B, Kohner E, Piehlmeier W, Kluthe S, Aldington S, Et al. A Telemedical Approach to the Screening of Diabetic Retinopathy : Digital Fundus Photography. Diabetes Care. 2000;23(3):345–8. PMID:10868863

2.17. Saari JM, Summanen P, Kivelä T, Saari KM. Sensitivity and specificity of digital retinal images in grading diabetic retinopathy. Acta Ophthalmol Scand. 2004;82(2):126–30. PMID:15043527 DOI: 10.1111/j.1600-0420.2004.00240.x

2.18. Aptel F, Denis P, Rouberol F, Thivolet C. Screening of diabetic retinopathy: Effect of field number and mydriasis on sensitivity and specificity of digital fundus photography. Diabetes Metab. 2008;34(3):290–3. PMID:18406188 DOI:10.1016/j.diabet.2007.12.007

2.19. Harding SP, Broadbent DM, Neoh C, White MC, Vora J. Sensitivity and specificity of photography and direct ophthalmoscopy in screening for sight threatening eye disease: the Liverpool Diabetic Eye Study. BMJ. 1995;311(7013):1131–5. PMID:7580708.

2.20. Murgatroyd H. Ellingford A, Cox A, Binnie M, Ellis JD, MacEwen CJ, et al. Effect of mydriasis and different field strategies on digital image screening of diabetic eye disease. Br J Ophthalmol. 2004;88(7):920–4. PMID:15205238. DOI:10.1136/bjo.2003.026385.

2.21. Hansen AB, Sander B, Larsen M, Kleener J, Borch-Johnsen K, Klein R, et al. Screening for diabetic retinopathy using a digital non-mydriatic camera compared with standard 35-mm stereo colour transparencies. Acta Ophthalmol Scand. 2004;82(6):656–65. PMID:15606460 DOI:10.1111/j.1600-0420.2004.00347.x

2.22. Scanlon PH. The English National Screening Programme for diabetic retinopathy 2003–2016. Acta Diabetol. Springer Milan; 2017;54(6):515–25. PMID:28224275 DOI:10.1007/s00592-017-0974-1

2.23. Herbert HM, Jordan K, Flanagan DW. Is screening with digital imaging using one retinal view

adequate? Eye (Lond). 2003;17(4):497–500. DOI: https://doi.org/10.1038/sj.eye.6700409

2.24. Maberley D, Cruess AF, Barile G, Slakter J. Digital photographic screening for diabetic retinopathy in the James Bay Cree. Ophthalmic Epidemiol. 2002;9(3):169–78. PMID:12045884.

2.25. Ku JJ, Landers J, Henderson T, Craig JE. The reliability of single-field fundus photography in screening for diabetic retinopathy: The central australian ocular health study. Med J Aust. 2013;198(2):93–6. PMID:23373499

2.26. Govinda A, DeVerteuil R. Systematic review of the diagnostic accuracy of the single, two and three field digital retinal photography for screening diabetic retinopathy. JBI Libr Syst Rev. 2011;9(16):491–537 PMID:27820519.

2.27. Norgaard M, Grauslund J. Automated Screening for Diabetic Retinopathy – A Systematic Review. Ophthalmic Res. 2018;60(1):9–17 https://doi.org/10.1159/000486284. PMID:29339646 DOI:10.1159/000486284

2.28. Burgess PI, Msukwa G, Beare NA V. Diabetic retinopathy in sub-Saharan Africa: meeting the challenges of an emerging epidemic. BMC Med. 2013;11(1):157. PMID:23819888 DOI:10.1186/1741-7015-11-157

2.29. Carmichael TR, Carp GI, Welsh ND, Kalk WJ. Effective and accurate screening for diabetic retinopathy using a 60 degree mydriatic fundus camera. South African Med J. 2005;95(1):57–61. PMID:15762251

2.30. Deb-Joardar N, Germain N, Thuret G, Manoli P, Garcin AF, Millot L, et al. Screening for diabetic retinopathy by ophthalmologists and endocrinologists with pupillary dilation and a nonmydriatic digital camera. Am J Ophthalmol. 2005;140(5):814-821. PMID:16310458 DOI:10.1016/j.ajo.2005.05.051

2.31. Bhargava M, Cheung CY, Sabanayagam C, Kawasaki R, Harper CA, Lamoureux EL, et al.

Accuracy of diabetic retinopathy screening by trained non-physician graders using non-mydriatic fundus camera. Singapore Med J. 2012;53(11):715–9. PMID:23192497

2.32. Guigui S, Lifshitz T, Levy J. Screening for diabetic retinopathy: review of current methods. Hosp Pract. 2012;40(2):64–72. PMID:22615080 DOI:10.3810/hp.2012.04.971.

2.33. Zhang X, Norris SL, Saadine J, Chowdhury FM, Horsley T, Kanjilal S, et al. Effectiveness of Interventions to Promote Screening for Diabetic Retinopathy. Am J Prev Med. 2007;33(4):318–35. PMID:17888859 DOI:10.1016/j.amepre.2007.05.002

2.34. Walker EA, Basch CE, Howard C, Zybert PA, Kromholz WN, Shamoon H. Incentives and Barriers to Retinopathy Screening Among African-Americans With Diabetes. J Diabetes Complications. 1997;11(5):298-306. PMID:9424171

2.35. Arora S, Kurji AK, Tennant MTS. Dismantling sociocultural barriers to eye care with tele-ophthalmology: Lessons from an Alberta Cree community. Clin Investig Med. 2013;36(2):57–63. PMID:23544606

2.36. Khandekar R. Screening and public health strategies for diabetic retinopathy in the Eastern Mediterranean Region. Middle East Afr J Ophthalmol. 2012;19(2):178-84. PMID:22623855 DOI:10.4103/0974-9233.95245

2.37. Adriono G, Wang D, Octavianus C, Congdon N. Use of eye care services among diabetic patients in urban Indonesia. Arch Ophthalmol. 2011;129(7):930–5. PMID:21746983 DOI:10.1001/archophthalmol.2011.147

2.38. Shamoon H, Zybert P, Basch CE, Walker EA, Howard CJ. The Effect of Health Education on the rate of ophthalmic examinations among African Americans with diabetes mellitus. Am J Public Health. 1999;89(12):1878–1882. PMID:10589324.

2.39. Harvey JN, Craney L, Nagendran S, Ng CS. Towards comprehensive population-based screening for diabetic retinopathy: operation of the North Wales diabetic retinopathy screening

programme using a central patient register and various screening methods. J Med Screen. 2006;13(2):87–92. PMID:16792832 DOI:10.1258/096914106777589669

2.40. Dandona R, Dandona L, John RK, Mccarty CA, Rao GN. Awareness of eye diseases in an urban population in southern India. Bull World Health Organ. 2001;79(2):96-102. PMID:11242828.

2.41. Hartnett ME, Key IJ, Loyacano MN, Horswell RL, DeSalvo KB. Perceived Barriers to Diabetic Eye Care-Qualitative study of patinets and physicians. Arch Ophthalmol. 2005;123(3):387–91. PMID:15767483 DOI:10.1001/archopht.123.3.387

2.42. Onakpoya OH, Adeoye AO, Kolawole BA. Determinants of previous dilated eye examination among type II diabetics in Southwestern Nigeria. Eur J Intern Med. 2010;21(3):176–9. PMID:20493418 DOI:10.1016/j.ejim.2010.01.009

2.43. Paz SH, Varma R, Klein R, Wu J, Azen SP. Noncompliance with Vision Care Guidelines in Latinos with Type 2 Diabetes Mellitus. The Los Angeles Latino Eye Study. Ophthalmology. 2006;113(8):1372–7. PMID:16769120 DOI:10.1016/j.ophtha.2006.04.018

2.44. Trento M, Bajardi M, Borgo E, Passera P, Maurino M, Gibbins R, et al. Perceptions of diabetic retinopathy and screening procedures among diabetic people. Diabet Med. 2002;19(10):810–3. PMID:12358866

2.45. Eijk KND Van, Blom JW, Gussekloo J, Polak BCP, Groeneveld Y. Diabetic retinopathy screening in patients with diabetes mellitus in primary care : Incentives and barriers to screening attendance. Diabetes Res Clin Pract. 2011;96(1):10–6. PMID:22137363 DOI:10.1016/j.diabres.2011.11.003

2.46. Taylor SP, Nicolle C, Maguire M. Cross-cultural communication barriers in health care. Nurs Stand. 2013;27(31):35-49. PMID:23641636.

2.47. Betancourt JR., Green AR, Carrillo JE. Cultural Competence in Health Care: Emerging

Frameworks and Practical Approaches. Feild Reposrt Weil Med Coll Cornell Univeristy [Internet]. 2002;(576):1–24. Available from: http://www.commonwealthfund.org/usr_doc/betancourt_culturalcompetence_576.pdf. Accessed on 19 Aug 2016.

2.48. Drainoni M, Lee-hood E, Tobias C, Andrew J, Systems NH. Cross-Disability Experiences of Barriers to Healthcare Access Consumer Perspectives. Journal of Disability Policy Studies. 2006;17(2)101–15. https://doi.org/10.1177/10442073060170020101

2.49. Marrone S. Understanding barriers to health care : a review of disparities in health care services among Indigenous populations. Int J Circumpolar Health. 2007;66(3):188–98. PMID:17655060

2.50. Penchansky R, Thomas J. The concept of access-Definition and relationship to comsumer satisfaction. Med Care. 1981;19(2):127–40. PMID:7206846

2.51. Lewis K, Patel D, Yorston D, Charteris D. A qualitative study in the United Kingdom of factors influencing attendance by patients with diabetes at ophthalmic outpatient clinics. Ophthalmic Epidemiol. 2007;14(6):375–80. PMID:18161611 DOI:10.1080/09286580701375195

2.52. Hipwell AE, Sturt J, Lindenmeyer A, Stratton I, Gadsby R, Hare PO et al. Attitudes, access and anguish : a qualitative interview study of staff and patients' experiences of diabetic retinopathy screening. BMJ Open 2014;4: e005498. doi:10.1136/bmjopen-2014-005498

2.53. Puent B, Nichols K. Patients' perspectives on noncompliance with diabetic retinopathy standard of care guidelines. Optometry. 2004;75(11):709–16. PMID:15597813

2.54. Yeo ST, Edwards RT, Fargher EA, Luzio SD, Thomas RL, Owens DR. Preferences of people with diabetes for diabetic retinopathy screening: A discrete choice experiment. Diabet Med. 2012;29(7):869–77. PMID: 22414336 DOI: 10.1111/j.1464-5491.2012.03636.x

2.55. Murgatroyd H, MacEwen C, Leese G. Patients' attitude towards mydriasis for diabetic eye disease screening. Scott Med J. 2006;51(4):35-7. PMID:17137147 DOI:10.1258/RSMSMJ.51.4.35

2.56. Sheppler CR, Lambert WE, Gardiner SK, Becker TM, Mansberger SL. Predicting adherence to diabetic eye examinations: Development of the compliance with annual diabetic eye exams survey. Ophthalmology. 2014;121(6):1212–9. PMID:24518614. DOI:10.1016/j.ophtha.2013.12.016

2.57. Chou CF, Sherrod CE, Zhang X, Barker LE, Bullard KM, Crews JE, et al. Barriers to eye care among people aged 40 years and older with diagnosed diabetes, 2006-2010. Diabetes Care. 2014;37(1):180–8. PMID:24009300 doi:10.2337/dc13-1507

2.58. Hwang J, Rudnisky C, Bowen S, Johnson JA. Socioeconomic factors associated with visual impairment and ophthalmic care utilization in patients with type II diabetes. Can J Ophthalmol. 2015;50(2):119–26. PMID:25863851 DOI:10.1016/j.jcjo.2014.11.014.

2.59. Lian JX, McGhee SM, Gangwani RA, Hedley AJ, Lam CL, Yap MK, et al. Screening for diabetic retinopathy with or without a copayment in a randomized controlled trial: Influence of the inverse care law. Ophthalmology. 2013;120(6):1247–53. PMID:23583166 DOI:10.1016/j.ophtha.2012.11.024.

2.60. Nsiah-Kumi P, Ortmeier SR, Brown AE. Disparities in diabetic retinopathy screening and disease for racial and ethnic minority populations-a literature review. J Natl Med Assoc. 2009;101(5):430–7. PMID:19476196.

2.61. Anderson S, Broadbent DM, Swain JYS, Vora JP, Harding SP. Ambulatory photographic screening for diabetic retinopathy in nursing homes. Eye (Lond). 2003;17(6):711–6. PMID:12928682. DOI:10.1038/sj.eye.6700487.

2.62. Khandekar R, Shah S, Al Lawatti J. Retinal examination of diabetic patients: Knowledge, attitudes and practices of physicians in Oman. East Mediterr Heal J. 2008;14(4):850–7.

PMID:19166168

2.63. Huang OS, Tay WT, Tai ES, Chb MB, Wang JJ, Saw S, et al. Lack of Awareness amongst Community Patients with Diabetes and Diabetic Retinopathy: The Singapore Malay Eye Study. Ann Acad Med Singapore. 2009;38(12):1048–55. PMID:20052439

2.64. Orton E, Forbes-Haley A, Tunbridge L, Cohen S. Equity of uptake of a diabetic retinopathy screening programme in a geographically and socio-economically diverse population. Public Health. 2013;127(9):814–21. PMID:23973045 DOI:10.1016/j.puhe.2013.04.015

2.65. Yan X, Liu T, Gruber L, He M, Congdon N, FL F, et al. Attitudes of Physicians, Patients, and Village Health Workers Toward Glaucoma and Diabetic Retinopathy in Rural China: a focus group study. Arch Ophthalmol. 2012;130(6):761-70. PMID:22801838 DOI:10.1001/archophthalmol.2012.145.

2.66. Preti RC, Saraiva F, Junior JAT, Takahashi WY, da Silva MER. How much information do medical practitioners and endocrinologists have about diabetic retinopathy?. Clinics (Sao Paulo). 2007;62(3):273–8. PMID:17589667

2.67. Yeo ST, Edwards RT, Luzio SD, Charles JM, Thomas RL, Peters JM, et al. Diabetic retinopathy screening: Perspectives of people with diabetes, screening intervals and costs of attending screening. Diabet Med. 2012;29(7):878–85. PMID:22414383 DOI:10.1111/j.1464-5491.2012.03637.x

2.68. Schoenfeld ER, Greene JM, Wu SY, Leske C. Patterns of Adherence to Diabetes Vision Care Guidelines Baseline Findings from the Diabetic Retinopathy awareness program. Ophthalmology. 2001;108(03):563–71. PMID:11237912

2.69. Blanchet K, Gilbert C, Lindfield R, Crook S. Eye Health Systems Assessment (EHSA): How To Connect Eye Care With The General Health. IAPB Technical Report [Internet]. 2012;(April). Available from: http://iceh.lshtm.ac.uk/eye-health-systems-assessment/. Accessed on 19 Aug 2016.

2.70. Leutz W. Five laws for integrating medical and social services: lessons from the United States 2.and the United Kingdom. Milbank Quarterly-Journal Popul Heal Policy. 1999;77(1):77–110. PMID:10197028

2.71. Ouwens M, Wollersheim H, Hermens R, Hulscher M, Grol R. Integrated care programmes for chronically ill patients: a review of systematic reviews. Int J Qual Heal Care. 2005;17(2):141–6. PMID:15665066 DOI:10.1093/intqhc/mzi016

2.72. Maruthappu M, Hasan A, Zeltner T. Enablers and Barriers in Implementing Integrated Care. Heal Syst Reform. 2015;1(4):250–6. https://doi.org/10.1080/23288604.2015.1077301.

2.73. World Health Organisation-Technical Report-May 2008. Integrated health services-what and why? [Internet]. WHO. 2008. Available from: https://www.who.int/healthsystems/technical_brief_final.pdf. Accessed on 19 Aug 2017.

2.74. World Health Organisation (WHO). Integrated care models: An overview. Health Service Delivery Program [Internet]. 2016. Available from: http://www.euro.who.int/__data/assets/pdf_file/0005/322475/Integrated-care-models-overview.pdf. Accessed on 19 Aug 2016.

2.75. Dudley L, Garner P. Strategies for integrating primary health services in low and middle income countries at the point of delivery. Cochrane database Syst Rev [Internet]. 2011;(7):CD003318. PMID:21735392 DOI:10.1002/14651858.CD003318.pub3

2.76. Atun R, Bennett S, Duran A. When do vertical (stand-alone) programmes have a place in health systems? Health System and Policy Analysis - WHO Regional Office for Europe. [Internet]. 2008. Available from: https://www.who.int/management/district/services/WhenDoVerticalProgrammesPlaceHealthSystems.pdf. Accessed on 19 Aug 2016.

2.77. Baxter S, Johnson M, Chambers D, Sutton A, Goyder E, Booth A. The effects of integrated care: A systematic review of UK and international evidence. BMC Health Serv Res.

2018;18(1):350. PMID:29747651 DOI:10.1186/s12913-018-3161-3

2.78. Tsiachristas A, Stein KV, Evers S, Mölken MR. Performing Economic Evaluation of Integrated Care : Highway to Hell or Stairway to Heaven? Int J Integr Care. 2016;16(4):3 DOI:http://doi.org/10.5334/ijic.2472

2.79. Shaw S, Rosen R, Rumbold B. An overview of integrated care in the NHS. What is integrated care? [Internet]. Research Report Nuffield Trust. 2011. Available from: http://www.nuffieldtrust.org.uk/sites/files/nuffield/publication/what_is_integrated_care_research_report_june11.pdf. Accessed on 19 Aug 2016.

2.80. Nolte E, McKee M.Caring for people with chronic conditions - A health system perspective. European Observatory on Health Systems and Policy Series. 2008 [internet]. Available from http://www.euro.who.int/__data/assets/pdf_file/0006/96468/E91878.pdf. Accessed on 20 Aug 2016.

Chapter 3

PRIOR WORK DONE LEADING TO THE PROJECT

My prior work leading to the project mainly comprised of the research undertaken for my Master's in public health for eye care in the year 2014 and the training and observerships done in UK and India during the first year of the PhD.

3.1 Situational analysis of availability of diabetic eye care service delivery in health care institutions of the Western province of Sri Lanka

My work builds on what I did for my MSc where I looked at the available infrastructure, human resources and services for screening and treatment of DR in Sri Lanka. I undertook previous work also in the Western province of Sri Lanka. The previous work, available evidence and preparatory work done helped me in identifying the research question. The lack of an organized effort for screening for DR at the physician clinics and the huge drop out when referred to an eye clinic by a physician were deemed as critical factors impeding prevention of vision loss in DM in Sri Lanka. The increasing life expectancy and consequently the proportion of people who are at risk of DM and its complications need a one-stop solution where comprehensive management of DM and its complications are integrated.

A situational analysis was conducted in the year 2014 to assess the availability of DR screening and treatment facilities in the Western province of Sri Lanka [3.1]. The public sector and private sector health care facilities, where there a specialist ophthalmologist or a retinologist was available were included in this study. I assessed these health care facilities for availability of DR screening services, technology and skilled human resources. There were 51 institutions in both public and private sectors providing specialised eye care. There were 25 (25/51, 49%) secondary level and 9 (9/51, 17.6%) tertiary level eye care service providers. There were 16 (16/51, 31.4%) government institutions. Majority (33/51, 64.7%) of the institutions were in the Colombo district [3.1].

3.1.1 Estimation of burden of DR screening and treatment and gap in service delivery in the Western province

There is no structured DR screening and follow up program in the Western province of Sri Lanka at present despite a high prevalence of DM. The survey found that there were only 135,816 opportunistic screening visits per year in the region [3.2]. However according to the estimated prevalence of DM and DR; it is expected that there should be 806,789 patient visits per year in the province, considering the population aged more than 35 years (Table 3.6). This estimation showed a huge unmet need in the population for DR screening annually. In addition, only about 13,553 laser sessions had been done in this region. However, the estimated burden showed a requirement of 124,243 laser sessions per year, showing that only about 1/10th of required laser sessions per year were done in this region [3.2].

Table 3.6 - Diabetic retinopathy screening services delivery gap analysis for the Western province of Sri Lanka - Year 2014 (Extracted from reference no [3.1])

District	**Colombo**	**Gampaha**	**Kalutara**	**Province Level**
Population >35 years	1,069,441	1,039,472	558,722	2,667,635
DR Screening burden * (by number of visits)	323,437	314,374	168,978	806,789
No: screened per year (by number of visits)	96,784	26,313	12,722	135,819
Proportion screened	29.9%	8.37%	7.5%	16.8%
DR Laser burden † (Number of procedures)	49,809	48,413	26,021	124,243
Number of laser procedures done per year	10,949	2604	0	13,553
Proportion of laser done	21.9%	5.37%	0	10.9%

*[Gap analysis baseline data – * - Prevalence of diabetes – 18.6%, prevalence of DR among the diabetics – 31.3%, † - Prevalence of STDR among the diabetics 10%, prevalence of blindness among the diabetics due to DR 4%, number of screening by the number of visits not by patient, Laser by number of laser sessions not by the patient number and assuming that one patient needs at least 4 laser sessions]*

3.1.2 Availability of eye care infrastructure and human resources for managing diabetic retinopathy in the Western province of Sri Lanka

Skilled human resources (HR) and infrastructure are major pre-requisites for development of a DR screening program in any setting [3.3]. HR development is a fundamental concept in a health system [3.4]. There was no scientific evidence from the Western province of Sri Lanka, in this regard to draw the attention of decision makers. The aim of this component of the situation analysis was to identify the inputs for a systematic DR screening program. Therefore, in the next stage of the survey, I assessed availability of HR and infrastructure for DR in eye care facilities. I collected data on infrastructure, HR and level of training and skills during the site visits by observation, frequency counting and interviewing [3.1,3.5]. One major limitation of this study was that we assessed the HR and infrastructure only at the eye care facilities. I did not assess the situation at non-ophthalmic settings in this survey [3.1,3.5].

3.1.3 Availability of human resources

There were 40 board certified (qualification awarded through the Post Graduate Institute of Medicine-Sri Lanka) general ophthalmologists and six retinologists in the Western province. Majority (77%, 31/40) of the ophthalmologists and retinologists (83%, 5/6) were based in the Colombo district. I observed that there were no retinologists in the public sector institutions of peripheral districts of Gampaha and Kalutara. There was no specific category as ophthalmic photographers / retinal readers. However, five eye care workers were trained and employed for this task. Considering the possibility of the same professional working in both public and private sectors according to the local regulations, there were 107 general ophthalmologists in this region. Of the general ophthalmologists, 21.4% (23/107) were in the public sector. Similarly, only 14% (3/22) of the retinologists were in the public sector. Fifty seven percent (61/107) of the general ophthalmology and 45% (10/22) of retinal clinics were in secondary level of service delivery centres [3.1,3.5].

Table 3.7 -District wise human resources ratios per 100,000 population (Table extracted from reference no [3.1] and [3.5])

Category	Colombo	Gampaha	Kalutara
Ophthalmologist	1:74,000	1:380,000	1:400,000
Retinologist	1:460,000	1:2,290,000	0
Medical officer	1:25,000	1:104,000	1:93,000
Optometrist	1:50,000	1:127,000	1:173,000
Clinic nurse	1:52,000	1:176,000	1:304,000
Operating theatre nurse	1:18,000	1:49,000	1:48,000
Clinic assistants	1:21000	1:63000	1:81000

I identified that only the ophthalmologists and retinologists in this region were competent in DR screening and treatment (mean skills score: retinologists - 0.98, 95% CI 0.9-1.0, general ophthalmologist - 0.81, 95% CI 0.78-0.84). The competency of the medical officers was comparatively low (Medical officers: <4 years in eye care, mean score - 95% CI 0.17-0.29, >4 years in eye care 95% CI 0.23-0.41) though they involved in screening and managing DR. There were no training programs or curricula for mid-level personnel [3.1,3.5].

3.1.4 Availability of infrastructure

Out of the 43 institutions included in my survey, there were 49 general ophthalmology clinics (since some institutions had facilities for more than one clinic) and eight vitreo-retinal (VR) clinics in the Western province. There were ten VR operating theatre facilities in the region, and this was not available in Kalutara district. Moreover, DR laser treatment facilities (n=13 eye units) were available only in Colombo and Gampaha districts. I observed that Colombo and Gampaha districts have the capacpity to deliver DR treatment services. I could observe that most of the ocular imaging facilities were in the private sector (81% of fundus photography and 89% of ocular angiography). Seventy seven percent of the laser treatment facilities and 80% VR major theatre facilities were also provided by the private sector [3.1,3.5].

Table 3.8 - Population adjusted (per 100,000) district wise distribution of infrastructure (Table extracted from reference no [3.1] and [3.5].

Category	Colombo	Gampaha	Kalutara
Total population	2,309,809	2,294,641	1,217,260
Slit Lamp Examination	3.85	1.35	0.98
Refraction	2.25	1.08	0.65
Fundus Imaging	0.43	0.04	0
Ocular Angiography	0.35	0.04	0
OCT Macular Imaging *	0.22	0	0
Laser Treatment	0.48	0.09	0
VR Minor Surgical facility	0.645	0.26	0.25
VR Major Surgical Facility	0.35	0.09	0
Phacoemulsification	0.78	0.35	0.41

* - Optical coherence tomography

When population adjusted (per 100,000) rates of infrastructure was evaluated, it was observed that the highest infrastructure rates were reported from the Colombo district. There was no infrastructure in ocular imaging, laser and VR major surgical facilities in Kalutara district. Most of the DR management infrastructure was in tertiary level institutions [3.1,3.5].

Western province of Sri Lanka has skilled retinologists and general ophthalmologists with knowledge and skills in screening and treatment of DR. All institutions had the essential equipment for performing the dilated fundoscopic examination, with refraction services. Besides this, infrastructure was underutilised for DR screening services in the Western province. The barriers to access DR screening should be assessed, considering the wide gap in service delivery. Capacity building of mid-level personnel, such as medical officers, is a vital requirement in establishment of a DR screening program in this region.

3.2 Courses of actions - Training and observerships on DR screening using retinal imaging

As this was the first ever scientific evaluation on using digital retinal imaging in Sri Lanka, I as the PhD student had to undergo several months of training on various modalities of DR screening in UK and India. With the guidance of my main supervisor, I was able to gain knowledge and hands on experience in various modalities of DR screening, including digital retinal imaging, during a training an observership visits to four states of India. This was very helpful to understand how an intervention would work in a practical setting. Further, I was able to observe the level of skills required in each model and to get an idea about the acceptance of DR screening by PwDM in India, which has cultural similarities to Sri Lanka.

I also had the opportunity to experience how these screening programs run in high-income settings with my observation visits within the English National Screening Program for DR. These visits covered: Moorfields Eye Hospital, Stoke Mandeville District Hospital, Mile End Hospital and one DR screening program in Brighton. This was helpful for me to understand the processes involved in DR screening, starting from primary screening of a PwDM up to the level of quality control of a program.

3.3 References: Chapter 3

3.1. Piyasena MP, Murthy G. A Situation Analysis and Mapping of Availabillity of Services for Diabetic Retinopathy in the Health Care Institutions of the Western Province of Sri Lanka. MSc Dissertation - LSHTM. [Internet]. LSHTM; 2014. Available from: https://intra.lshtm.ac.uk/library/MSc_CEH/2013-2014/107722.pdf

3.2. Piyasena PN, Murthy GVS. A situation analysis of diabetic eye care service delivery in health care institutions of the Western Province of Sri Lanka. Ceylon Med J. 2017 Sep 30;62(3):205-206. http://doi.org/10.4038/cmj.v62i3.8527

3.3. Wilson J, G Jungenr. Principles and Practice of Screening of Disease [Internet]. 1968. Available from: http://www.who.int/bulletin/volumes/86/4/07-050112bp.pdf. Accessed on 16 Aug 2016.

3.4. Hongorn C, Mcpake B . How to bridge the gap in human resources for health. Lancet. 2004;364(9443):1451–6. PMID:15488222 DOI:10.1016/S0140-6736(04)17229-2

3.5. Piyasena MMPN, Murthy GVS. Availability of eye care infrastructure and human resources for managing diabetic retinopathy in the western province of Sri Lanka. Indian J Ophthalmol 2019 (in process). DOI: 10.4103/ijo.IJO_1754_18

Chapter 4

RATIONALE AND JUSTIFICATION

4.1 Conceptual framework of defining the research question and achieving the aim

I intended to assess the feasibility of an integrated DR screening program in the Western province, Sri Lanka before applying it at regional / national level. There were no specific guidelines to develop a DR screening modality in a LMIC like Sri Lanka. The best practice of evidence based health care depends on communicating and translating the available evidence usefully and carefully [4.1]. Implementing a new strategy in a context is an iterative process that would require assessment of feasibility and pilot testing leading to refinement. This would facilitate identification of the best suited strategy for a local context [4.2]. In addition, the most suitable practice should be adopted to the context with the emphasis on socio-cultural acceptability [4.1]. In this approach main considerations are purpose of the proposed modality, performance relative to the gold standard, actual performance in the setting, and understanding of how target groups benefited by the system.

In this feasibility study we are planning to determine whether an integrated DR screening model is appropriate for this context in order to develop a relevant and sustainable DR screening program [4.3]. This was necessitated by, a lack of evidence from the local context. The main aspect of this feasibility study is assessment of the 'practicality' of the proposed modality [4.3]. Here, we are interested in whether the proposed modality would work in the system in the first instance and whether it would be sustainable in the long run. This feasibility study in the Western province of Sri Lanka is a pre-requisite before implementing a program and this would enable us to assess the likelihood of success of a future program [4.4]. A previous study showed that to select appropriate interventions in Asian LMICs, it is necessary to address demand side barriers as well as the supply side barriers at the same time [4.5]. It will be helpful to assess the acceptability of the suggested model, participants characteristics and resource management in advance [4.6].

Translating evidence into practice is a challenging task [4.1]. The scope of this project was to identify an appropriate modality to improve the uptake of DR screening and integration in the general health system at an appropriate level [4.7]. Service readiness, developing skilled human resources and developing appropriate infrastructure were considered in the health system approach for this research question, leading to universal coverage [4.8]. Feasibility studies involved assessment of five main aspects. They were: 1) Operational feasibility, 2) Cultural, legal and political feasibility (some classifications legal as separate component), 3) Technical feasibility, 4) Economic feasibility and 5) Schedule feasibility (Table 4.9). The technical feasibility of integrating the DR screening at medical clinics has been assessed in this study [4.9]. The DR screening is proposed to be integrated at tertiary levels of service delivery assuming less resistance for task shifting and availability of facilities for further assessment and treatment. The main focus was technical feasibility and areas such as cultural acceptability of the proposed modality and practicality had been considered when designing the feasibility study [4.10].

Table 4.9 - Components of feasibility assessment

Operational Feasibility	**Cultural, Political and Legal Feasibility**	**Technical Feasibility** **(Main focus of this project)**	**Economic Feasibility**	**Schedule Feasibility**
How well the proposed DR screening model solves the problem?	Will the service users and providers accept the change?	Is the proposed DR screening model practical in this setting? Does Western province - Sri Lanka possess the necessary infrastructure and technological expertise to implement a DR screening program using digital imaging?	What are the costs of DR screening using digital imaging? What are the benefits of DR screening?	Are the time lines realistic for the proposed DR screening program model?

A systematic review on strategies for integrating primary health services and WHO guidelines mentioned that integration increases the coherence and efficiency of services from both service users and providers [4.11–4.13]. Integration of non-ophthalmic personnel for DR screening was considered in

this study. This will allow comprehensive diabetic care service delivery under one roof. The use of services had been mentioned as just an 'operational proxy' and there are many other dimensions such as affordability and acceptability, that should be addressed to improve access [4.5]. Though the underpinning mechanisms that socio-economically deprived PwDM end up in sight loss due to DR is unclear. Previous studies showed that this could be due to barriers to access [4.14]. As described in Medical Research Council-UK guidelines, a key concern in development of a complex intervention was whether it would be effective in day to day practice (Figure 4.12) [4.15].

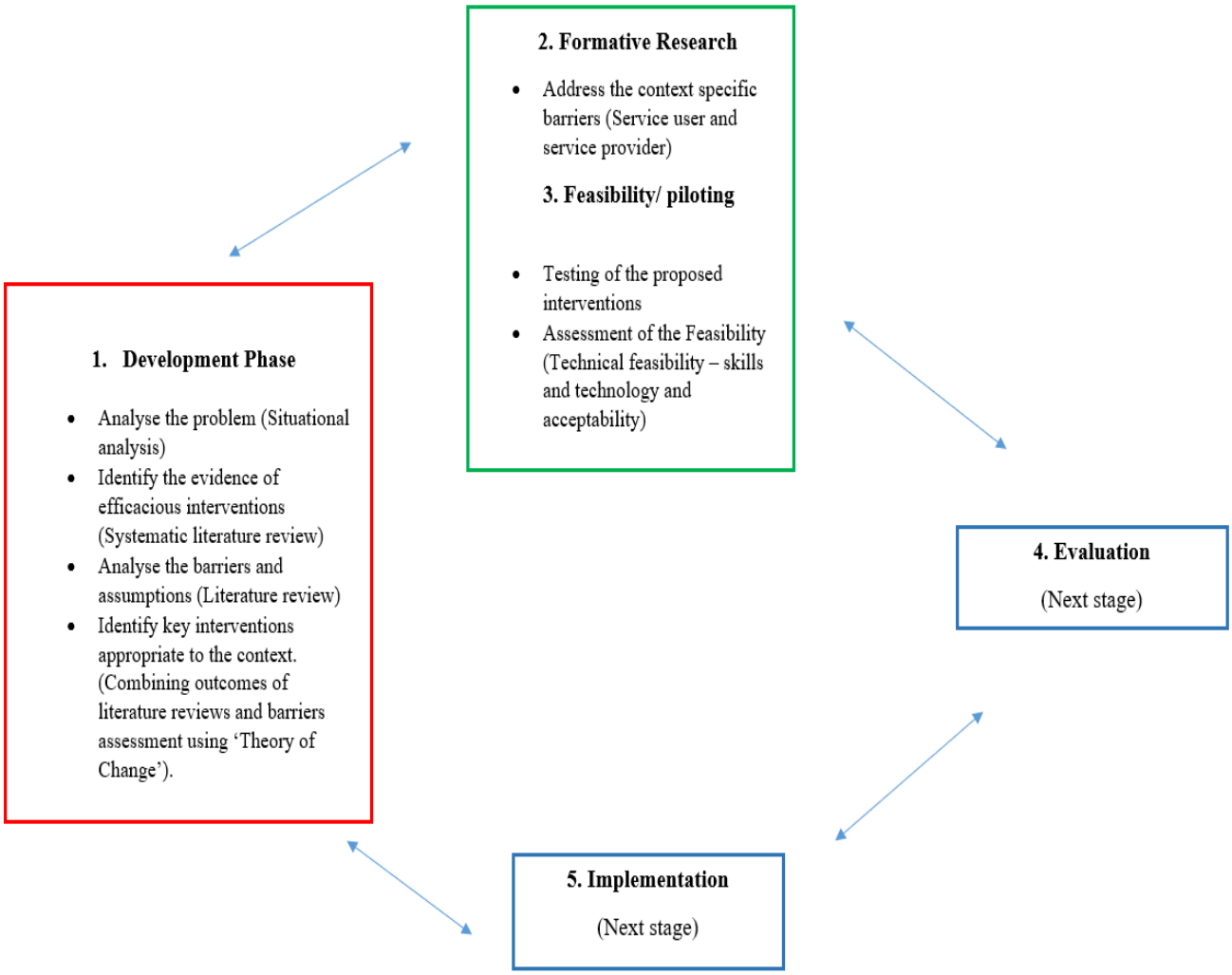


Figure 4.12 - Schematic representation of the steps involves in the feasibility study (steps 1, 2 and 3). (The 4th and 5th steps are beyond the remit of this project) (Adopted from Medical Research Council – UK guidelines) [4.15].

4.2 Theory of change

4.2.1 Mapping of how the change can happen in the Western province of Sri Lanka based on *"Theory of Change"*

In preventive strategies, decisions made are distinctive for each setting, according to the expectations and available resources [4.12]. We need to assess six dimensions to understand the functionality of an eye health system. i.e., governance, health financing, service delivery, human resources, medical products and health information systems [4.7]. In this study we focused on tertiary level of service delivery, where there are adequate levels of HR and infrastructure to screen and treat DR. DR screening by non-ophthalmic personnel has been suggested in most of the technical reports. Ophthalmologists are a scarce HR even in HICs [4.12]. The WHO and ICO consultations stated that adequate level of DTA in detecting any level of DR could be achieved by various non-ophthalmic cadres [4.12]. Therefore, the best-suited alternative HR was identified and validated for primary screening in this study.

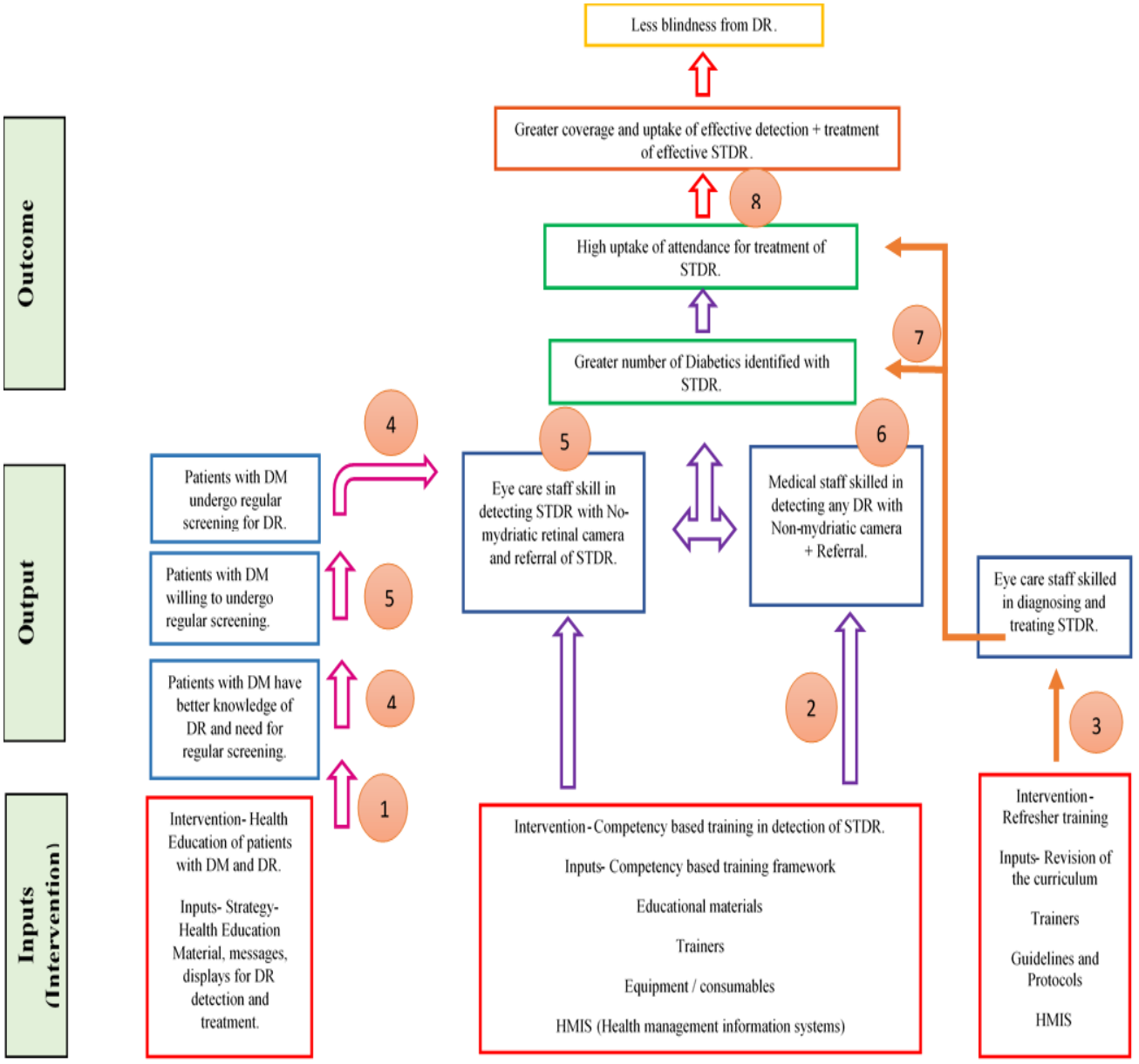
I designed this study by considering situational analysis data and the evidence in the literature. The process of how this change can happen in the Sri Lankan context (action movements) was mapped following assessment of barriers and using the "Theory of Change". To identify the content of the framework, formative research was done that identified, the barriers and 'potential' enablers and their relationships. The PwDM' knowledge, attitude, behavioural patterns and perceived barriers in accessing DR screening were assessed before developing the interventions as explained in behavioural models [4.16,4.17]. A health educational intervention (HEI) to improve the uptake of DR assessment and treatment services at ophthalmologist's clinic by PwDM in the Western province of Sri Lanka was considered in the next stage [4.17]. The effectiveness of similar interventions had been assessed in some other disciplines such as cardiac care and primary care as documented in the literature [4.18,4.19]. It has been postulated that the following (see figure 4.13) barriers may be encountered in the process of achieving the desired goal of less number of people with blindness and vision impairment due to DR. We explored two strategies of achieving this goal in this feasibility study. They were;

1) Service provider-based intervention (propose an appropriate DR screening modality) and

2) Service user-based intervention (HEI).

Further this hypothesis has been developed based on the assumption that this modality will improve the uptake of DR screening by the population of PwDM presenting at the tertiary care level.

I selected the most suitable DR screening modality following a formative research component. This consisted of an assessment of barriers and enablers through a systematic review of literature and qualitative research studies with PwDM and providers in the Western province of Sri Lanka. We observed that DR screening at medical clinics by the physicians who treat the PwDM was a feasible strategy to start the primary screening. I assessed the avenues for development of an integrated DR screening modality using the World Health Organization (WHO) health systems building blocks approach. According to the outcome of formative research work (qualitative research with service users and providers and systematic literature reviews), we proposed 2-field digital retinal imaging using a hand-held retinal camera, by physicians at the medical clinic as a feasible modality. The DTA of a DR screening modality depends on the imaging system, human resources and characteristics of the PwDM. Therefore, we validated the proposed DR screening modality before applying it at the population level. We assumed that establishing evidence regarding the level of validity of this modality in such a context is a key factor prior to lobbying for establishing and scaling up a system of DR screening. Afterwards we developed an 'HEI' in local languages to improve the uptake of DR assessment and treatment at ophthalmologist's clinic. This targets those with a referable level of DR at the medical clinic. We assessed acceptability of the HEI in a sample of PwDM and among the providers involved in delivering the HEI using qualitative research methods. We will evaluate the implementation and scalability of the proposed modality following this study.



Situation – High number of people with blindness due to DR, wide service delivery gap in DR screening and treatment service

Available evidence – Early screening and treatment reduce the progression of DR

Target systems – Diagnosed PwDM under medical care in the Western province of Sri Lanka

Assumptions based on modelling – Medical care personnel skilled in detection referable DR using a screening intervention and behaviour change health educational intervention would improve the uptake of screening and treatment services at ophthalmologist clinic

Figure 4.13 - Theory of change idea mapping (1-8 numbers denotes - assumed processes in DR screening and treatment where an intervention can be implemented - number 1 and 2 interventions were considered for this study)

There is a need to develop a model and test its feasibility in Sri Lanka. Though there are many barriers for provision of DR screening services in the Western province of Sri Lanka, there is adequate capacity to manage the increased workload following implementation of a screening program as estimated and shown in the following table.

Table 4.10 - DR treatment burden assessment and capacity to deliver services at the Western province [4.22, 4.23]

Population	Number of people with diabetes and DR	Work load of DR Treatment
• Total population of the Western province - 5.82 million • Population >18yrs (69.6%) - 4.05 million	• Number of people with diabetes in the Western province (age > 18 yrs) - 754,230 • Number of people with with any DR (>18yrs) - 206,659 • Number of people (>18yrs) with vision threatening DR (VTDR) - 20,666	• Number of laser procedures required per year - 165,327 (by number of laser sessions) • Human Resources - retinologists : population ratio - Colombo district 1:460,000 • Infrastructure - • Laser facilities (per 100,000 population) - 0.2 • Vitreo retinal major theatre facilities (per 100,000 population) - 0.17

Reasons for choosing the Western province are as follows;

- Demography - most populated province in Sri Lanka [4.20].
- Evidence - highest prevalence of DM [4.21], wide gap in DR screening service delivery [4.22] and availability of human resources and infrastructure for DR screening and treatment [4.22,4.23].
- Logistics - Logistically feasible to conduct the study.

4.3 References: Chapter 4

4.1. Shaw RL, Larkin M, Flowers P. Expanding the evidence within evidence-based healthcare: thinking about the context, acceptability and feasibility of interventions. Evid Based Med. 2014;19(6):201–3. PMID:24799447 DOI:10.1136/eb-2014-101791.

4.2. French SD, Green SE, O'Connor DA, McKenzie JE, Francis JJ, Michie S, et al. Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains. Implement Sci. 2012;7(38):1–8. PMID:22531013 DOI:10.1186/1748-5908-7-38

4.3. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, et al. How We Design Feasibility Studies. Am J Prev Med. 2009;36(5):452–7. PMID:19362699 DOI:10.1016/j.amepre.2009.02.002

4.4. Smithto H, Caroline H, Smith T. Feasibility studies: Their importance in the design of clinical trials. J Physiother Pain Assoc. 2013;(35):12–7.

4.5. Jacob B, Ir P, Bigdeli M, Annear P, Damme W. Addresing acces barriers to health services: an analytical framework for selecting appropriate interventions in low-income Asian countries. Health Policy Plan. 2011;27(4):288-300. PMID:21565939 DOI:10.1093/heapol/czr038

4.6. Orsmond GI, Cohn ES. The distinctive features of a feasibility study: Objectives and guiding questions. OTJR Occup Particip Heal. 2015;35(3):169–77. PMID:26594739 DOI:10.1177/1539449215578649

4.7. Blanchet K, Gilbert C, Lindfield R, Crook S. Eye Health Systems Assessment (EHSA): How To Connect Eye Care With The General Health. IAPB Technical Report [Internet]. 2012;(April). Available from: http://iceh.lshtm.ac.uk/eye-health-systems-assessment/. Accessed on 19 Aug 2016.

4.8. Blanchet K, Gilbert C, deSavigny D. Rethinking of eye health systems to achieve universal

coverage: the role of research. Br J Ophthalmol. 2014;98(10):1325-8. PMID: 24990874. DOI: 10.1136/bjophthalmol-2013-303905

4.9. Criel B, De Brouwere V, Dugas S. Integration of vertical programmes in multi-function health services [Internet]. Vol. 3, Studies in Health Services Organisation & Policy. 1997. 36 p. Available from: https://www.researchgate.net/publication/42779702_Integration_of_Vertical_Programmes_in_Multi-Function_Health_Services. Accessed on 19 Aug 2017.

4.10. Eldridge SM, Lancaster GA, Campbell MJ, Thabane L, Hopewell S, Coleman CL, et al. Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework. PLoS ONE 2016;11(3): e0150205. doi:10.1371/journal.pone.0150205

4.11. Dudley L, Garner P. Strategies for integrating primary health services in low- and middle-income countries at the point of delivery. Cochrane database Syst Rev. 2011;(7):CD003318. PMID: 21735392 DOI: 10.1002/14651858.CD003318.pub3

4.12. World Health Organization. Prevention of blindness from diabetes mellitus. Geneva WHO [Internet]. 2005;1–48. Available from: https://www.who.int/blindness/Prevention%20of%20Blindness%20from%20Diabetes%20Mellitus-with-cover-small.pdf. Acceseed on 16 Aug 2016.

4.13. World Health Organisation. Integrated health services-what and why? [Internet]. Technical Brief. 2008;(1):1–10. Available from: https://www.who.int/healthsystems/technical_brief_final.pdf. Accessed on 16 Aug 2016.

4.14. Patel M. The Socioeconomics of Diabetic Retinopathy. Data from the United Kingdom quantify the societal burden of diabetic eye [Internet]. Retinal Physician. 2018. p. 1–9. Available from: https://www.retinalphysician.com/issues/2009/september-2009/the-socioeconomics-of-diabetic-retinopathy. Accessed on 16 Aug 2017.

4.15. Craig P, Dieppe P, Macintyre S, Health P, Unit S, Michie S. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;337:a1655 doi: 10.1136/bmj.a1655

4.16. Bandura A. Toward a unifying theory of behavioral change [Internet]. Psychological Review. 1977;84(2):191–215. http://dx.doi.org/10.1037/0033-295X.84.2.191

4.17. Whitehead D. A social cognitive model for health education/health promotion practice. J Adv Nurs. 2001;36(3):417–25. PMID: 11686756

4.18. Noordman J, van der Weijden T, van Dulmen S. Communication-related behavior change techniques used in face-to-face lifestyle interventions in primary care: A systematic review of the literature. Patient Educ Couns. 2012;89(2):227–44. PMID:22878028. DOI:10.1016/j.pec.2012.07.006.

4.19. Ghisi GL, Abdallah F, Grace SL, Thomas S, Oh P. A systematic review of patient education in cardiac patients: Do they increase knowledge and promote health behavior change? Patient Educ Couns. 2014;95(2):160–74. PMID:24529720 DOI:10.1016/j.pec.2014.01.012.

4.20. Census of Population and Housing 2012. Department of Census and Statistics of Sri Lanka [Internet]. 2012. Available from: http://www.statistics.gov.lk/PopHouSat/CPH2012Visualization/htdocs/index.php?usecase=indicator&action=Data&indId=. Accessed on 19 Aug 2014.

4.21. Katulanda P, Rathnapala D, Sheriff R, Matthews D. Province and ethnic specific prevalence of diabetes among Sri Lankan adults. Sri Lanka J Diabetes Endocrinol Metab. 2012;1(1):2–7. DOI: http://dx.doi.org/10.4038/sjdem.v1i1.4180

4.22. Piyasena MP, Murthy G. A Situation Analysis and Mapping of Availabillity of Services for Diabetic Retinopathy in the Health Care Institutions of the Western Province of Sri Lanka. MSc Dissertation - LSHTM. [Internet]. 2014. Available from: https://intra.lshtm.ac.uk/library/MSc_CEH/2013-2014/107722.pdf

4.23. Piyasena MMPN, Murthy GVS. Availability of eye care infrastructure and human resources for managing diabetic retinopathy in the western province of Sri Lanka. Indian J Ophthalmol 2019 (in process). DOI: 10.4103/ijo.IJO_1754_18

Chapter 5

HYPOTHESIS, RESEARCH QUESTIONS, AIMS AND OBJECTIVES

5.1 Research Hypothesis

My hypothesis is that trained physicians would accurately identify those who have referable level of retinopathy at the medical clinics using a proposed DR screening modality. This improves access for DR screening for the PwDM. A service user-based health educational intervention would improve the referral uptake at the next level of ophthalmologists' / retinologists' clinic, for those who have been identified as having referable level of DR using the proposed modality.

5.2 Research questions

I addressed the following specific research questions:

- What are the barriers to access DR screening services?
- What is the best screening method for physicians undertaking screening for DR in the Western province of Sri Lanka? and
- Would a health educational intervention be feasible and acceptable to improve the uptake of services at ophthalmologists' / retinologists' clinic by those who have been identified by the physicians as having referable level of retinopathy?

5.3 Aim and objectives

5.3.1 Aim

To assess the technical feasibility of integrating DR screening services into public sector medical care and to assess whether health education improves the referral uptake at ophthalmologists' / retinologists' clinic by the PwDM who have been identified as having referable level of DR.

5.3.2 Objectives

- **Objective 1 -**
- 1.1) To Identify documented barriers (themes) to access DR screening services by service users and barriers / enabling factors in provision of DR screening services (provider perspectives) through systematic literature search.
- 1.2) To identify barriers in accessing DR screening services by people with diabetes and to identify the barriers and enabling factors of service providers in delivering DR screening services in the Western province.

- **Objective 2 -**
- 2.1) To assess the diagnostic accuracy of digital retinal imaging using different field strategies, pupil status and human resources through systematic literature search.
- 2.2) To determine the most appropriate DR screening modality for the Western province and to assess its validity.

- **Objective 3 -**
- 3.1) To assess the feasibility and acceptability of a health educational intervention integrated with DR screening to improve the referral uptake at ophthalmologist's / retinologist's clinic by those who have been identified as having referable level of DR.

5.3.3 Progression of the project work according to the objectives

The project work conducted according to the objectives was as follows.

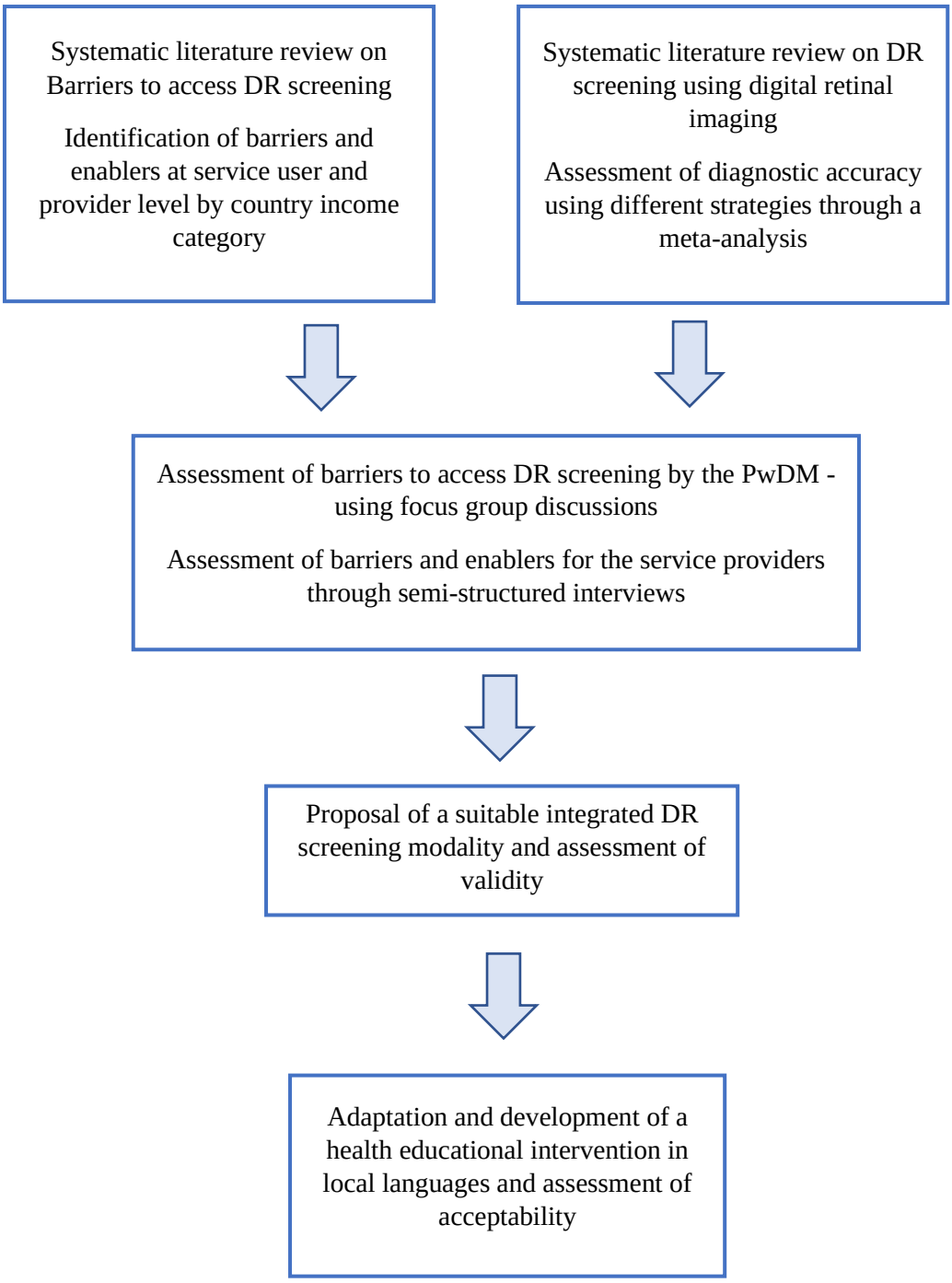


Figure 5.14 - The tasks of the project work conducted according to the objectives of the study.

Chapter 6

METHODS

6.1 Ethical clearance

Ethics Review Committees of the National Eye Hospital of Sri Lanka and from the London School of Hygiene and Tropical Medicine (LSHTM)-UK provided ethics approval. The National Eye Hospital of Sri Lanka-Ethics Committee is the only national level tertiary centre in Sri Lanka that reviews eye care related research projects. I obtained permission from the respective heads of the institutions and heads of the units where applicable. I applied separately for ethical clearance for the stages before and after upgrading (Appendix 1).

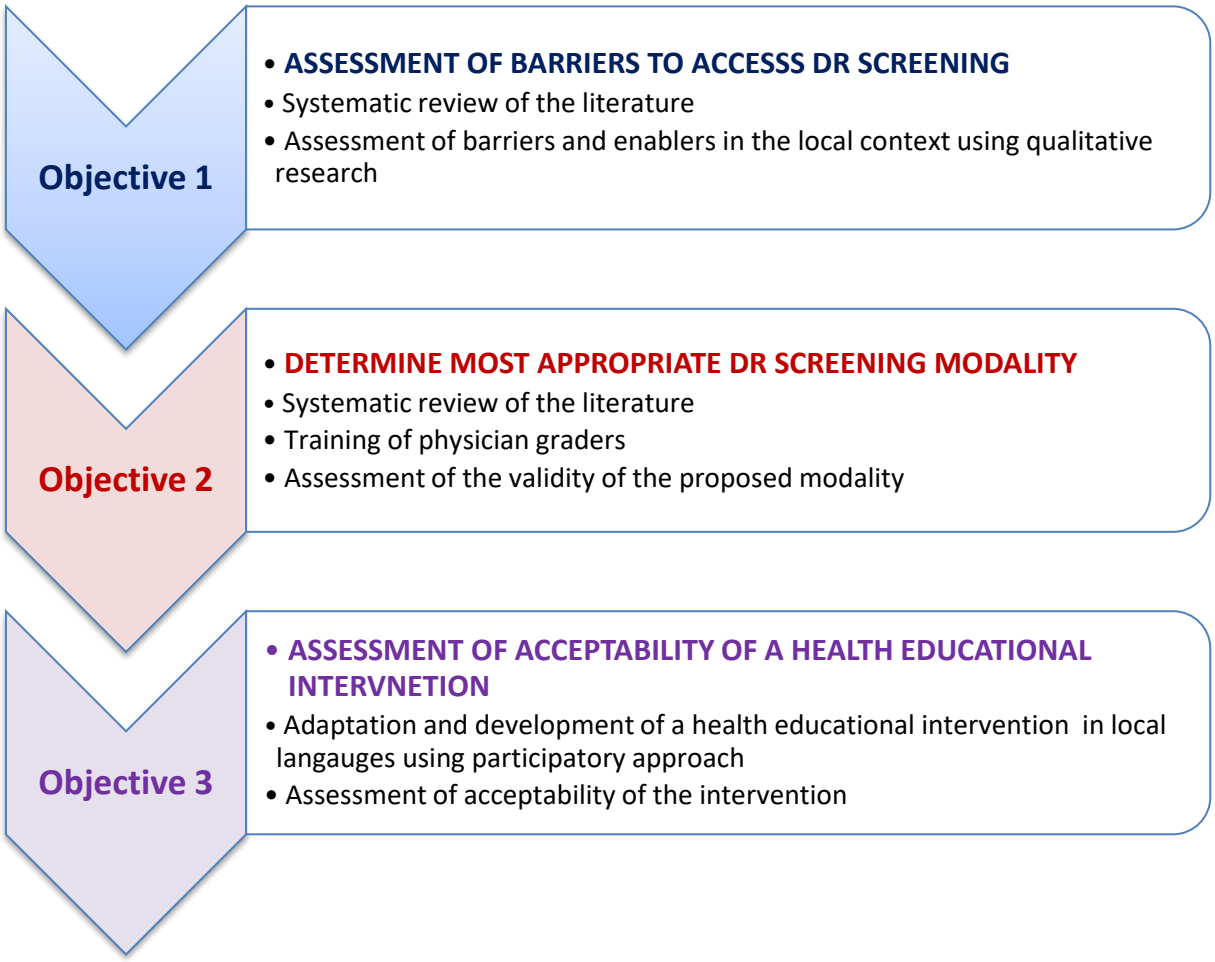


Figure 6.15 - Sequential implementation of the research project according to the objectives

6.2 Study design and main stages of the research project

This project was comprised of mixed methods and was conducted in three stages (see Figure 6.15). In the first stage, I conducted a systematic literature review to assess the barriers and enablers of DR screening globally. In this review, I identified barriers under the domains of service user (PwDM) and service provider. I categorized the barrier themes by country income category. This was needed to identify obstacles that could be faced in development of a DR screening program in the Western province, Sri Lanka. I then assessed barriers and enablers to access and provision of DR screening in the local context using qualitative research methods.

In the second stage, I conducted a systematic review to assess the most suitable screening method using digital imaging. In this review, I calculated summary estimates of diagnostic test accuracy (DTA) of DR screening using different pupil status, field strategies and for different non-ophthalmic HR. This helped me to select most effective strategy of DR screening for the Western province of Sri Lanka. I proposed a feasible DR screening modality using the key findings of this review and formative research after validating the same.

In the final stage, a health education intervention was adapted and developed in local languages. I assessed the acceptability of the health education intervention in improving the uptake of DR screening assessment from a medical clinic to an ophthalmologist's clinic following referral.

6.2.1 Objective 1

6.2.1.1 Formative systematic literature review - Assessment of barriers to access DR screening services by service users, and challenges and enablers for the providers

The first systematic literature review was designed to review the available evidence on barriers to access DR screening. The PICOC (population, intervention, comparison, outcome and context) framework was followed in the development of the protocols [6.1]. In the reporting, 'Preferred Reporting Items for Systematic Reviews and Meta-Analyses' (PRISMA) guidelines were followed [6.2]. I extracted titles and abstracts from the database to a reference manger software following electronic data-

base search. Two reviewers first independently reviewed and identified relevant articles for detailed assessment. I reviewed papers in the data extraction and synthesis. Table 6.11 represents the summary of the protocol and the detailed protocol and results are described in Chapter 7 - publication 1.

Table 6.11 - Summarised protocol of the systematic review 1

	Systematic Review 1
Population	Diagnosed PwDM (service user). Service providers involved in managing PwDM and people with DR.
Intervention	Not a requirement (if any-Interventions to improve the uptake of DR screening - interventions based on user) (if any-interventions to improve the adherence to the recommended screening guidelines-interventions based on provider).
Comparison	Not a requirement (if any-adherence to recommended DR screening vs non-adherence-user) (if any-adherence to recommended guidelines-provider).
Outcome	Barriers or enablers to uptake of DR screening by users (service users' perspectives). Barriers or facilitators in provision of DR screening (service providers' perspectives).
Context	Health facility based PwDM management, sub-divided by country income category.
Type of Study Designs	Not restricted.
Inclusion Criteria	(Mentioned in the publication draft).
Exclusion Criteria	(Mentioned in the publication draft).
Information Sources	-MEDLINE -The Cochrane library -EMBASE

Method of Assessment of Risk of Bias	Critical Appraisal of Skills Program (CASP) for case control, qualitative, cohort and RCT and National Institute of Health-Quality Assessment Tool (NIH-QAT) for cross sectional studies [6.3,6.4].

6.2.1.2 Qualitative study on assessment of barriers confronting PwDM and challenges faced by the providers in the Western province of Sri Lanka

I assessed barriers to access DR screening by PwDM using focus group discussions (FGD). The challenges faced by the providers and enablers for provision of DR screening or development of a DR screening program in the local context were assessed by semi-structured interviews (SSI).

Preparation, research team and reflexivity

I developed topic guides for FGD and SSI after a detailed literature review and in consultation with an adviser in qualitative research. The topic guides were translated into two local languages (Sinhala and Tamil), piloted and changes made where appropriate. I selected co-moderators (sociologists in medical research) locally and conducted training sessions to familiarize them with the topics.

Study setting

Three public sector heath care institutions in the Western province were included considering the central location, high turnover and diversity of the PwDM attending daily. Further, I considered availability of resources for the treatment of DR in these institutions, considering the overall aim of the project.

Image file 6.1 - Selection of the eligible and consented participants for the FGDs at medical, general eye and retinal clinics.

Selection of the participants

Service users

A purposive sample of PwDM attending for medical care, general eye care and retinal care participated in the FGDs. Presence of diabetes mellitus (with or without DR) was confirmed from medical records. They were divided into subgroups based on location of recruitment (medical clinic, general eye clinic and retinal clinic), gender (male, female), and native language (Sinhala-Sinhala ethnic group, Tamil-Tamil and Moor ethnic groups).

Service providers

A purposive sample of service providers was selected according to their engagement in clinical management of PwDM and institutional / national level decision making capacity in prevention of DR blindness and visual impairment. They were mainly clinicians, hospital administrators, representatives from professional bodies and program planners under the Ministry of Health.

Method of data collection

Investigators made non-participatory observation visits to understand the processes in management of PwDM and DR. Written informed consent was obtained from the PwDM and service providers for

participation, audio recording and usage of anonymous quotes in the publications. The FGD / SSI were conducted in a closed room at hospital / institution to maintain the privacy of the participants. Each FGD lasted 45-90 minutes and carried on until we reached the level of data saturation. All FGD were recorded (audio) and later transcribed for analysis. Each SSI was 20-40 minutes and was audio recorded with the consent of participants. The main investigator / moderator recorded field notes when permission was not there for audio recording. For analysis, all the SSI was transcribed.


Image file 6.2 - Conducting focus group discussions at National Hospital of Sri Lanka and National Eye Hospital - Colombo with the local sociologists.

Data analysis

We used 'thematic analysis' for analysing the qualitative data. The main investigator and a team of local sociologists (under supervision of an adviser in qualitative research from LSHTM-UK) conducted the analysis. Two data coders did the initial coding in local languages. A series of concepts were documented while reading the responses. Focused coding was generated after triangulation. Each initial coding was revised again, and similar codes were categorised under a broad theme. We used inductive methods and constructive approach to develop valid and meaningful themes using the collected data. These themes with quotations were later translated into English for publications / thesis presentation. The results were reported according to the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines [6.5]. Chapter 8 and 9 publication draft 2 and 3 describe the results.

6.2.2 Objective 2

6.2.2.1 Formative systematic literature review-DTA of DRS using digital imaging

The second systematic review looked at the available literature on DRS using digital imaging. Same guidelines were followed (i.e., PICOC and PRISMA) as in the first review. The following table

represents a summary of the protocol and detailed protocol and results are described in the Chapter 10 -publication 4.

Table 6.12 - Summarised protocol of the systematic review 2

	Systematic Review 2
Population	The diagnosed adult PwDM attending for DR screening at an established health care facility.
Intervention	Index test-A defined on-site DR screening and grading modality using digital retinal imaging which we conducted in a permanent health care facility. Reference standard-A pre-defined accepted reference standard (ETDRS 7-filed imaging or mydriatic bio-microscopy by ophthalmologist) to compare the findings of the index test.
Comparison	DR screening modality of the index test compared to an accepted reference standard
Outcome	1ry - DTA of the index test compared to the reference standard 2ry - DTA of non-ophthalmic graders compared to the reference standard
Context	Diagnosed PwDM at an established health care facility
Type of Study Designs	Cross sectional observational study
Inclusion Criteria	(mentioned in the published article)
Exclusion Criteria	(mentioned in the published article)
Information Sources	-MEDLINE -Cochrane Library
Method of Assessment of Risk of Bias	Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) [6.6].

6.2.2.2 Training and assessment of physician graders in the Western province of Sri Lanka

6.2.2.2.1 Training curriculum

The main objective was to train general physicians in a tertiary level medical clinic to capture and grade different levels of DR using digital imaging (using a hand held digital retinal camera, independently). This curriculum was developed as a training module, applicable to a resource poor setting. This was the first training module on hand held digital retinal cameras in Sri Lanka. This has been adopted from existing successful DR screening training programs in HICs and following International Council of Ophthalmology (ICO) guidelines [6.7]. Institutional needs assessment was done by a situational analysis described in Chapter 3. The needs at individual level (providers' skills - task based, i.e., ability to screen and grade DR) were assessed by formative research. The potential graders and DR screening sites (i.e., medical clinics) were identified at this stage. The current role of the potential physician graders and their gaps in knowledge with regard to DRS and grading were identified during the formative research.

- Current role - Physicians' current role is medical management of a PwDM and refer them to an eye clinic for DR screening annually.
- Expected role - DR screening and grading using a non-mydriatic camera at medical clinics by physicians (in addition to the medical management).

Purpose - Purpose of the training program was to train the physicians to accurately identify and classify different levels of DR in PwDM presenting at outpatient medical care (Referable criteria were recommended for the local context after the validation study).

Learning objectives

-To train physicians on non-mydriatic and mydriatic digital retinal imaging using a hand-held retinal camera.

-To train physicians to pharmacologically dilate the pupils at the medical clinic.

-To train medical officers grading on DR, macular signs and image quality/gradability according to a locally adopted classification system (developed based on English National DR screening program guidelines - UK).

Setting - Training was conducted at a tertiary level vitreo-retinal department in the Western province. Hands on training of imaging and grading was conducted at the retinal clinic and then at the medical clinic where validation study was conducted.

Outcome of the training - The expected outcome of the training was skill physicians to independently perform retinal imaging using a hand-held digital camera and grading using the locally adopted classification system (including image quality/gradability) at a medical clinic.

Outline of the content - The content of the curriculum mainly comprised of knowledge and skills components.

- Knowledge component - Normal anatomy of retina, pathogenesis of DR, grading of DR and pharmacological dilatation of pupils.
- Skills component - handling a hand-held retinal camera, techniques of imaging, gradability of imaging, dilatation of pupils using mydriatic agents and grading of the DR status.

Modes of learning - I used active adult learning process in this training by making the participants responsible for acquiring their own skills. Competency based education and self-learning methods were applied as described in the literature [6.8–6.10]. The training was conducted in two small groups (n=4 each) due to limitation of resources and difficulty in mobilising all physicians at the same time from their duty rotations.

Competency based education (CBE) model of DR screening using digital imaging

a) Skills component - The main investigator and two consultant retinologists led practical training on handling technical features of camera, techniques of retinal imaging and capturing of 2-fields.

Technique of imaging - Technique of handling camera showed using video tutorials initially. Afterwards, physicians were trained to capture two fields of retina in a retinal clinic setting.

Field 1 - Align the centre of the macula at the intersection and optic disc towards the nasal retina. Centre points of macula region and optic disc should be on horizontal diameter.

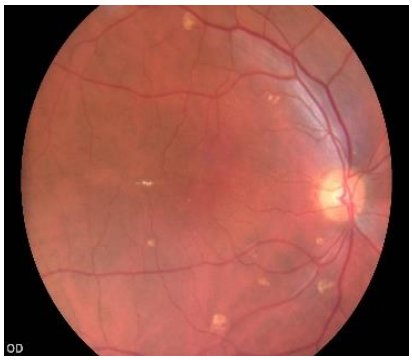


Figure 6.16 - Retinal field 1

Field 2 - Centre the temporal edge of the optic disc at the inter-section, with a partial view of the macula.

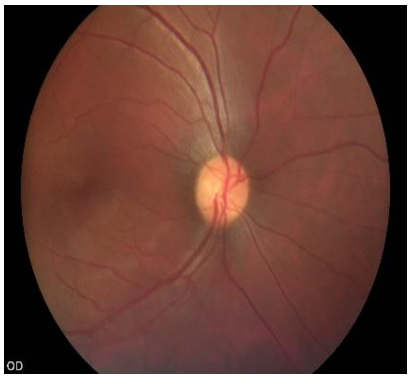


Figure 6.17 - Retinal field 2

Physicians were trained to capture the same fields in each eye following the pharmacological dilatation of the pupils.

Table 6.13 - Components of the required skills and method of assessment

Competency Domain	Competency expected by the graders in the context	Learning method options	Method of assessment
1.Handling of hand held non-mydriatic retinal camera by physician graders	Usage of retinal camera at medical clinic minimising technical failures	Self-learning of tutorials provided by manufacturer (video tutorial link) Self-learning of user manual supplied by manufacturer (user manual link) Practical handing of camera by each participant to familiarise with the device.	Demonstration of technical features of camera by the physician - assessment by main investigator
2.Imaging of required retinal fields (2 field technique) by physician grader	Retinal imaging of PwDM presenting at outpatient retinal and medical clinics	Self-learning of tutorials provided by manufacturer (video tutorial link) Teaching of techniques of retinal imaging by main investigator Self-practical learning of two field imaging on minimum of 15 patients at a clinic setting	Physician grader practice sessions and demonstrations - assessment by main investigator Assessment of gradability and applicability (according to the required fields) of images (self-assessment by the physicians and compare the findings with retinologist (using saved images)

3.Dilating pupils using mydriatic agents	Pharmacological dilatation of pupils of persons with ungradable images	Teaching and demonstration of performing mydriasis	Practical demonstration of pharmacological mydriasis by physician grader - assessment by main investigator
4.Assessing quality of images	Identification of gradable and ungradable images at medical clinic	Demonstration of categorisation of gradability of images by main investigator	Identification of reasons for ungradability / poor quality of images while practicing at medical clinic setting by grader - under supervision of main investigator Testing of graders' finding of ungradability in the final assessment using a set of retinal images (by examination).
5.Grading of the DR status according to the given guidelines	Grading of DR of PwDM at the medical clinic	Teaching by trainer retinologists of grading of retinal images. Practical sessions of grading of retinal images using a set of images. Self-learning of DR grading using a self-directed web source (self learning web link)	Testing of graders findings of 40 images compared to a reference standard (by examination)

b) Knowledge component - Instructor (a specialist retinologist) led training sessions were conducted to teach anatomy of retina, pharmacological dilatation of pupils and identification of signs of DR on fundus images for the whole group in the 1st week.

Table 6.14 - Content of the knowledge component

Level	Theoretical content	Outcome	Trainer activity	Learner activity	Time	Resources needed
1.Knowledge on retina	Normal anatomy of retina	Identify normal structures of retina	Teaching physician graders	Label structures of retina	1 hour	Power point presentation slides of anatomy of retina
2.Knowledge on mydriasis	Pharmacology of mydriasis and contraindications for mydriasis	Correct method of instillation of eye drops and identify risks and side effects	Teaching theoretical content Demonstration of instillation of eye drops	Practical learning of instillation of eye drops at retinal clinic after excluding contraindications	2 hours	Power point presentation Practical demonstrations at retinal clinic
3.Knowledge on signs of DR	Pathogenesis and risk factors for DR	Identify DR signs on fundus images	Teaching theoretical content Practical demonstration of signs of DR using digital images	Grading of retinal signs in given images	8 hours	Power point presentation. Printed educational material on DR signs and grading. Electronic copy of the ICO 2017 DR guidelines (ICO guide web link)

6.2.2.2.2 DR classification system for the local context

DR screening guideline was developed adapting the English national screening program for DR [6.11]. A simplified classification was used in the medical clinics.

DR grading classification

Table 6.15 - Adapted DR classification for the validation study

Signs	No DR (R0)	Mild BDR[d] / NPDR[e] (R1)	Moderate BDR / NPDR (R2)	Severe NPDR (R3)	Proliferative DR (PDR[f]) (R4)
Microaneurysms	No	Few	Multiple	Multiple	Present
Hard Exudates [a]	No	Few	Multiple	Multiple	Present
Cotton wool spots	No	Occasional	Multiple	Multiple	Present
Intra retinal haemorrhage [a]	No	Few	>20 in 1-3 quadrants	>20 in 4 quadrants	Present
Venous beading	No	Occasional	Present in 1-2 quadrants	Present in >2 quadrants	Present
IRMA [b]	No	No	Present ~1 quadrant	Prominent >1 quadrant	Present
NVD [c]	No	No	No	No	Present
NVE [c]	No	No	No	No	Present
Vitreous / pre-retinal haemorrhage	No	No	No	No	Present - advanced PDR
Traction	No	No	No	No	Present - advanced PDR
Fibrosis	No	No	No	No	Present - advanced PDR

[a] Not within the definition of maculopathy
[b] Intra retinal microvascular abnormalities
[c] Neo-vascularisations over the disc / elsewhere
[d] Background DR, [e] NPDR – Non-proliferative DR, [f] PDR-Proliferative DR

Table 6.16 - Macular signs classification

	Maculopathy absent (M0)	**Maculopathy present (M1)**
Signs up to 2-disc diameters from the centre of fovea	No signs	Presence of hard exudate/s and / or blot haemorrhage/s (Referable)

Method of evaluation of the image quality

The physician grader evaluated the image quality and gradability during the grading. If images were detected to be of poor quality when capturing, they were requested to find out a reason. If correctable, they were requested to re-shoot the required fields. If it was not correctable, physicians were asked to document the possible reasons.

Levels of gradability

1. Very good - Can see 100% of the imaged field clearly

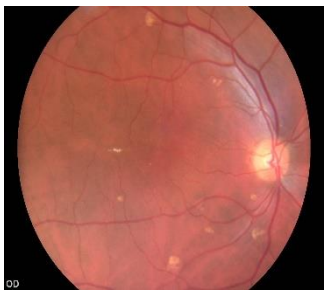


Figure 6.18 - Example of 100% clear image

2. Good - Can see only about 75% of the field clearly

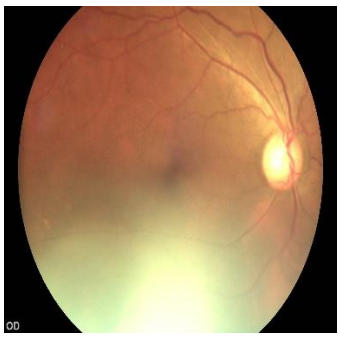


Figure 6.19 - Example of 75% image clarity

3. Satisfactory - Can see only about 50% of image.

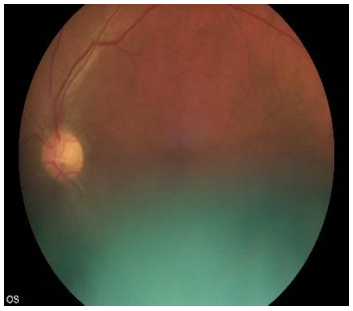


Figure 6.20 - Example of 50% image clarity

4. Poor - Can see < 50% of the retinal field.

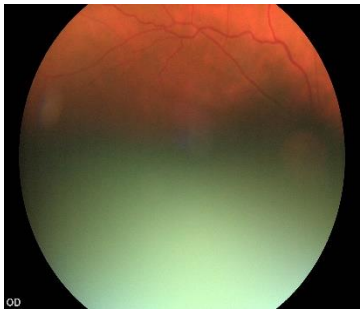


Figure 6.21 - Example of un-gradable image

The category of un-gradability applied only for this category.

6.2.2.2.3. Assessment of the physician graders

The training was evaluated to assess to what extent participants (n=8 physicians) improved their ability to grade an image by using a standard set of retinal images (n=40) from the local context. The graders findings were compared, and kappa agreement was calculated, compared to a retinologist. The physicians (n=2) who had the highest level of agreement were selected for the validation study.

6.2.2.3 Validation study protocol [Published protocol paper moved to end of the Chapter 6]

Development and Validation of a diabetic retinopathy screening intervention using a hand held non-mydriatic digital retinal camera by physician graders at a tertiary level medical clinic - Validation study protocol

The validation study protocol has been published in the open source of Journal of Medical Internet Research (Study Protocols) and the manuscript is attached at the end of Chapter 6 separately.

6.2.3 Objective 3

We developed a local context specific health educational (HE) intervention (HEI) by adapting available resources on improving DR screening and referral uptake at ophthalmologist's clinic. This was done in 2 phases: i.e., 1) development phase and 2) field testing phase as described in Figure 6.22.

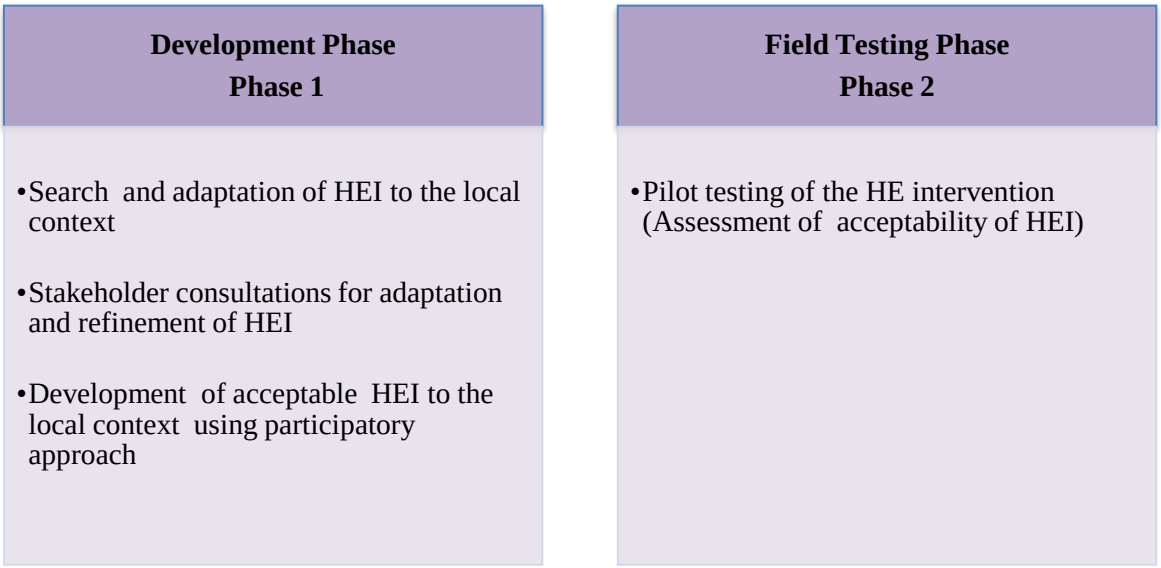


Figure 6.22 - Phases of the adaptation and development of HEI for the local context

6.2.3.1 Objective 3.1-Phase 1 - Adaptation and development of HEI in local languages

a) Search, review and selection and adaptation of available HE material

In the first phase, we searched for the existing HE material in improving the uptake of DR screening and DR assessment following a referral to eye clinics. The materials identified were then categorised and archived by the medium of delivery. They were assessed using HE material development guidelines (using a guideline of 'Patient Education Materials Assessment Tool-PEMAT) [6.12].

Image file 6.3 - preliminary stages of HEmaterial adaptation - discussion with the research team (Research assistants and sociologists)

b) Incorporation of findings of formative research (FGDs with PwDM and SSI with providers)

The service users' and service providers' perceptions with regard to current HE provided and development of HEIs in the Western province was assessed during the formative (using qualitative methods) research conducted before upgrading. Relevant findings (themes) of this study were incorporated in the process of development of HEI specific to the local context.

Image file 6.4 - Continuation of HE material development

c) Key Stakeholder consultation- 1st Meeting-Preliminary adaptation of the HEI by reviewing sample material

The key stakeholders' consensus was obtained on adaptation of HEI appropriate to the local context in local languages (Tamil and Sinhala). One main aim of this consultation was to define content framework and medium of delivery of the intervention. We focused on the following areas of HE intervention adaptation during the consultation meeting: 1) Defining the target group/audience, 2) Defining the content of the intervention and cultural relevance (content framework and inclusion of a component on behavioural change), 3) Defining the mode of delivery (medium of delivery, location of delivery and personnel involved).

Table 6.17 - Key stakeholders for consultation (suitable representatives from following authorities)

Public health sector	Service delivery personnel
1) Health Education and Promotion Unit-Ministry of Health-Sri Lanka 2) College of Community Physicians of Sri Lanka 3) Diabetes Education Unit-National Hospital of Sri Lanka 4) Vision 2020 Program (DR blindness prevention program)-Ministry of Health-Sri Lanka 5) Department of Sociology (Medical anthropology) 6) Media personnel (a newspaper reporter) 7) A person with diabetes and a person with DR from the Western province (patient representative)	8) Association of Vitreo Retina Specialists of Sri Lanka 9) College of Ophthalmologists of Sri Lanka 10) Association of Optometrists-Sri Lanka 11) Ceylon College of Physicians-Sri Lanka 12) College of Endocrinologists-Sri Lanka

Image file 6.5 - Conducting an interview with the head of the diabetic retinopathy screening programme - Vision 2020 country program of Sri Lanka

Image file 6.6 - HE material assessment with a group of stakeholders

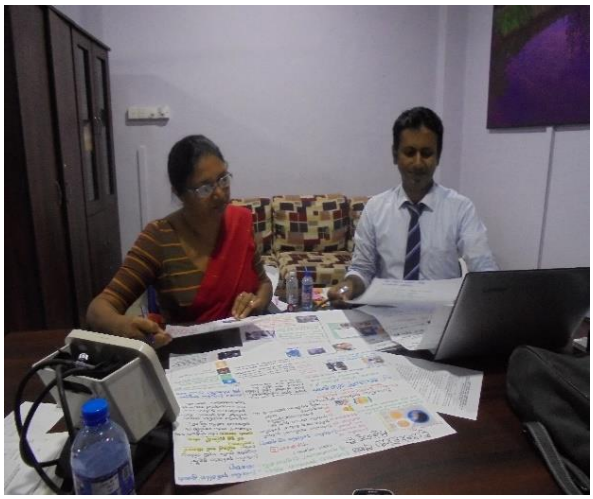


Image file 6.7 - Assessment of HE material with an expert patient (A PwDM identified in the validation study - a retired sociologist)

d) Participatory workshop with a sample of PwDM and DR in development of the HEI

We conducted a participatory workshop (8 sessions-4 in each medium-Sinhala and Tamil) with a purposive sample of PwDM and people with DR divided in to 2 groups by native language, to incorporate their ideas on development and adapting HEI to the local context. In the initial sessions, need assessment with regard to the uptake of DR screening and assessment at the ophthalmologist clinic was done. We assessed the participants' ideas and perceptions about the acceptability, comprehension of key messages, content design and medium of delivery. In the final phase, participants were provided with a guidance in the development and assessment of HEI. In the final stage they were provided with samples of provisional material in local languages to comment. Key findings of the participatory work were discussed among the participants and presented by the moderators. Participatory workshops were audio recorded with their consent and the group work key findings were noted and documented by the moderators on flip charts.

Table 6.18 -Activity schedule of the participatory workshop

Day	Participants	Activity
Day 1	All	Introduced to the research question by main investigator
	Subgroup 1 - Sinhala Subgroup 2 - Tamil	Group work on identifying needs, problems and solutions on accessing services at ophthalmologist's / retinologist's clinic following referral from medical clinic-facilitated by moderators
	Subgroups 1 and 2	Exposure to adapted and developed provisional HE interventions-facilitated by moderators
Day 2	Subgroups 1 and 2	Development / modification of HE interventions appropriate to the local context by incorporating participants' ideas - facilitated by moderators
Day 3	Subgroup 1	Presentation and discussion of findings of assessment of developed HE interventions by participants - facilitated by main investigator with co-moderators.
Day 4	Subgroup 2	

Image file 6.8 - Conducting participatory workshops and assessment of provisional HE material

e) Stakeholder consultation-2nd meeting-content validity assessment and refinement

After preliminary development of HEI stake holders' consensus was obtained about information available on material (clinical, educational, technical and affective assessment) before assessing it with services users, using HE material development guidelines used in cancer research [6.13]. The stakeholders' consensus was also obtained for selection of appropriate medium for delivery for the local context. The outcome of the participatory workshops was submitted to the stakeholders in order to receive their opinion on finalizing the HEI. Based on the findings of the participatory work and based on stakeholders' consensus HEI was further modified and defined in local languages for the Western province of Sri Lanka.


Image file 6.9 - Shooting of the video HE intervention

6.2.3.2 Objective 3.2 - Phase 2 - Field testing of the health educational intervention-Assessment of feasibility and acceptability of HE intervention

The developed HEI was tested on a purposive sample of PwDM identified as having referable level DR identified at medical clinics (n=45).

- **Service user-Inclusion criteria**-PwDM (>18 years of age) attending for medical care and identified as having referable level of DR at the medical clinic.
- **Exclusion criteria**-PwDM who have undergone DR treatment / currently under DR screening or DR treatment / currently under any HE to promote referral uptake.
- **Service providers**-A sample of service providers at medical clinic and eye clinic (personnel delivered the HEI, physicians and ophthalmologists).

The baseline demographic and clinical history data were collected using a questionnaire schedule following informed consent. In the next step proposed HEI was delivered to them at the medical clinic by physician graders (assisted by trained research assistants for Tamil medium). The acceptability of the HEI by the participants was assessed using semi-structured interviews (SSI), by inviting them to participate in the interview at medical / eye clinic with a period of 4 weeks. The SSI topic guide has been developed according to a predefined coding structure of dimensions of acceptability using open

ended questions. In addition, acceptability of the HEI was assessed among a sample of service providers, in the final stage of the study.

Image file 6.10 - HE intervention delivery and assessment

Data Analysis

The service users' demographic data were analysed quantitatively. The qualitative data on acceptability of the intervention by service users and service providers were analysed by thematic analysis and main themes derived were presented under a predefined coding structure used in the development of topic guides. The recommendations for further steps of HEI on improving referral uptake in DR in the Western province of Sri Lanka were made according to the outcome of the field-testing.

6.3 References: Chapter 6

6.1. Petticrew M, Roberts H. Systematic Reviews in the Social Sciences: A Practical Guide. Synthesising the evidence. USA:Wiley-Blackwell; 2006. p 336-342.

6.2. Moher D, Liberati A, Tetzlaff J, Altman DG, Grp P. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. Ann Intern Med. 2009;151(4):264-9. PMID: 19622511

6.3. Critical Appraisal Skills Program - CASP Check Lists [Internet]. CASP UK. 2017. Available from: http://www.casp-uk.net/casp-tools-checklists. Accessed on 01 Aug 2017.

6.4. National Institute of Health - USA. Quality Assessment Tool for Observational Cohort and Cross Sectional Studies [Internet]. NIH QAT. Available from: https://www.nhlbi.nih.gov/health-pro/guidelines/in-develop/cardiovascular-risk-reduction/tools/cohort. Accessed on 01 Aug 2017.

6.5. Tong A, Sainsbury P, Craig J. Consolidated criterio for reporting qualitative research (COREQ): a 32- item checklist for interviews and focus group. Int J Qual Heal Care. 2007;19(6):349–57. https://doi.org/10.1093/intqhc/mzm042

6.6. Whiting PF, Rutjes AWS, Westwood ME, Mallet S, Deeks JJ, Reitsma JB, et al. Research and Reporting Methods Accuracy Studies. Ann Intern Med. 2011;155(4):529–36.

6.7. International Council of Ophthalmology - ICO Guidelines for Diabetic Eye Care. Updated 2017 [Internet]. Available from http://www.icoph.org/downloads/ICOGuidelinesforDiabeticEyeCare.pdf. Accessed on 15 Jan 2017.

6.8. Gruppen LD, Mangrulkar RS, Kolars JC. The promise of competency-based education in the health professions for improving global health. BMC Human Resources for Health. 2012;10:43. https://doi.org/10.1186/1478-4491-10-43

6.9. Cancedda C, Farmer PE, Kerry V, Nuthulaganti T, Scott KW, Goosby E, et al. Maximizing the Impact of Training Initiatives for Health Professionals in Low-Income Countries : Frameworks, Challenges, and Best Practices. PLoS Med. 2015;12(6):e1001840. PMID:26079377. doi:10.1371/journal.pmed.1001840

6.10. Rowe AK, Savigny D De, Lanata CF, Victora CG. How can we achieve and maintain high-quality performance of health workers in low-resource settings ?. Lancet. 2005;366(9490): 1026-35. PMID:16168785 DOI:10.1016/S0140-6736(05)67028-6

6.11. Scanlon PH. The English National Screening Programme for diabetic retinopathy 2003–2016. Acta Diabetol. 2017;54(6):515–25. PMID:28224275. DOI:10.1007/s00592-017-0974-1

6.12. Shoemaker SJ, Wolf MS, Brach C. Development of the Patient Education Materials Assessment Tool (PEMAT): a new measure of understandability and actionability for print and audiovisual patient information. Patient Educ Couns. 2014;96(3):395-403. PMID:24973195 DOI:10.1016/j.pec.2014.05.027

6.13. Guidelines for the Development of Patient Education Materials. Report by Scotia Nova Cancer Care Programs [Internet]. 2004;(March). Available from: http://www.cdha.nshealth.ca/nova-scotia-cancer-care-program-3. Accessed on 01 Dec 2016.

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
E: registry@lshtm.ac.uk

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Mapa Mudiyanselage Prabhath Nishantha Piyasena
Principal Supervisor	Prof.G.V.S.Murthy
Thesis Title	A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	Journal of Medical Internet Research (JMIR) - Protocols		
When was the work published?	Dec / 2018		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**

**If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.*

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	N/A
Please list the paper's authors in the intended authorship order:	
Stage of publication	Choose an item.

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceived the concept of validation of a suitable diabetic retinopathy screening modality. I designed the study and presented the protocol at the PhD upgrading. Afterwards, under guidance of the upgrading panel and supervisors I revised the protocol. I underwent training and observerships in

	digital retinal imaging in United Kingdom and four states in India to acquire necessary skills to train the physician graders in Sri Lanka. I developed a local context specific diabetic retinopathy grading system and a training curriculum to train physician graders. Afterwards, I trained and assessed the physician graders under supervision of a local retinologist. I prepared this manuscript and revised it under supervision of supervisors and advisers. Other co-authors approved the final manuscript for submission. In addition I made the corrections and edited the manucript according to the JMIR editor's and reviewers' comments. This protocol was published in Dec/2018.

Student Signature: [redacted] **Date:** 27/03/2019.

Supervisor Signature: [redacted] **Date:** 27/03/2019

Protocol

Development and Validation of a Diabetic Retinopathy Screening Modality Using a Hand-Held Nonmydriatic Digital Retinal Camera by Physician Graders at a Tertiary-Level Medical Clinic: Protocol for a Validation Study

Mapa Mudiyanselage Prabhath Nishantha Piyasena[1], MSc, MBBS; Venkata S Murthy Gudlavalleti[1], MD, MSc; Clare Gilbert[1], MD, FRCOphth, MSc; Jennifer LY Yip[1], MRCOphth, FFPH, PhD; Tunde Peto[2], MD, MHealth Ed, PhD, FHCO; David MacLeod[1], PhD; Charith Fonseka[3], MS, FRCS, FRCOphth; Aruna Kulatunga[4], MD, FRCP; BGWMKCB Bandutilake[3], MD, FRCOphth; Mangala Dhanapala[3], MD, FICO; Lalani Pathirana[4], MBBS, DFM; Heshani Dissanayake[4], MBBS

[1]Clinical Research Department, International Centre for Eye Health, London School of Hygiene and Tropical Medicine, London, United Kingdom
[2]School of Medicine, Dentistry and Bio-medical Science, Queen's University, Belfast, Ireland
[3]Vitreo-retina Unit, National Eye Hospital, Colombo, Sri Lanka
[4]National Hospital of Sri Lanka, Colombo, Sri Lanka

Corresponding Author:
Mapa Mudiyanselage Prabhath Nishantha Piyasena, MSc, MBBS
Clinical Research Department
International Centre for Eye Health
London School of Hygiene and Tropical Medicine
Keppel Street
London, WC1E 7HT
United Kingdom
Phone: 44 2079588316
Fax: 44 2074365389
Email: Prabhath.piyasena@lshtm.ac.uk

Abstract

Background: Visual impairment and blindness from diabetic retinopathy (DR), which can be reduced by early screening and treatment, is an emerging public health concern in low-income and middle-income countries (LMICs) owing to the increasing prevalence of diabetes mellitus (DM). However, no systematic screening exists in most LMIC settings. The Western province of Sri Lanka has the highest prevalence of DM (18.6%) in the country. A situational analysis identified a marked gap in DR screening (DRS) and treatment services uptake in this region; only opportunistic screening is practiced currently.

Objective: The aim of this protocol is to describe the methods of development and validation of a DRS intervention using a hand-held nonmydriatic digital camera by physician graders in a non-ophthalmological setting at a tertiary-level medical clinic to propose a valid and feasible modality to improve uptake.

Methods: DRS modality was developed after assessing barriers and identifying the most appropriate personnel, methods, and location for screening services, following formative research work. The validation will be conducted in a public sector tertiary care center in the Western province of Sri Lanka. The selected physicians will be trained on capturing and grading images according to a valid locally adopted protocol. Two physicians rated high on training will screen a sample of 506 people with DM at a medical clinic. They will use nonmydriatic and mydriatic 2-field imaging strategy. The validity of the proposed screening procedure will be assessed and compared with the mydriatic indirect biomicroscopic examination by a senior retinologist.

Results: The validity of screening by physician graders will be analyzed and the sensitivity, specificity, and predictive values (with 95% CIs) calculated by the dilation status and for each grader. The diagnostic accuracy at each level of severity of DR will be assessed to define the most appropriate referable criteria. Data is currently being collected.

Conclusions: The outcome of this study will be useful for the detection of a defined level of DR at non-ophthalmological setting to filter the people with DM before referral to an eye clinic. This will be helpful to improve the uptake and identify risk groups

6.2.2.3 Validation study protocol

Development and Validation of a diabetic retinopathy screening modality using a hand held non-mydriatic digital retinal camera by physician graders at a tertiary level medical clinic - Protocol for a validation study

Piyasena MMPN, Gudlavalleti VSM, Gilbert C, Yip JL, Peto T, MacLeod D, Fonseka C, Kulatunga A, Bandutilake B, Dhanapala M, Pathirana L, Dissanayake H. Development and Validation of a Diabetic Retinopathy Screening Modality Using a Hand-Held Nonmydriatic Digital Retinal Camera by Physician Graders at a Tertiary-Level Medical Clinic: Protocol for a Validation Study. JMIR Res Protoc 2018;7(12): e10900. DOI: 10.2196/10900. PMID: 30530458. PMCID: 6305894

Abstract

Introduction

Visual impairment and blindness from diabetic retinopathy (DR) (which can be reduced by early screening and treatment) is an emerging public health concern in low and middle-income countries (LMIC) due to increasing prevalence of diabetes mellitus (DM). However, there is no systematic screening in most of LMIC settings. The Western province of Sri Lanka has the highest prevalence of DM (18.6%) in the country. A situational analysis identified a significant gap in DR screening (DRS) and treatment services uptake in this region, and only opportunistic screening is practiced currently. This paper describes the methods of development and validation of a DRS intervention using a hand held nonmydriatic digital camera by physician graders in a non-ophthalmological setting, to propose a valid and feasible modality to improve uptake.

Objective

This study aims to validate DRS using a hand held nonmydriatic digital camera by trained physician graders at a tertiary level medical clinic.

Methods

The DRS modality was developed, after assessing barriers and identifying the most appropriate personnel, methods and location for screening services, following formative research work. The

validation will be conducted in a public-sector tertiary care centre in Western province of Sri Lanka. The selected physicians will be trained on capturing and grading images according to a valid locally adopted protocol. Two physicians rated high on training will screen a sample of 506 people with diabetes (PwDM) at a medical clinic. They will use nonmydriatic and mydriatic two field imaging strategy. The validity of the proposed screening procedure will be assessed and compared with the mydriatic indirect bio-microscopic examination by a senior retinologist.

Results

Validity of screening by physician graders will be analysed and sensitivity, specificity and predictive values (with 95% confidence intervals) calculated by dilation status and for each grader. The diagnostic accuracy at each level of severity of DR will be assessed to define the most appropriate referable criteria.

Conclusion

The outcome of this study will be useful for detection of a defined level of DR at non-ophthalmological setting to filter the PwDM before referral to an eye clinic. This will be helpful to improve the uptake and identify the risk groups in advance to prevent sight threatening DR. Evidence from this study will be useful for implementation of a DRS program in this region and in similar communities.

Key words

Diabetes, diabetic retinopathy, digital imaging, hand held retinal camera, screening, Sri Lanka.

Registered report identifier number - RR1-10.2196/10900

Introduction

The prevalence of diabetes mellitus (DM) and the number affected is increasing rapidly in all regions. The International Diabetes Federation (IDF) estimated 425 million people had diabetes in 2017 which will increase to 629 million in 2045 globally [1]. This increase expected to be the highest in low and middle-income countries (LMIC) compared to the high-income countries (HIC) [2]. Diabetic retinopathy (DR) is a common microvascular complication of DM which can lead to visual impairment and blindness if not detected early and treated [3]. Many studies report that visual loss from DR can be largely prevented by early screening and appropriate treatment [4–6]. Diabetic retinopathy screening (DRS) can be done in two ways, systematic screening similar to national level programs in HIC versus opportunistic screening and case detection, which is common in low income settings. Most of the LMIC are unlikely to have full population-based screening program due to resources constraints. Current method of DRS in most LMIC is direct ophthalmoscopy which has a lower diagnostic accuracy and found to be ineffective even after training [7]. The mydriatic bio-microscopic examination by an ophthalmologist is practically not possible in these countries due to low number of ophthalmologists and eye clinics are over burdened with highly prevalent blinding conditions such as cataract [8].

The reasons for unavailability of DRS programs (DRSP) in LMIC settings are mostly due to lack of skilled human resources, lack of financial resources and due to lack of evidence of what works in the local system [9-11]. Therefore, it would be important to understand the approaches for screening, especially in non-ophthalmologist settings. Conventional digital cameras need a larger space, skilled photographers and large image storage devices. In addition, systematic screening using sophisticated table top imaging systems incur high capital investment though they are cost effective [12]. The hand-held digital cameras are easy to move, require minimum space, minimum power consumption and are user friendly [13]. In addition, nonmydriatic hand held cameras are less discomforting to the participants and can be used while people with DM (PwDM) are waiting in front of a physician for

consultation. Usage of the camera without pupil dilatation is comfortable to PwDM, as well as easy for the provider. However, the latter, depends on the quality of the image, available for grading [14].

There are various photographic studies, looked at the diagnostic test accuracy (DTA) of DRS using digital imaging. Most of these studies used static table top imaging systems and conducted in HICs. These studies have shown sensitivity of 68-97% and specificity of 71-100% in nonmydriatic imaging using ophthalmic human resources as index graders [15-18]. Similarly, in mydriatic imaging, most of the studied have used table top imaging systems, index test graders were ophthalmic human resources and conducted in HICs. These studies have shown sensitivity of 77-97% and specificity of 76-98% in mydriatic digital imaging [19-22]. There is a gap in evidence in digital retinal imaging in LMICs using non-ophthalmic human resources. In addition, usage of context specific imaging systems such as hand held digital retinal camera in non-ophthalmic setting was not reported in current literature.

Sri Lanka has achieved a remarkable development in the health sector. However, there are public health concerns such as DR which have not been addressed to date [23]. The crude prevalence of DM in Sri Lanka was 12.6% (>20 years), being highest in Western province (18.6%, 95%CI 15.8-21.5%) [24]. In the Western province there are approximately 750,000 (>18 years) PwDM, 150,000 (20%) of whom are likely to have non-proliferative DR (NPDR). A situational analysis conducted in this region shown that number undergoing opportunistic screening and free treatment at the public sector was far lower than the estimated need [25]. There is no systematic DRS in Western province despite the high prevalence of DM [25]. There is no published data on this topic from Sri Lanka. The aim of this protocol is to describe the methods of validation of a DRS approach using digital imaging by physician graders in a tertiary level public sector medical clinic. This will demonstrate functional and technical feasibility of using a hand-held digital camera, in a LMIC non-ophthalmologist setting, and assess the diagnostic accuracy.

Methods

Ethics review committees of National Eye Hospital - Colombo - Sri Lanka and London School of Hygiene & Tropical Medicine - United Kingdom granted ethics approval.

Development of the DRS modality and training

Initial formative research showed that nonmydriatic digital retinal imaging at medical clinics by general physicians was a potential option for the local setting. Nine general physicians were selected from a tertiary level institution following informed consent and underwent a competency-based training by two retinologists from a tertiary centre, which included the following: capturing retinal fields using a hand-held fundus camera, identification of signs of DR (including macular signs) using images and DR grading according to an adapted classification system (Table 1). DR signs are graded at 4 levels as; none - R0, mild non-proliferative DR (NPDR) - R1, moderate NPDR - R2, severe NPDR - R3 and proliferative DR (PDR) and above - R4. Macular changes are graded as none - M0; exudate/s - or blot haemorrhage/s within 2-disc diameters from the centre of the fovea - M1 (table 2). Guidelines were used to standardize reporting of image quality, which included ungradable images based on the proportion of the retina visible for grading (figure 1). After the training, Physicians were tested using a set of standard images of DR and the two who reached the required level of agreement with the retinologist (k=0.8-0.9) were selected as graders in the validation study.

Figure 1. Evaluation of image quality - levels of gradability based on the proportion of the image which can be graded

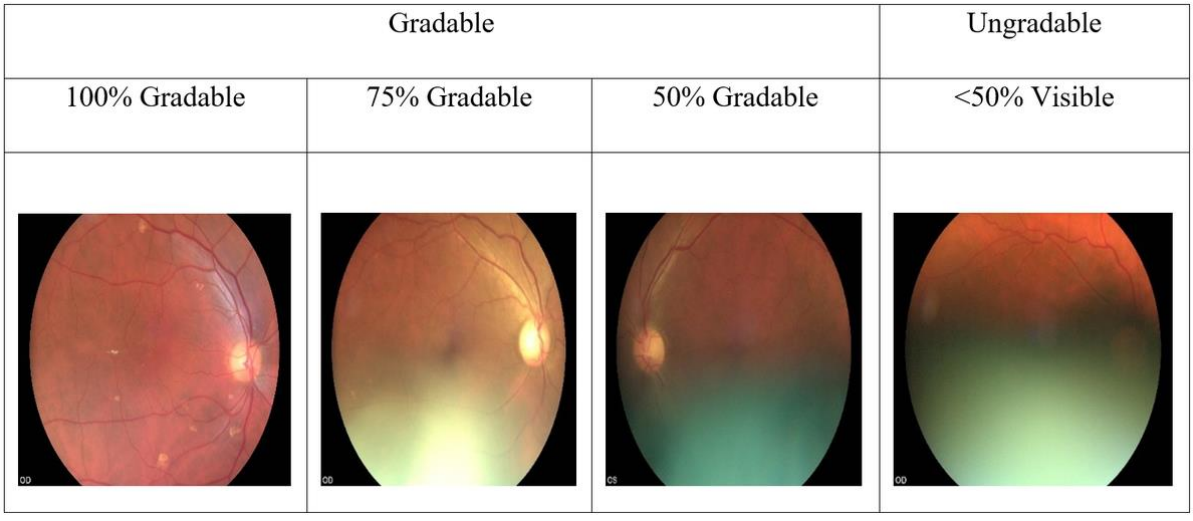


Table 1. Adapted diabetic retinopathy classification for the validation study

Signs	No DR (R0)	Mild BDR[d] / NPDR[e] (R1)	Moderate BDR / NPDR (R2)	Severe NPDR (R3)	Proliferative DR (PDR[f]) (R4)
Microaneurysms	No	Few	Multiple	Multiple	Present
Hard Exudates [a]	No	Few	Multiple	Multiple	Present
Cotton wool spots	No	Occasional	Multiple	Multiple	Present
Intra retinal haemorrhage [a]	No	Few	>20 in 1-3 quadrants	>20 in 4 quadrants	Present
Venous beading	No	Occasional	Present in 1-2 quadrants	Present in >2 quadrants	Present
IRMA [b]	No	No	Present ~1 quadrant	Prominent >1 quadrant	Present
NVD [c]	No	No	No	No	Present
NVE [c]	No	No	No	No	Present
Vitreous / pre-retinal haem-orrhage	No	No	No	No	Present - ad-vanced PDR
Traction	No	No	No	No	Present - ad-vanced PDR
Fibrosis	No	No	No	No	Present - ad-vanced PDR

[a] Not within the definition of maculopathy
[b] Intra retinal microvascular abnormalities
[c] Neo-vascularisations over the disc / elsewhere
[d] Background DR, [e] NPDR – Non-proliferative DR, [f] PDR-Proliferative DR

Table 2. Macular signs classification

	Maculopathy absent (M0)	Maculopathy present (M1)
Signs up to 2-disc diameters from the centre of fovea	No signs	Presence of hard exudate/s and / or blot haemorrhage/s (Referable)

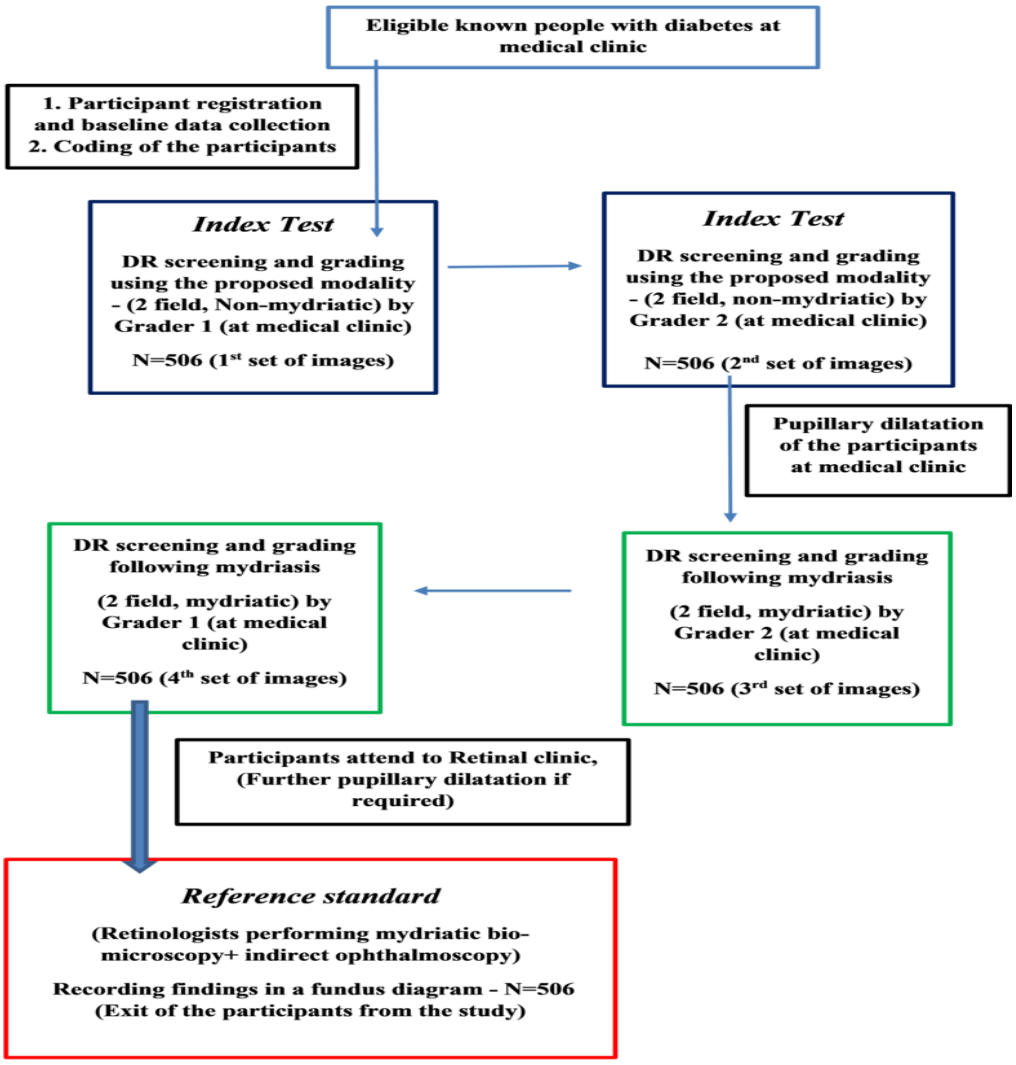
Sample calculation and recruitment

The sample size (n=506) was calculated based on 95% confidence intervals, 10% margin of error, expected sensitivity 70% and prevalence of moderate NPDR among PwDM of 20%. This included an additional 25% to take account of ungradable images. Interim analysis will be undertaken to ascertain

the level of ungradable images (i.e. <50% of the retina visible) and the sample size increased, if required.

This study is a prospective observational study by design. A consecutive sample of diagnosed PwDM (>18 years) without previous DRS at an eye clinic will be eligible to participate, after giving written informed consent. Eligible participants will be recruited by trained research assistants when PwDM present for routine medical care at the main tertiary centre in Colombo. The PwDM with previous retinal screening, DR related treatment (laser treatment, intra-vitreal injections and pars-plana-vitrectomy), and those who were currently under any DRSP or treatment will be excluded from study. Participants flow diagram is shown in figure 3. Participants characteristics will be documented into a questionnaire schedule by research assistants on recruitment.

Figure 2. Participants flow diagram in the validation

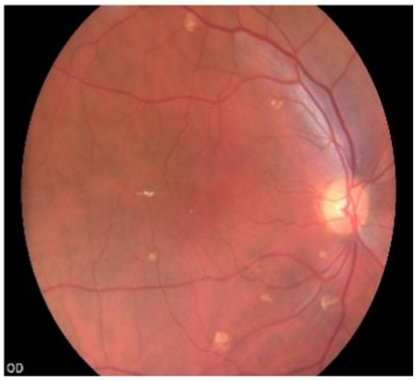
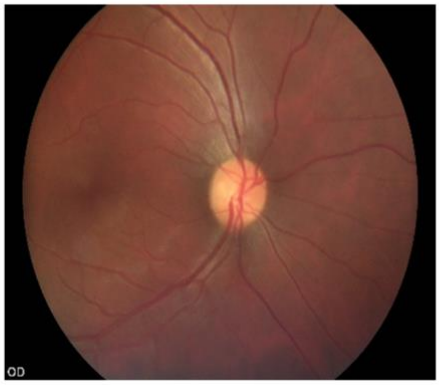


Imaging system, capturing images and grading

Two field nonmydriatic and mydriatic retinal images will be captured and stored. (figure 2). Participants will undergo digital retinal imaging (using Carlzeiss-Visuscout100® hand held non-mydriatic fundus camera-2017-Germany) by the physician graders at the time of presentation. This imaging system has a 40^0 field of view with 5 mega pixels (5 MP CMOS, resolution 800x480) and captures colour and red free images in a focus range of –20 D (diopters) to +20 D. The minimum pupil size required is 3.5mm and 9 light emitting diodes (LED) are available for internal fixation.

Firstly, two field (1^{st} field-macula centred, 2^{nd} field-disc centred) (figure 2), 40^0 retinal images will be captured in each eye by each physician grader without pupillary dilatation. Subsequently, participants' pupils will be dilated using 2.5% phenylephrine and the same fields will be captured, following adequate mydriasis (5-6 mm).

Figure 3. Two retinal fields captured

Field 1- Centred on the macula	Field 2 - Centred on the optic disc
	

Each set of images will be coded and stored by research assistants after capturing. The coded image sets will be given back to the same physician graders for grading. During grading, the nonmydriatic images will be graded first. The graders will be masked to the history and clinical examination findings. The retinopathy and macular signs will be identified and entered by the physician graders into a

hard copy data table. Finally, it will be entered into a MS Excel data sheet by research assistants. The grading data consistency checks and cleaning will be done by an independent statistician.

Reference test

The reference test will entail a detailed, dilated fundus examination by an experienced retinologist using slit-lamp bio-microscopy with a 90D lens and indirect ophthalmoscopy using a 20D lens. This examination will take place as early as possible, after imaging. The retinologist will be masked to the clinical status and physician graders' findings. In addition, a detailed anterior segment examination (clarity of cornea, status of lens) and media (vitreous) examination will be done by the reference test grader. The lens opacity will be graded according to the lens opacity classification system - three (LOCS 111).

Quality assurance and agreement analysis

For quality assurance 15% of each nonmydriatic and mydriatic image sets will be evaluated by the retinologist for technique, ability to image the required field and gradability. Fifteen percent of each hundred image sets will be given back to the physician graders for double grading to assess the repeatability and intra-grader agreement in 1st attempt and 2nd attempt of grading images. A sample of the same images sets (n=200) will be graded by the retinologist to calculate inter-grader agreement.

Data analysis

We will analyse the validity of screening by physician graders and calculate sensitivity, specificity and predictive values with 95% confidence intervals for each method of screening and by grader. The analysis will be conducted by including and excluding the ungradable images and considering each eye as unit of analysis, and by person considering the worst eye. Intra and inter-grader agreement (kappa) for both mydriatic and nonmydriatic index tests will be calculated and compared to the findings by the retinologist. Subgroup analysis will be conducted for identification of presence / absence of DR (any DR), moderate NPDR and above with / without macular signs, to make recommendations for a referable criterion for the local context. In addition, a multiple logistic

regression analysis will be conducted to identify the factors that could be used to predict the image gradability.

Results

The physician graders have been trained and currently, validation is being done in the Western province of Sri Lanka. The results of this study will be published in detail according to the Quality Assessment of Diagnostic Accuracy Study guidelines (QUADAS-2) [26]. Data will be entered using MS Excel (2016) worksheet and transferred into STATA/IC-v14.2 (2015-USA) analytical package following cleaning, consistency checks and analysis. The sensitivity, specificity and predictive values for each strategy and each level of DR will be presented using average of the same variables of two physician graders (non-mydriatic and mydriatic separately), compared to the reference standard, along with 95% confidence intervals.

Discussion

The level of skills acquired by the physician graders is an important factor in the screening outcome. Different non-ophthalmologist graders have conducted DRS successfully in some settings [27–29]. We will describe the diagnostic accuracy of detection of DR by physician graders. In addition, we will be able to study the effect of a range of population characteristics on the validity of detecting DR using imaging and to understand the role of non-ophthalmic personnel in order to make recommendations for a systematic DRSP. We will describe the referral criterion applicable to this local context based on the validation study results. Defining a referable level DR at a non-ophthalmological setting, in a context where there is no systematic DRS will filter out those not needing a referral and therefore reduce the workload at ophthalmologist's clinic. The 7-field imaging strategy used in early treatment diabetic retinopathy study (ETDRS) is considered as the gold standard in DRS [30]. However, this technique is practically not feasible in this context due to resources constrains. Therefore, we proposed to use the locally accepted reference standard of retinologist's examination as the suitable reference standard. Digital retinal imaging has previously shown

diagnostic accuracy levels that would comply with accepted standards of established national level screening programs [15,22,31].

There are a few studies (conducted in HICs) which used non-ophthalmologist human resources in DRS, with which we could compare our results. In Singapore a non-mydriatic fundus camera showed a sensitivity of 69.8% (95% CI 61.3-77.2%) and specificity of 94.4% (95% CI 92.3-96.1%) for non-physician graders using a single field [32]. A study done in UK in DRS by general practitioners using 35mm colour images showed that detecting any level of DR increased, 62.6% (95% CI 55.9-69.4%) with direct ophthalmoscopy to 79.2% (95% CI 73.6-84.9%) using retinal photographs (and specificity remained unchanged (direct ophthalmoscopy 75.0% (95% CI 69.5-80.5%) vs 73.5% (95% CI 68.0-79.1%) [33]. They concluded that retinal photography by trained general practitioners in primary care settings, could attain an acceptable level of detection of sight threatening DR (STDR) (87%) [33]. In Thailand use of single field digital nonmydriatic imaging showed a sensitivity 80% and specificity of 96% in a sample of PwDM where 54.7% were 41-60 years old and 45.3% had 1-5 years of diabetes [34].

Another important consideration in this study would be gradability of the images. The image gradability will depend on the lens opacity, media opacity, pupil size and reflectivity of the fundus. We envisaged poor gradability in nonmydriatic imaging considering the high prevalence of cataract in this local setting. Further iris colour, age and other population characteristics may affect the quality of images [14]. Scanlon P. et al. showed that in the > 80 years of age group the technical failure rates reduced from 41.6% to 16.9% following mydriasis [35]. This study concluded that the odds of having one eye ungradable increases by 2.6% (95% CI 1.6-3.7%) for each extra year since diagnosis of DM and major cause of ungradability was having central cataract (57%) [35]. We will describe the factors affecting gradability of images in addition to the DTA results.

Conclusion

In this study we will demonstrate the diagnostic accuracy of the physician graders compared to the retinologist, to make recommendations for developing an integrated DRSP in LMICs where there is no systematic DRS. The outcome of this study will be useful for implementation of a systematic DRSP in this region and in similar communities.

References cited in submitted manuscript (Chapter 6.2.2.3)

1. IDF. International Diabetes Federation-Diabetes Atlas - 08th Edition - 2017. International Diabetes Federation. 2018-07-05. URL: https://www.idf.org/e-library/epidemiology-research/diabetes-atlas.html. Accessed: 2018-07-05. (Archived by WebCite® at http://www.webcitation.org/70gZUlK5J)

2. Shaw JE, Sicree RA, Zimmet PZ. Global estimates of the prevalence of diabetes for 2010 and 2030. Diabetes Res Clin Pract. 2010;87(1):4–14. PMID: 19896746 DOI: 10.1016/j.diabres.2009.10.007

3. Williams R, Airey M, Baxter H, Forrester J, Kennedy-Martin T, Girach A. Epidemiology of diabetic retinopathy and macular oedema: a systematic review. Eye. 2004;18(July):963–83. PMID: 15232600 DOI: 10.1038/sj.eye.6701476

4. UK Prospective Diabetes Study (UKPDS) Group. [no authors listed]. Intensive blood-glucose control with sulphonyl ureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet. 1998;352(9131):837–53. PMID: 9742976

5. Klein R, Knudtson MD, Lee KE, Gangnon R, Klein BEK. The Wisconsin Epidemiologic Study of Diabetic Retinopathy xxii. The Twenty-Five-Year Progression of Retinopathy in Persons with Type 1 Diabetes. Diabetes. 2009;115(11):263-0279. PMID: 19068374 DOI: 10.1016/j.ophtha.2008.08.023

6. Indications for photocoagulation treatment of diabetic retinopathy: Diabetic Retinopathy Study

Report no. 14. The Diabetic Retinopathy Study Research Group. International ophthalmology clinics. 1987;27(4):239-253. PMID: 2447027

7. Gerhs K, Chong L, Gusman G, Street D. Can we educate primary care physicians about diabetic retinopathy after graduation? Preliminary results of the diabetic retinopathy education study. Invest Ophthalmol Vis Sci. 1993; 34:1182–5.

8. Bamashmus MA, Gunaid AA. Regular Visits to a Diabetes Clinic Were Associated with Lower Magnitude of Visual Disability and Diabetic Retinopathy - A Hospital Based Historical Cohort Study in Yemen. Diabetes Technol Ther. 2009;11(1):45-50. doi: 10.1089/dia.2007.0299. PMID: 19132855

9. Adriono G, Wang D, Octavianus C, Congdon N. Use of eye care services among diabetic patients in urban Indonesia. Arch Ophthalmol. 2011;129(7):930–5. doi: 10.1001/archophthalmol.2011.147. PMID: 21746983

10. Burgess PI, Msukwa G, Beare NA V. Diabetic retinopathy in sub-Saharan Africa: meeting the challenges of an emerging epidemic. BMC Medicine 2013;11(1):157. https://doi.org/10.1186/1741-7015-11-157

11. Muecke JS, Newland HS, Ryan P, Ramsay E, Aung M, Myint S, et al. Awareness of diabetic eye disease among general practitioners and diabetic patients in Yangon, Myanmar. Clin Exp Ophthalmol. 2008;36(3):265-73. doi: 10.1111/j.1442-9071.2008. 01724.x

12. James M, Turner D, Broadbent D, Vora J, Harding S. Cost effectiveness analysis of screening for sight threatening diabetic eye disease. BMJ. 2000;320(7250):1627–31. PMID: 10856062 PMCID: PMC27406

13. Tran K, Mendel TA, Holbrook KL, Yates PA. Construction of an inexpensive, hand-held fundus camera through modification of a consumer “point-and-shoot” camera. Investig Ophthalmol Vis Sci. 2012;53(12):7600–7. doi: 10.1167/iovs.12-10449. PMID: 23049089

14. Banaee T, Ansari-Astaneh MR, Pourreza H, Faal Hosseini F, Vatanparast M, Shoeibi N, et al.

Utility of 1% Tropicamide in Improving the Quality of Images for Tele-Screening of Diabetic Retinopathy in Patients with Dark Irides. Ophthalmic Epidemiol. 2017;24(4):217–21. https://doi.org/10.1080/09286586.2016.1274039

15. Baeza M, Orozco-Beltrán D, Gil-Guillen VF, Pedrera V, Ribera MC, Pertusa S, et al. Screening for sight threatening diabetic retinopathy using non-mydriatic retinal camera in a primary care setting: To dilate or not to dilate? Int J Clin Pract. 2009;63(3):433–8. PMID: 19222628. DOI: 10.1111/j.1742-1241.2008.01921.x

16. Aptel F, Denis P, Rouberol F, Thivolet C. Screening of diabetic retinopathy: Effect of field number and mydriasis on sensitivity and specificity of digital fundus photography. Diabetes Metab. 2008;34(3):290–3. PMID: 18406188 DOI: 10.1016/j.diabet.2007.12.007

17. Scanlon PH, Malhotra R, Thomas G, Foyt C, Kirkpatrick JN, Lewis-Barned N, et al. The effectiveness of screening for diabetic retinopathy by digital imaging photography and technician ophthalmoscopy. Diabet Med. 2003;20(6):467–74.

18. Lopez-Bastida J, Cabrera-Lopez F, Serrano-Aguilar P. Sensitivity and specificity of digital retinal imaging for screening diabetic retinopathy. Diabet Med. 2007;24(4):403–7. PMID: 17298591 DOI: 10.1111/j.1464-5491.2007.02074.x

19. Maberley D, Cruess AF, Barile G, Slakter J. Digital photographic screening for diabetic retinopathy in the James Bay Cree. Ophthalmic Epidemiol. 2002;9(3):169–78. PMID: 12045884

20. Murgatroyd H. Effect of mydriasis and different field strategies on digital image screening of diabetic eye disease. Br J Ophthalmol. 2004;88(7):920–4. PMID: 15205238 PMCID: PMC1772219 DOI: 10.1136/bjo.2003.026385

21. Al Sabti K, Raizada S, Wani VB, Al Ajmi M, Gayed I, Sugathan TN. Efficacy and reliability of fundus digital camera as a screening tool for diabetic retinopathy in Kuwait. J Diabet Complications. 2003;17(4):229–33. PMID: 12810247

22. Hansen AB, Hartvig NV, Jensen MS, Borch-Johnsen K, Lund-Andersen H, Larsen M. Diabetic retinopathy screening using digital non-mydriatic fundus photography and automated image analysis. Acta Ophthalmol Scand. 2004;82(6):666–72. PMID: 15606461 DOI: 10.1111/j.1600-0420.2004.00350.x

23. UNDP. UNDP's role and leadership on achieving the MDGs in Sri Lanka. United Nations. 2018-07-05. URL:http://www.lk.undp.org/content/srilanka/en/home/post-2015/mdgoverview.html. Accessed: 2018-07-05. (Archived by WebCite® at http://www.webcitation.org/70gZkAVim)

24. Katulanda P, Rathnapala D, Sheriff R, Matthews D. Province and ethnic specific prevalence of diabetes among Sri Lankan adults. Sri Lanka J Diabetes Endocrinol Metab. 2012;1(1):2–7. DOI: http://doi.org/10.4038/sjdem.v1i1.4180

25. Piyasena PN, Murthy GVS. A situation analysis of diabetic eye care service delivery in health care institutions of the Western Province of Sri Lanka. Ceylon Med J. 2017;62(3):205–6. DOI: http://doi.org/10.4038/cmj.v62i3.8527

26. Whiting PF, Rutjes AWS, Westwood ME, Mallet S, Deeks JJ, Reitsma JB, et al. Research and Reporting Methods Accuracy Studies. Ann Intern Med. 2011;155(4):529–36. PMID: 22007046. DOI: 10.7326/0003-4819-155-8-201110180-00009

27. Henricsson M, Karlsson C, Ekholm L, Kaikkonen P, Sellman A, Steffert E, et al. Colour slides or digital photography in diabetes screening-a comparison. Acta Ophthalmol Scand. 2000;78(2):164–8. PMID: 10794249

28. Sundling V, Gulbrandsen P, Straand J. Sensitivity and specificity of Norwegian optometrists' evaluation of diabetic retinopathy in single-field retinal images - a cross-sectional experimental study. BMC Health Serv Res. 2013;13:17. https://doi.org/10.1186/1472-6963-13-17

29. Kuo HK, Hsieh HH, Liu RT. Screening for diabetic retinopathy by one-field, non-mydriatic,

45° digital photography is inadequate. Ophthalmologica. 2005;219(5):292–6. PMID: 16123556 DOI: 10.1159/000086114

30. Early Treatment Diabetic Retinopathy Study Group. Grading diabetic retinopathy from stereoscopic colour fundus photographs - An extension of the modified Airlie House classification: ETDRS report number 10. Ophthalmology. 1991;98 (5):786-806. PMID: 2062513

31. Perrier M, Boucher MC, Angioi K, Gresset JA, Olivier S. Comparison of two, three and four 45 degrees image fields obtained with the Topcon CRW6 nonmydriatic camera for screening for diabetic retinopathy. Can J Ophthalmol.2003;38(7):569–74. PMID: 14740798

32. Bhargava M, Cheung CYL, Sabanayagam C, Kawasaki R, Harper CA, Lamoureux EL, et al. Accuracy of diabetic retinopathy screening by trained non-physician graders using non-mydriatic fundus camera. Singapore Med J. 2012;53(11):715–9. PMID: 23192497

33. Owens D, Gibbins R, Lewis P, Wall S, Allen J, Morton R. Screening for diabetic retinopathy by general practioners: Ophthalmoscopy or retinal photography as 35 mm colour transparencies? Diabet Med. 1998;15(2):170–5. PMID: 9507921 DOI: 10.1002/(SICI)1096-9136(199802)15:2<170::AID-DIA518>3.0.CO;2-H

34. Ruamviboonsuk P, Wongcumchang N, Surawongsin P, Panyawatananukul E, Tiensuwan M. Screening for diabetic retinopathy in rural area using single-field, digital fundus images. J Med Assoc Thai. 2005;88(2):176–80. PMID: 15962667

35. Scanlon P, Foy C, Malhotra R, Aldington S. The Influence of Age, Duration of Diabetes, Cataract, and Pupil Size on Image Quality in Digital Photographic Retinal Screening. Diabetes Care. 2005;28(10):2448-53. PMID: 16186278

Image file - (not included in the publication)

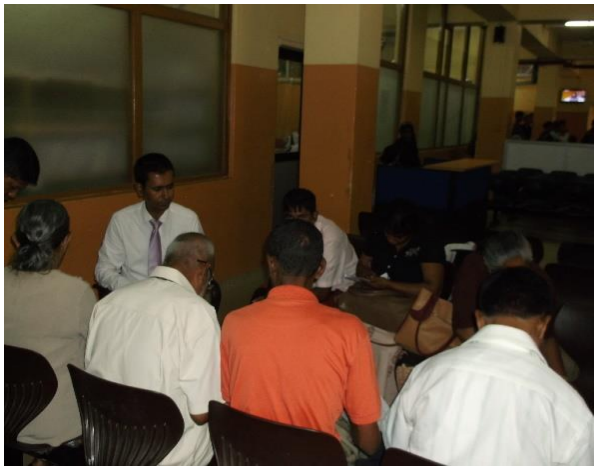



Image file 6.11 - Recruitment of PwDM and conducting screening interventions validation study at the medical clinic by selected physician graders

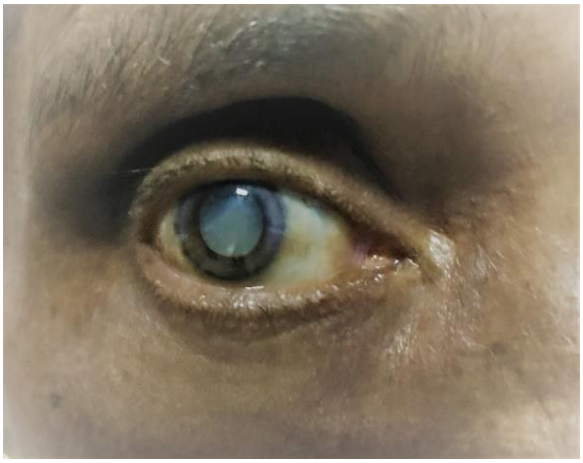


Image file 6.12 - Pupil dilatation of a PwDM and a PwDM identified with mature cataract at the screening.

Image file (not included in the publication)

Image file 6.13 - Preparation and conducting the reference standard test at the retinal clinic of National Eye Hospital - Colombo.

RESULTS

Preamble to Chapters 7 to 13

Preamble

The next sections of the thesis comprised of results and the main discussion. In the first section of the thesis, I present results, according to the objectives numbered 1 to 3. Afterwards, I have presented the main discussion of the thesis. In order to identify the submitted / published mansucripts, those have been marked with page borders. In addition, MS Word document of the manuscript has been provided for better readability. The manuscripts and lists of references were formatted according to the respective journal guidelines. The information sheets, consent forms, data collection questionnaire schedules and additional files were included in Appendices no: 2 to 10. Appendix 11 contains the open sources' copyright statements and permission letters from the co-authros.

Results pertaining to objective number 1 (Chapter 7, 8 and 9)

The chapters 7, 8 and 9 provide results for objective number 1 on assessment of barriers to access DRS in three separate publication drafts. These manuscripts have been submitted for consideration of publication under open sources of PLoS ONE and Bio Med Central (BMC). The chapter 7 describes the barriers / enablers to access DRS by PwDM and challenges / facilitators faced by the providers in provision of these services. This is a narrative literature review which described the barriers themes by country income setting. I have revised the chapter 7, according to the editor's and reviewers' comments from PLoS ONE.

The next two chapters; 8 and 9; contain two publication drafts on the formative qualitative research work conducted in the Western province of Sri Lanka. The first manuscript describes the services users' perspectives and the next manuscript highlights providers' perspectives on accessing DRS services in the Western province. I have revised chapters 8 and 9 according to the editor's and reviewer's comments from the BMC Public Health and Health Services Research.

Results pertaining tobjective number 2 (Chapter 10, 11 and 12)

The chapters 10, 11 and 12 contain results for the objective numbered 2. The chapter 10 consisted of a published article of assessing the diagnostic test accuracy of digital retinal imaging through a meta-analysis. This has already been published in BMC-Systematic reviews. The chapter 11 illustrates the outcomes of training of physician graders. The chapter 12 describes the results of the validation of the proposed DRS modality in the Western province of Sri Lanka. This manuscript has been submitted to the BMC-Ophthalmology open sources, reviewed and accepted for publication.

Results pertaining to objective number 3 (Chapter 13)

The chapter 13 contains the results for the objective numbered 3. The submitted manuscript draft describes the process of adaptation and development of a health educational intervention in local languages to improve the referral uptake at eye clinics. This has been submitted to the BMC-Public Health (sub section on health behaviour, health promotion and society), reviewed and accepted for publication.

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
E: registry@lshtm.ac.uk

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Mapa Mudiyanselage Prabhath Nishantha Piyasena
Principal Supervisor	Prof.G.V.S.Murthy
Thesis Title	A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	N/A		
When was the work published?	N/A		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	**Yes**

**If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.*

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	PLoS ONE - Systematic Reviews - Open Source
Please list the paper's authors in the intended authorship order:	Piyasena MMPN, Gudlavalleti VSM, Yip JLY, Gilbert C, Zuurmond M, Peto T, Gordon I, Hewage S, Kamalakannan S.
Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceived the concept of this review, prepared the methodology, conducted a preliminary review and presented at the upgrading. Afterwards, under guidance of the upgrading panel and supervisors, I revised the protocol. I conducted the data bases searches, extraction of titles and abstracts and reviewed

	those for eligibility comapred with a co-reviewer. After identifying the eligible articles, I reviewed full reports and extracted the data and assessed the methodological quality for inclusion in the review. Following a co-reviewer's opinion I synthesised the qualitative and quatititative data by country income level. I prepared this manuscript and revised it under supervision of supervisors and advisers and submitted to PLoS ONE in May/2018. I received reviewer's comments by Nov/2018 and review was updated and corrected according to the reviewers' comments by Jan/2019. Revised manuscript re-submitted in Jan/2019.

Student Signature: [redacted] **Date:** 27/03/2019.

Supervisor Signature: [redacted] **Date:** 27/03/2019

PLOS ONE

RESEARCH ARTICLE

Systematic review on barriers and enablers for access to diabetic retinopathy screening services in different income settings

Mapa Mudiyanselage Prabhath Nishantha Piyasena[1]*, Gudlavalleti Venkata S. Murthy[1], Jennifer L. Y. Yip[1], Clare Gilbert[1], Maria Zuurmond[2], Tunde Peto[3], Iris Gordon[1], Suwin Hewage[4], Sureshkumar Kamalakannan[5]

1 Clinical Research Department, Department of Infectious and Tropical Diseases, International Centre for Eye Health, London School of Hygiene and Tropical Medicine, London, United Kingdom, **2** Clinical Research Department, Department of Infectious and Tropical Diseases, International Centre for Evidence in Disability, London School of Hygiene and Tropical Medicine, London, United Kingdom, **3** Centre for Public Health, Faculty of Medicine, Health and Life Sciences, School of Medicine, Dentistry and Biomedical Sciences, Queen's University, Belfast, Northern Ireland, **4** Retina Unit, Department of Vitreo-retina, National Eye Hospital, Colombo, Sri Lanka, **5** Department of Eye Health and Disability, Indian Institute of Public Health, Public Health Foundation of India, Hyderabad, Telangana, India

* Prabhath.piyasena@lshtm.ac.uk

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Abstract

Background

Diabetic retinopathy (DR) can lead to visual impairment and blindness if not detected and treated in time. Knowing the barriers/enablers in advance in contrasting different country income settings may accelerate development of a successful DR screening (DRS) program. This would be especially applicable in the low-income settings with the rising prevalence of DR.

Objectives

The aim of this systematic review is to identify and contrast the barriers/enablers to DRS for different contexts using both consumers i.e., people with diabetes (PwDM) and provider perspectives and system level factors in different country income settings.

Methods

We searched MEDLINE, Embase, CENTRAL in the Cochrane Library from the databases start date to December 2018. We included the studies reported on barriers and enablers to access DRS services based at health care facilities. We categorised and synthesized themes related to the consumers (individuals), providers and the health systems (environment) as main dimensions according to the constructs of social cognitive theory, supported by the quantitative measures i.e., odds ratios as reported by each of the study authors.

Main results

We included 77 studies primarily describing the barriers and enablers. Most of the studies were from high income settings (72.7%, 56/77) and cross sectional in design (76.6%, 59/

Chapter 7

Systematic Review on Barriers and Enablers for Access to Diabetic Retinopathy Screening Services in Different Income Setting

Piyasena MMPN, Murthy GVS, Yip JYL, Gilbert C, Zuurmond M, Peto T, Gordon I, Hewage S, Kamalakannan S. Systematic Review on Barriers and Facilitators for Access to Diabetic Retinopathy Screening Services in Different Income Settings. PLoS ONE 14(4): e0198979. https://doi.org/10.1371/journal.pone.0198979

Abstract

Background

Diabetic retinopathy (DR) can lead to visual impairment and blindness if not detected and treated in time. Knowing the barriers/enablers in advance in contrasting different country income settings may accelerate development of a successful DR screening (DRS) program. This would be especially applicable in the low-income settings with the rising prevalence of DR.

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Main Results

We included 77 studies primarily describing the barriers and enablers. Most of the studies were from high income settings (72.7%, 56/77) and cross sectional in design (76.6%, 59/77). From the perspectives of consumers, lack of knowledge, attitude, awareness and motivation were identified as major barriers. The enablers were fear of blindness, proximity of screening facility, experiences of vision loss and being concerned of eye complications. In providers' perspectives, lack of skilled human resources, training programs, infrastructure of retinal imaging and cost of services were the main barriers. Higher odds of uptake of DRS services was observed when PwDM were provided health education (odds ratio (OR) 4.3) and having knowledge on DR (OR range 1.3-19.7).

Conclusion

Knowing the barriers to access DRS is a pre-requisite in development of a successful screening program. The awareness, knowledge and attitude of the consumers, availability of skilled human resources and infrastructure emerged as the major barriers to access to DRS in any income setting.

Key words - Barriers, Challenges, Enablers, Facilitators, Diabetes, Diabetic retinopathy, Screening, Health systems.

Systematic review registration number - Not Registered

[Pre-print unedited draft was available for open review at - https://www.biorxiv.org/content/10.1101/335638v1]

Introduction

Diabetes mellitus (DM) is one of the most prevalent non-communicable diseases which imposes a significant impact on health systems. The International Diabetes Federation (IDF) estimated that there were 425 million people with diabetes (PwDM) in the world in year 2017 and this will increase to 629 million by 2045 [1]. It has been emphasised that efforts should be made to prevent the complications of DM as per the targets set in St Vincent declaration in 1989 [2]. It was targeted to reduce the blindness due to diabetic retinopathy (DR) by one third, by raising awareness among the PwDM and by improving the capacity to deliver services by the providers. DR is a common microvascular complication of the eyes caused by chronic hyperglycaemia. Blindness due to DR is common among the working age populations and it is becoming a global issue due to rising prevalence of DM [3]. Though proportion of blindness due to DR is low compared to other causes of blindness, expenditure related to DR is a burden to any health system [4].

Penchansky and Thomas described the concept of access as the *"degree of fit"* between clients and the health system [5]. Healthcare access for PwDM has an especially significant role in the prevention of sight loss due to DR. Access to health care remained a vague concept, until recently, impeding the work of health care policy makers. Optimal access to health care was defined by Rogers et al., (1999) as *"providing the right service at the right time in the right place"* [6]. In generic literature it is mentioned that access has multiple dimensions and it is not merely the entry in to the healthcare system [5]. Further it is an outcome of people's potential to use health care and manifestations of patients actual use [7]. Donabedian has observed that the proof of access is use of service, not simply the presence of a facility [8]. Some authors argue that it depends on acceptability of the services as well [9,10]. It is mentioned that inequalities have been observed in detection and treatment of DR which require multi-sectoral engagement [11]. Further, universal coverage cannot be achieved without addressing the barriers [12]. One review mentioned that there are many reasons for underutilization of eyecare and that the risk of blindness varies with the context [13]. It has been shown that culturally

competent care should be delivered in a diverse patient community overcoming the sociocultural barriers [14,15]. This is especially relevant with regard to healthcare delivery for DR.

Screening of DR can be done opportunistically or proactively. Current literature shows that proper disease control of DM, diabetic retinopathy screening (DRS) and early identification and treatment of pathologies will reduce progression of sight threatening DR (STDR) [16-20]. Awareness of the need for detecting DR at a symptomless stage is a key factor in uptake and regular follow up of DRS services [21]. There are many obstacles for implementation and maintaining satisfactory level of uptake in DRS at a program level. One important approach to address this issue is identification of barriers and enablers in the system in advance. The barriers to access DRS could vary according to the country income level and various system factors in each setting. Different economic and socio-cultural factors would affect the access. Knowing the impeders in each setting will enable successful implantation of DRS strategies. Especially this will enable to identify effective strategies for low and middle-income settings, as we can expect a rise in number with DR in future [1]. Defining a barrier will enable implementation of public health strategies to improve access [5]. The barriers such as lack of knowledge and awareness on DR by the consumers and lack of training, skills and screening equipment for the providers would impede the access to DRS. A barrier could lead to a different outcome for a certain community such as difficulties in mobility for people with disabilities [22]. In system assessments authors mentioned that economic and logistic reasons hinder the provision of screening services [23]. Yet, it is mentioned that effective strategies are frequently underutilised in developing countries to overcome such barriers [24]. Therefore, it is necessary to understand the potential barriers in accessing and challenges in provision of DRS services in any health system.

The successful uptake of DRS services depends on the personal factors related to the consumer as an agency [25]. These factors may be modifiable or not modifiable according to the environment. The required behavioural change techniques for a target population could be hypothesised using various

behavioural models. The "*social cognitive theory*" explains how persons acquire and maintain specific behavioural patterns and it provides the basis of most intervention strategies to overcome a defined barrier [26]. A person's behaviour influences and is influenced by personal factors and the social environment ('Reciprocal determinism') [27]. This will lead to self-efficacy of the person to achieve confidence for performing a particular behaviour. We hypothesised that identification of barriers at individual PwDM and provider / system level as the environment would enable to identify the impeders in advance. Therefore, assessment of behavioural patterns and perceived barriers in accessing DRS services may be useful in developing strategies for a successful DRS program in any context.

The current evidence provides information on barriers without considering the settings. However, barriers to access DRS are different in various country income levels and health systems. One review described interventions to promote DRS uptake [28]. In addition, there was another Cochrane review on quality improvement interventions to increase DRS attendance [29]. Another recently published review has also considered the barriers to access DRS without specifying the setting [30]. In addition, this review mostly focused on improving the attendance at existing services. In our review we explored the barriers in broader dimensions including planning and implementation especially in low income settings, without limiting to attendance. Moreover, most of the available reviews described barriers based on modifiable themes or factors that would affect DRS uptake. However, we proposed to identify non-modifiable barriers as well, since this knowledge will be useful to identify the defaulters / those who are at risk of sight loss in advance. In addition, another review has included studies only after the year 2003 considering the effective implementation of programs following 'St Vincent Declaration' [31]. However this review was then limited to the studies only from high income countries (HIC) since most of the programmes were implemented in European countries [31].

Most of the available studies had provided the evidence of barriers to access DRS services according to the presumed typology of barriers. The processes related to DRS uptake can be considered at three

levels i.e., consumer, service provider and eyecare system. Therefore, in this review we categorised the reported themes or variables under above categories. We specifically tried to assess the challenges faced by the providers at established healthcare facilities that have DRS services, in addition to studying barriers for consumers. In broad definitions, barriers to access to DRS are not only limited to the access issues at the point of delivery, but it also involves all the steps which take place starting from perceptions of a PwDM at one end to the whole eye care system at the other end which are inter-related and connected to each other.

Objectives

The overall aim of the review was to explore barriers to access DRS in various country income settings. The review has the following specific objectives.

-To assess the barriers and enablers to uptake of DRS services by PwDM by country income category.

-To assess the challenges faced by the services providers in provision of DRS services and to identify the enablers for development of a DRS program in each setting.

The secondary objectives of this review were;

-To assess the socio-demographic and economic factors that could affect DRS uptake.

-To assess the barriers or enablers to develop a DRS program in a health care system.

Methods

We included studies that focused on assessing barriers and enablers to access DRS. In addition, we found studies that described factors affecting the uptake of DRS services. Following criteria were used for assessment of eligibility of the studies. (There is no protocol registration for this review and

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist was included as S1 Table 1 in Appendix 5).

Inclusion of studies -

-Consumers - The studies which have assessed the barriers at group or individual level of PwDM at or who had been referred to a permanent health care facility for DRS.

-Service providers - Studies in which participants were service providers who have direct contact with PwDM in a permanent health care institution and / or clinical decision makers / other stake holders involved in DRS service-related decision making.

Exclusion of studies -

-Studies which have obtained the study sample from the general population without specifying the status of DM.

-Absence of standard diagnostic criteria for DM.

-Studies assessing barriers for eye care in general, without specifying DRS.

-Studies assessing barriers for screening DM complications in general, without specifying the barriers for DRS.

We did not restrict the studies for inclusion by study design. We included studies that used qualitative, quantitative and mixed methods.

Type of participants

We included the studies that have covered PwDM who were attending an existing DRS program, diabetic medical care or an eye care facility.

Type of interventions

We included studies that delivered or considered DRS primarily at an established health care facility. We defined the DRS as performance of dilated retinal screening using imaging (digital / colour films) or by direct / indirect ophthalmoscopy by a trained / skilled eye care professional (preferably an ophthalmologist / retinologist) to identify the signs of DR.

Type of outcome measures

We defined access as all level of factors affecting the processes of DRS in a health care facility.

Phenomena of interest

We included the studies which have assessed barriers or enablers to access DRS by PwDM and challenges or incentives faced by providers in provision of screening services in current screening programs or at opportunistic screening.

Search method for the identification of studies

We searched Ovid MEDLINE, Embase and CENTRAL in the Cochrane Library from the databases inception up to 15th December 2018. The search strategy was developed by an information specialist from Cochrane Eyes and Vision (IG) (search terms available in S2 Table 2 in Appendix 5). We did not use any filtering methods to limit the results by study design, year of publication or language. This yielded a comprehensive coverage of published articles. However due to resource restraints we were not able to translate any non-English reports.

Data collection and analysis

Two reviewers (MMPNP and SK) independently assessed the eligibility of inclusion by going through titles and abstracts of 16,388 articles after, importing them to an EndNote® library. The potential articles (full papers as identified by either or both reviewers) were retrieved from publishers. These papers were then assessed independently by the two reviewers (MMPNP and SK). Disagreements between the reviewers were resolved by a 3rd arbitrary reviewer (GVSM). Reviewers assessed full papers independently to retrieve accurate data. We aimed to include all relevant studies from different

income settings to avoid bias in selecting articles. Therefore, we were able to extract a range of barrier themes with a greater variation and a greater conceptual diversity.

Data extraction and management

We developed an MS Office Excel® data sheet to directly transfer extracted data from full articles. The topics to be extracted were developed according the "Strengthening the Reporting of Observational Studies in Epidemiology" (STROBE) statement and modelling has been done according to the review question [32]. The accuracy of extracted data was cross-checked by a third reviewer (SH).

We extracted information on first author's name, year of publication, country of study (by income category), place of the study, sample size, gender distribution, mean age, method of diagnosing DM, level of DM and DR of the participants and method of DRS in the 1st set of data. In the next step we collected information on type of study design, objective, study setting, data sources, sampling strategy and time period when study was conducted. The methodological quality assessment and applicability for review question were done separately as subsequently described. We extracted the results and main outcomes of each study according to the review question.

In the synthesis of evidence "informants" were authors of the individual studies rather than the participants. The authors' interpretations were presented as narrative themes supported by numerical values of statistical significance levels wherever available.

While authors' interpretations were primarily collected from the results section of each paper, sometimes interpretations were also found in the discussion section. These were also extracted when relevant and if adequately supported by data. Finally, we tabulated the results by level of income of the country according to the World Bank 2016 classification.

Assessment of risk of bias in included articles

We carried out the risk of bias and quality assessment according to the guidelines of critical appraisal of skills program (CASP) tools for case-control, qualitative, cohort and randomised controlled study designs [33] and National Institute of Health, United States quality assessment tool (NIH-QAT) for observational cohort and cross sectional study designs [34]. Two reviewers (SH and MMPNP) independently applied the set of quality criteria to each included study. We appraised how well the individual studies which contributed to narrative synthesis, were conducted using the above tools. Emphasis was given more to the applicability of the study according to the inclusion criteria. It has been noted that applicability to the review question was the main concern in the synthesis rather than the overall level of quality of a study (S3 Table - Appendix 5).

Assessment of methodological limitations

When several studies with varied methodological limitations contributed to a finding, we made an overall judgement about the distribution of strengths and weaknesses of the study rather than for individual components in the tools.

Assessing coherence

We assessed the coherence of each review finding by looking at extent to which we could identify a clear pattern across the data contributed by each of the individual studies. This was supported by when clarity of the themes was consistent across different contexts and the variations were explained by the study authors according to the data collected, when supported by numerical data (odds ratios). This was further strengthened when findings were drawn from different settings.

Data synthesis

Most of the eligible studies were observational and descriptive in nature hence narrative reporting approach was used to generate new insights. We analysed and synthesised the descriptive and qualitative

data narratively supported by other associated variables with levels of statistical significance. We described the barriers and enablers according to the dimensions of the typology of barriers and this in turn was tied with processes involved in DRS. We followed a content analysis, by developing themes a priori and tabulation and frequency counting to identify the major themes. We considered consumer, provider and system factors as the major constructs according to the social cognitive theory. Themes were presented graphically using harvest plots. When describing the themes, we did not re-phrase the original findings or conclusions mentioned by authors. We used imputations up to a certain degree in describing enabler themes.

Considering the participants of the studies, the themes that emerged were divided in to three categories complying with the objectives of the systematic reviews. These categories were consumer perspectives, provider perspectives and system factors. We assumed that this type of decomposition will be helpful to commission to inform strategies for development of a successful program and enhance the policy relevance and applications.

Results

Results of the search

Search and study selection procedures are summarized in the PRISMA flow diagram (Figure 1). The database search identified a total of 16,388 records. Duplicate records were removed, and we assessed 16,331 titles and abstracts for potential inclusion in the review. We excluded 16,204 records based on the information given in the title and abstract. After assessing the full text of 127 reports of studies, we excluded 50 studies which did not meet the inclusion criteria and included a total of 77 studies in the review.

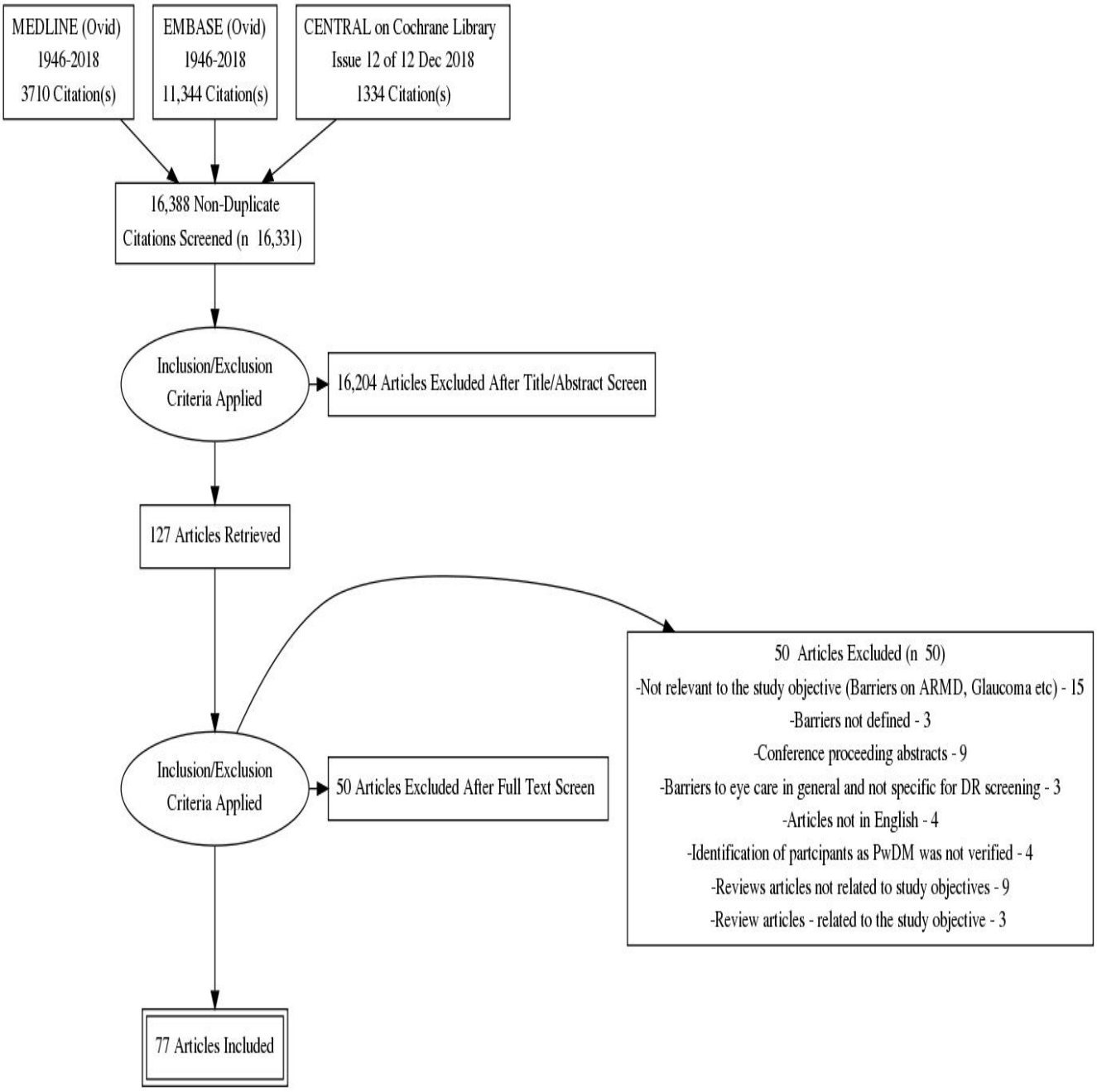

Figure 1. PRISMA Flow chart

Overview of the included studies

We identified a total of 16,331 titles and abstracts and considered 127 full text papers for inclusion in this review and data were extracted from 127 full reports. Seventy-seven (77/127, 60.6%) studies were eligible for inclusion in the narrative review according to the objectives. The S4 Table in Appendix 5 file contains the details of participants and settings.

Included studies

This analysis mainly comprised of cross-sectional observational studies. In the included 77 studies, there were 59 (59/77, 76.6%) cross sectional observational studies (observational 33, retrospective studies 8, postal surveys 1, telephone interview 2, 1 mixed method audit and 14 population-based studies (14/77, 18.1%)). Other study designs were 3 controlled trials (3/77, 3.9%),1 case control study (1/77, 1.3%), 4 cohort studies (4/77, 5.2%) and 8 qualitative studies (8/77, 10.4%). There were also 2 reviews (2/77, 2.6%) in the included studies.

Methodological quality of the studies

The methodological quality assessments of included studies are presented in S3 Tables 1 to 5 in Appendix 5 according to the study design. In the included cross-sectional studies, 96% (57/59) of the studies clearly stated study objective matching the review question. Sample size justification was not available in 51% (30/59) of the studies. Participation of eligible persons i.e., facility based diagnosed PwDM, at least 50% was not seen in seven (7/59, 12%) studies and eight studies (8/59, 13%) did not report on this aspect. Four of the studies (4/59, 7%) had not recruited the participants from a similar population. The outcome measures were not clearly defined in 14 studies (14/59, 24%) and confounders were not adjusted in eleven studies (11/59, 19%).

An acceptable method of recruitment of the cohort was not followed in all four of the included cohort studies. In included randomised controlled study designs, applicability of the results to the PwDM was not observed in two studies (2/3, 66%). In qualitative study designs, most of the quality assessment criteria were met except, relationship between researcher and the participants were not adequately considered in two studies (2/8, 25%) and in one study (1/8, 12.5%) recruitment strategy was inappropriate; i.e., those who had worse vision (no perception to light in any eye) had been excluded from the qualitative interviews. There was one case-control design with appropriate methodology.

Study populations/groups

All the studies main group of respondents were PwDM. Some authors have sought barrier perspectives form providers as well. Fifty-four studies (70.1%, 54/77) described barriers related to consumers, providers and eye care system, 3 studies on consumers and system (3.9%, 3/77), 2 studies on provider and system (2.6%, 2/77) and 12 studies on consumer and provider (15.6%, 12/77). Only 5 studies (6.5%, 5/77) described barriers of consumers only and one study has focused only on providers (1.3%, 1/77). In these 77 studies, two studies reported the outcome as a review [35,36].

Study Settings-by income

Only three (4.8%, 3/63) studies were from low income countries (LIC) (Sub-Saharan Africa (as a review), Tanzania and Nepal) [35,37,38]. Eleven were from lower middle income countries (LMIC) (14.2%, 11/77) (Indonesia, India, Yemen, Kenya, Myanmar, Nigeria and Bangladesh) [39–49], seven from upper middle income countries (UMIC) (9.1%, 7/77) (Turkey, Iran, Mediterranean countries and China) [50–56] and 56 from HICs (72.7%, 56/77); (17/77 - 22.1% from United Kingdom, 20/77 - 25.9% from United States, Other 40/77 - 51.9% - Germany, France, Ireland, Singapore, Canada, Oman, Hong Kong, South Korea, Australia, Taiwan, Italy and Netherland) [21,57–111].

Setting-by type of institution

Most of the data collections were done under the primary level general practices, local clinics, rural outreach clinics and primary care clinics (20/77, 25.9%) [44,48,49,59,60,63,66,67,69,71,85,89,92,93, 95,102,105,106,109,110]. There were 14 population-based studies (14/77, 18.1%) [45, 54, 55, 61,62, 75,76,79,81,88,90,91,98,100]. Eleven studies were conducted at tertiary level institutions (11/77, 14.3% - 8 eye clinics, 1 diabetic clinic, 1 general medical clinic and 1 endocrinology clinic) [37–39, 41,46,47,50,53,99,111,112]. Seven studies were conducted in existing DRS programs (7/77, 9.1%) [64,86,87,96,97,103,107]. Nine studies were conducted at secondary level medical and diabetes clinics (9/77, 12.7%) [43,51,68,70,74,84,104,108,113].

Five studies were conducted by analysing existing data bases (5/77, 6.5%) [72,77,78,80,83]. There was one study where authors did not mention about the setting, however we could assume it was at an ophthalmologist clinic through an insurance scheme [73] and two studies reported the barriers as a review [35,36]. Two studies collected the sample of PwDM at a screening camp and at an annual campaign.[40,101]. One study was conducted in a an ambulatory clinic based at a nursing home [57]. Three studies conducted at eye clinics (3/77, 3.9%; 2 at general eye clinic [42,94] and 1 optometry practice [82]. One study conducted using at a model of not for profit health model [65]. A study exclusively on providers' perspectives recruited stakeholders at national level [56].

Synthesis

Our main objective was to identify barriers or enablers to access DRS. Our findings are summarised in the S5 and S6 Tables in Appendix 5 files according to the country income.

Narrative summary - Barriers

The following main themes were derived from descriptive and qualitative studies (S5 Table 1 to 4 in Appendix 5).

Low income countries

The most prominent barriers to access DRS among the consumers in LIC were lack of knowledge on DM eye complications, lack of awareness about importance of eye examination and lack of knowledge about availability of eye clinics. Among providers, main challenges were lack of skilled human resources and lack of access to DR imaging and treatment infrastructure. Further, non-existence of a referral system and lack of multi-disciplinary care approach were barriers to provision of DRS services. In LIC, lack of a national policy and competing disease priority environments were the main obstacles in the system (S5 Table 1).

Lower middle-income countries

Consumers' barriers related to knowledge and awareness could be observed in the LMIC as well. This was associated with poor general education and low functional health literacy. Most of the studies found that health beliefs such as no need of screening at asymptomatic stage, misconceptions on DR and unawareness of the need for regular screening affected the attitude of uptake of services. In addition, studies with PwDM reported that lack of time and lack of family support hindered access. Additionally, financial barriers and disabilities emerged as themes of barriers.

In providers perspectives lack of DM health education and financial constraints were the main barriers. Lack of human resources, uneven distribution of skilled personnel, lack of availability of equipment i.e., imaging technology, DRS related consumables such as pupil dilating drops and treatment facilities were observed as main service provider barriers. Some studies reported that lack of knowledge and awareness on DR among the physicians, lack of skills in identifying DR as well. In addition, low referral rates and time constraints in busy eye clinics were the main challenges faced by providers in LMICs in provision of DRS services. In system analysis lack of training, lack of accessible eye centres, poor public transportation systems and lack of epidemiological studies were emerged as main barriers (S5 Table 2).

Upper middle-income countries

The lack of awareness and knowledge on DR emerged as the main barrier among the PwDM in UMIC. This was associated with low literary and poor educational levels in UMIC as well. Poor physician-patient communication was also a barrier in these countries. In provider perspectives scarce human resources, lack of training, high number of PwDM were the main challenges faced. In addition, poor provider awareness on screening guidelines and lack of imaging technology hindered provision of services. In the system analysis limitations in prevention and health promotion, poor usage of prevalence data, lack of information systems, lack of auditing systems, civil unrest, disparity in urban and rural services, lack of transportation and problems in insurance schemes were the main barriers to accessing DRS services (S5 Table 3).

High income countries

In HIC living alone, problems in mobility, multiple comorbidities, negative self-perceptions, problems in accessing general practitioner, effects of mydriasis prohibiting driving, reluctance to change behaviour, disliking the method of examination, change of residence, problems in securing appointments, being employed, extended vacations were observed as the main barriers among the consumers. In some HIC, lack of knowledge regarding eye examination, lack of knowledge on need of screening during asymptomatic stage, misconceptions, lack of awareness of eye care, lack of flexibility in adjusting attitude and behaviour and lack of understanding of rationale and importance of annual eye examination were observed as barriers to access DRS services. Even in the HIC socio-economic inequalities, poor communication skills, social deprivation and poorer literacy were barriers to access DRS services among some communities.

In the providers perspectives; level of experience of the screener, lack of attention by the general practitioners, non-adherence to guidelines, lack of information provided to patients, lack of physician recommendations, lack of coordination between general practitioners and screeners, limited knowledge on DR among the health professionals, long waiting time (large number of patients per doctor), failure to refer by general practitioner, perceptions of side effects of mydriasis, limited knowledge-attitude and practice of physicians, limited experience in using ophthalmoscope, long waiting time for treatment, lack of communication between screening services and practices were mentioned as barriers. Providers mentioned that problems associated with consumers such as confused and immobile patients, unawareness of importance of mydriasis, poor physician-patient communication, different perceptions in making appointments, after effects of mydriasis, fear of laser, and wrong assumption on patient's level of knowledge could hinder to access DRS services.

In HIC system analysis lack of understanding among the specialities, frequent change of staff, lack of human resources, unavailability of medical records, lack of adequately trained optometrists, lack of proper referral and reminding system, lack of insurance coverage, financial barriers, unavailability of national programs, problems in transportation and lack of screening programs in remote areas were barriers to access or provision of DRS. The studies reported that among system factors, integration of

screening to the general health systems, governance, quality and safety should be considered in conducting screening programs (S5 Table 4).

Overall barriers themes using harvest plots

Considering the number of times a theme appeared irrespective of the country income level; lack of knowledge (19/77 studies, 25%), lack of awareness (15/77, 20%), low educational attainment and poor literacy (16/77, 21%), asymptomatic nature of DR (16/77, 21%), financial barriers (31/77, 40%) and time and priority issues (12/77, 16%) emerged as the major themes at consumer level. Similarly, at the provider level accessibility issues related with appointments (23/77, 30%), lack of human resources (10/77, 13%), lack of knowledge and awareness among the providers (11/77, 14%), lack of screening infrastructure (11/77, 14%), cost of services (11/77, 14%) and deficiencies in educating the users (21/77, 27%) reported as major barriers (Figure 2 and Figure 4).

Narrative summary - Enablers

Themes of enablers are summarised in the S5 Tables 1 to 4 in Appendix 5 files according to the country income category.

Low income countries

In LIC settings consumers' knowledge on DR, having a family member with DM and prior fundus examination were enablers to attend DRS. Provision of imaging and treatment infrastructure, increased human resources, provision of training on retinal care and prioritisation of development of subspecialties were mentioned as enablers for the providers (S5 Table 1).

Lower middle-income countries

The enablers for uptake of services by the consumers were presence of symptoms, more severe DM and comorbidities, better understanding of risk factors and detrimental effects, patient satisfaction over the modality of screening and presence of visual impairment / blindness. Training of non-

ophthalmologist physicians on DRS, availability of fundus camera, educational strategies aimed at both patients and physicians, reminders of the serious consequences of failure to undergo DRS, availability of written communication when referring for screening and public health education using media were emerged as enablers to improve uptake of DRS services in LMIC (S5 Table2).

Upper middle-income countries

Higher literacy, person's concern about the vision loss, severe DR stage and having knowledge on DR were the main enablers for users of DRS services uptake. In UMIC awareness among the physicians DM complications, availability of referral guidelines, availability of continuous medical education programs, training of human resources, involvement of community groups and community-based health education were enablers to improve DRS services by provider side (S5 Table 3).

High income countries

The main enablers for screening uptake in HICs were awareness of eye care and possibility of treating DR, positive reinforcement through negative screening results, worrying about vision loss, attending DM education classes, discussion of DM complications with health care professionals, trust on provider, having health insurance with eye care services coverage, higher level of education and being obliged to attend for screening. Adherence to the best practice guidelines by the consumers and having eyes examined by primary care physicians were enablers.

In HIC availability of educational interventions, DM education programs, adherence to guidelines, targeted screening of high-risk groups, reinforcing the importance of eye examination by health care providers, constant screening location, personalised strategies on follow up (phone calls and door to door visits), on-line patient access booking system, recall system, showing fundus photograph and teaching patients, ability to change appointments were incentives for uptake of DRS services. The studies conducted in remote areas reported that mobile tele-screening models it-self was an enabler to improve access (S5 Table 4).

Overall enabler themes using harvest plots

Considering the number of times, a theme appeared irrespective of the country income level; presence of symptoms (15/77, 19%), presence of DR or other eye diseases (15/77, 19%), higher level of education (12/77, 15%), better attitude (12/77, 15%) and high income (10/77, 13%) were the main enablers for the PwDM. In providers perspective having health education on regular eye examination (46/77, 60%) and factors convenient for the users (31/77, 40%) were main enablers (Figure 3 and Figure 5).

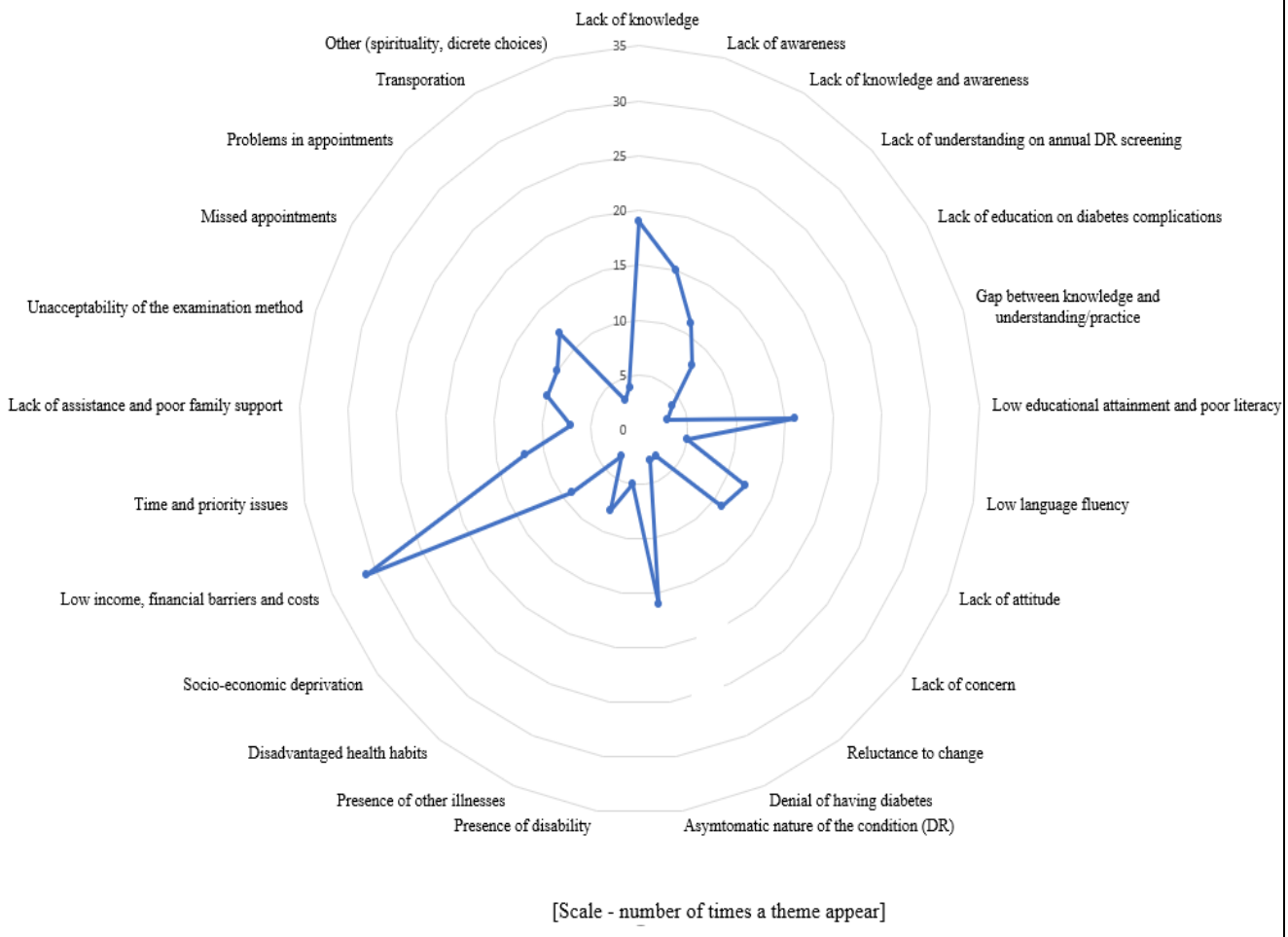

Figure 2. Harvest plot showing user barriers

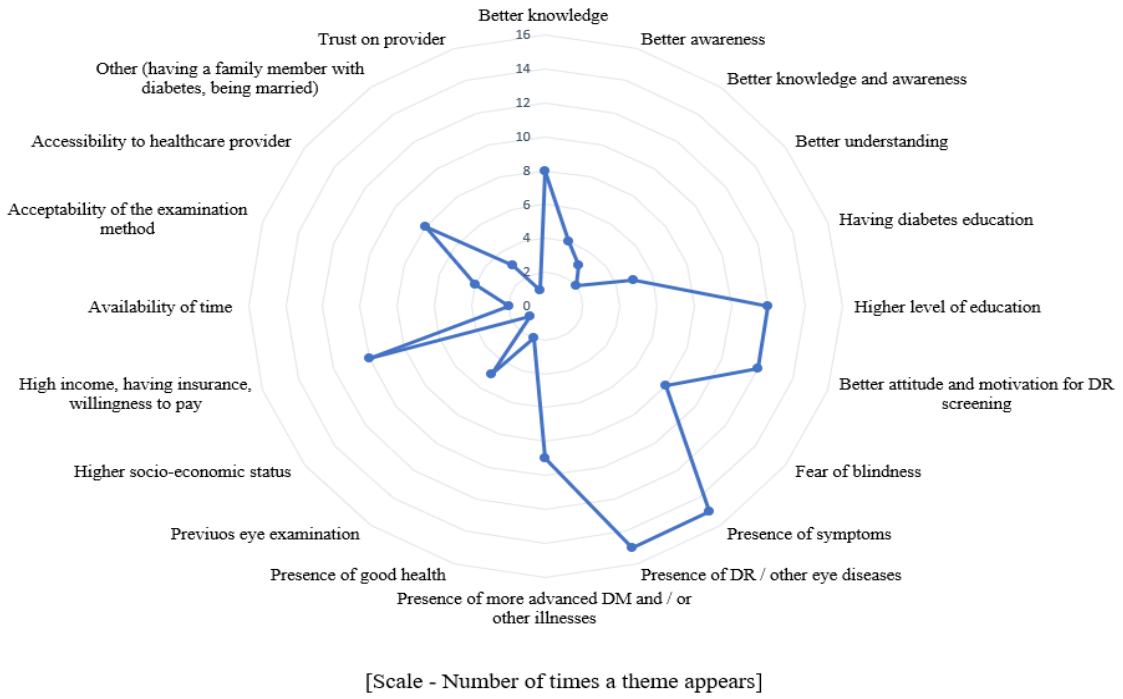

Figure 3. Harvest plot showing user enablers

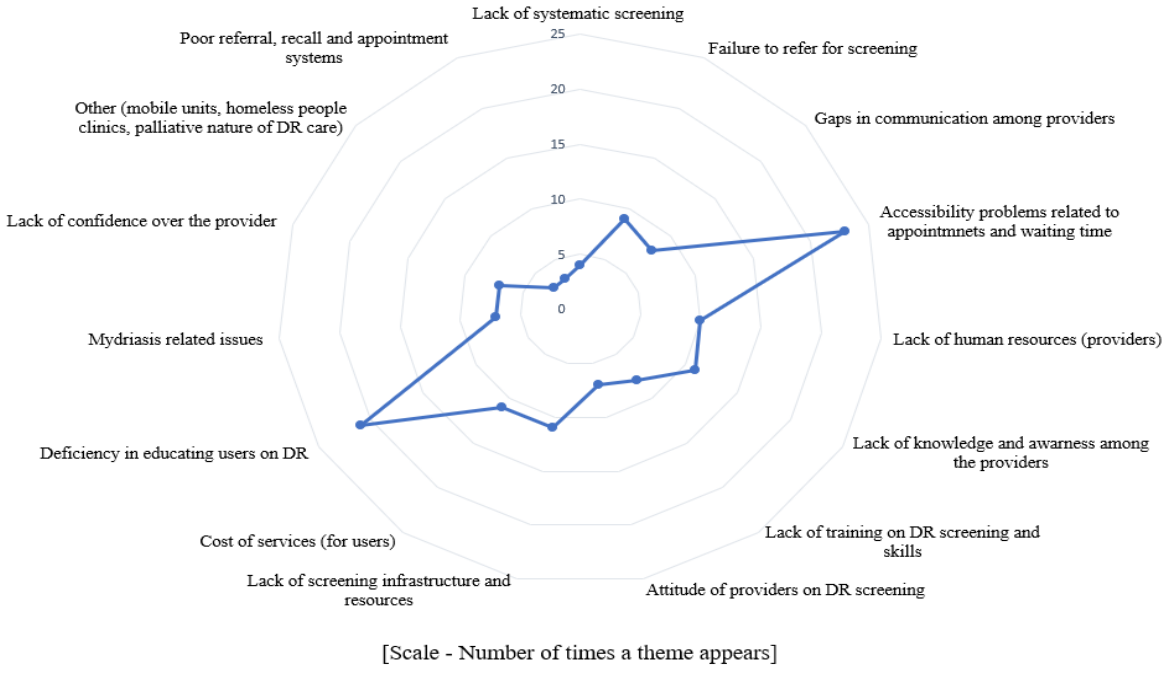

Figure 4. Harvest plot showing provider barriers

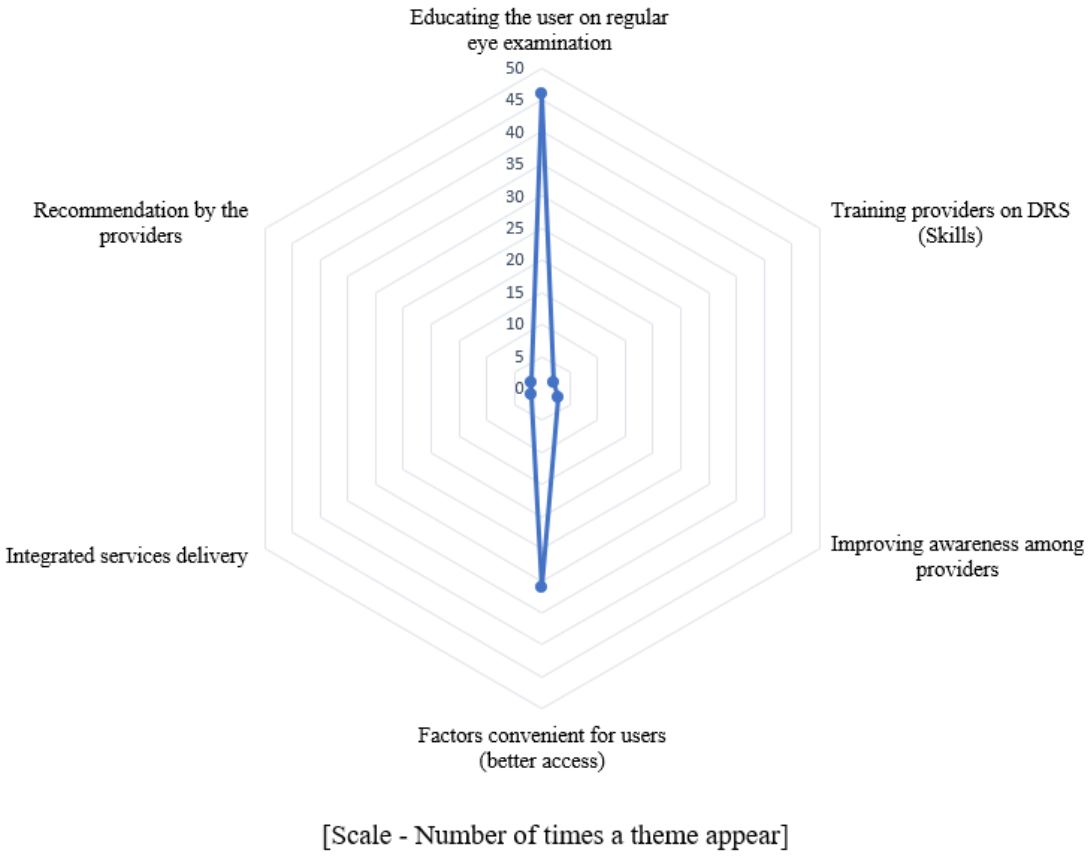

Figure 5. Harvest plot showing providers enablers

Quantitative Data Synthesis

The data extracted for quantitative synthesis are available as supporting information S5 Table file in Appendix 5.

Knowledge and Awareness

The main barriers identified in this systemic review were factors associated with consumers. The most consistent barrier across most of the studies was knowledge regarding DR. One study mentioned that knowledge (mean knowledge score 4.7 among those who had examination vs 3.6 without examination ($p<0.001$) and awareness about DR was associated with seeking screening services (odds ratio (OR) 1.52, 95%CI 1.1-2.1, p=0.01) [39]. This concept was further emphasised in a randomised controlled

trial conducted to evaluate the effectiveness of a health educational intervention, where the intervention arm participants had higher odds of eye examination status (OR 4.3, 95% CI 2.4-7.8) [68]. A study from China showed that having a higher DR knowledge score was a potential predictor for ever had an eye examination. (OR 1.31, 95% CI 1.1-1.5, P<0.001) [53]. Similarly, a study conducted in Bangladesh reported that awareness of DM (OR 8.47, 95% CI 3.95-18.18) and DR (OR 5.15, 95% CI 1.89-14.01) were associated with improved uptake of DRS services [48].

In a study conducted to enhance the compliance with DRS recommendations, it was seen that when PwDM were given educational material and a notification there was a significant difference in screening uptake (OR 1.4, McNemars X^2=102.7; P < 0.0001) [114]. A study conducted in Tanzania showed that those who had knowledge on damages to eye due to DM had higher odds of undergoing dilated fundus examination in the past year (OR 19.7, 95% CI 7.0-55.2) [38].

Even the knowledge on DM alone was associated with uptake of DRS. A study mentioned that less practical knowledge about DM (OR 1.5, 95% CI 1.2-2.1) was a factor associated with non-adherence [88]. A similar finding was reported in the study conducted by Srinivas et al., (2017) in India, which shows good knowledge of DM was associated with good practice of DR (OR 3.95, 95% CI 1.97-7.94 p<0.01) [41]. On the other hand another study mentioned that knowledge on effects of DR on vision was an incentive for uptake of DRS (OR 3.3, 95% CI 2.0-5.5) [93]. It was seen that awareness on possibility of treating DR was an incentive for attending screening (OR 1.6, 95% CI 0.9-3.0) [93]. In contrast, a study conducted in Nigeria showed that associations between knowledge, attitude and practice and authors concluded that there was no significant correlation between knowledge and practice (correlation coefficient r=0.086, p=0.385) [47].

Factors associated with awareness

Most of these studies had analysed the various patient characteristics and disease factors associated with awareness. Lack of awareness was associated with older age (OR 10.4, p=0.03), poorly controlled HbA1c (OR 4.9, p<0.001) and male gender (OR 1.2, 95% CI 0.7-1.8, p=0.47) [61]. Huang et al., (2013) showed that unawareness was associated with lower education (primary or less, adjusted

OR 1.9, 95% CI 1.4-2.5, p<0.0001), lower income (Singapore $ <2000, adjusted OR 1.7, 95% CI 1.2-2.5, p=0.003) and poorer literacy (unable to write - adjusted OR 1.4, 95% CI 1.0-2.0, p=0.03) [115]. Katibeh et al., (2017) also showed that a good level of awareness on DR was associated with secondary or higher education (OR 1.88, 95% CI 1.23-2.88, p=0.004) [55]. Thapa et al., (2012) mentioned that literate patients are more likely to have awareness on DR (OR 2.7, 95% CI 1.3-5.6, p=0.006) [37]. One study showed that higher awareness on DR was seen among the more educated people (OR 1.8, 95% CI 0. 9-3.4, p=0.0000) [54]. Those who have a history of prior fundus evaluation elsewhere (other than retinal clinics in this study) had higher odds of having awareness on DR (OR 11.9, 95% CI 5.7-25.2) p<0.001) [37].

Attitude

It was also reported that PwDM themselves may not have the judgemental ability over seeking care and recommendation by the provider would improve access (OR 341, 95%CI 164-715, proportion of attendees 99.4% vs non-attendees 34.5%) [93]. In health seeking behaviour, those who thought eye examinations were needed every 6 months (OR 1.2, 95% CI 1.1-1.4) and those who worry much regarding their vision (following telephone call intervention, OR 3.47, 95% CI 1.8-6.8) showed higher odds of DRS uptake [108,116]. A study showed that perception of a PwDM should have eye examination every 12 months (OR 2.62, 95% CI 1.7-4.1, p<0.0001) was associated with previous dilated eye examination [71]. Another study showed that fear among patients on impaired vision was an incentive for DRS (OR 1.9, 95% CI 1.5-2.5) [93]. Lian et al., (2018) reported that those who worry more about vision loss were highly likely to attend screening (OR=1.72, 95% CI 1.31-22.26, p<0.001) [105].

Secondary outcomes of quantitative data - Factors associated with uptake of screening / adherence / regular follow up

Service user costs

One major factor associated with undergoing DRS was having an insurance scheme. This was observed mainly in the paid systems, when services are delivered at a user fee and health services were not available free of charge. Having an insurance coverage either national or private, depending on the

context, was associated with compliance for annual eye examination (National health insurance, OR 2.2, 95% CI 1.2-4.3 p=0.02) [89], increased eye screening (private health insurance, OR 3.2, 95% CI 2.2-4.7, p=0.00) [62] and higher chance of undergoing screening (health insurance - type not specified, adjusted OR 1.7, 95% CI 1.4-2.2) [78]. It is shown that those who have vision loss (blindness) are 100% willing to pay for the services (mean amount willing to pay-No DR - Taiwan dollars (NTD) 468.9 ± 327.7 vs Blindness NTD 822.2 ± 192.2, p=0.0005) [91].

One randomised controlled trial showed that PwDM are less likely to undergo DRS when a co-payment is applied compared to the free services (OR 0.6, 95% CI 0.5-0.7) [67]. Those who had no health insurance (OR 2.5, 95% CI 1.7-3.7) were less likely to be compliant with screening [81]. Sheppler et al., (2014) mentioned that those who had an insurance coverage complied more with annual eye examination (OR 2.2, 95% CI 1.1-4.3, p =0.02) [89]. Lian et al., (2013) showed that being in the pay groups was negatively associated with uptake of screening (OR 0.6, 95% CI 0.5-0.7) following random allocation of PwDM to screen for DR at a user fee (US $ 8) or for free [67]. The study done by Moss et al., (1995) showed that having a health insurance with eye examination covered (OR 3.3, 95% CI 2.2-5.1, p<0.0001) was associated with previous dilated eye examination [71].

Family income

Two studies found that a higher family income was associated with having had a dilated eye examination (US $ >50,000 vs US $ <40,000, OR 1.9, 95% CI 1.3-2.9 [90] and US $ >35,000, OR 1.3, 95%CI 0.8-2.2) [98]. The study done by Paskin-Hall et al., (2013) showed that those who have a higher income ($35,000-$49,000 adjusted OR 1.3, 95% CI 1.1-1.5) had higher odds of undergoing DRS [78]. Another study done in South Korea by Rim et al., (2013) showed that those who were in the highest monthly income quintile (OR 1.4, 95% CI 1.1-1.8, p<0.01) had higher odds of undergoing screening [83].

Gender

The odds of having had a dilated fundoscopy in the past year was high among women (OR 1.2, 95% CI 0.9-1.5) [90] and past eye care use decreased by being male (OR 0.5, 95% CI 0.3-0.8, p<0.01)

[79]. However a study done in UK showed males had higher odds of attending screening following invitation (OR 1.4, 95% CI 1.1-1.7) [111]. Therefore, role of gender with regard to uptake of DRS could be context specific.

Age

The PwDM > 70 years of age showed higher odds of having undergone dilated fundoscopy compared with those <40 years of age (OR 1.9, 95% CI 1.5-2.6) [90]. Most of the studies showed that older PwDM had higher odds of undergoing screening (age >65 years, OR 2.6, 95% CI 1.6-4.1)[98], (OR 1.02, p<0.001) [72].

It was observed that eye care services utilization with in a 12 month period, was lower in those who are younger (age 20-39 years, OR 0.1, 95% CI 0.01-0.70 p<0.05) [79]. Similarly, a study done in UK showed that younger age was associated with non-attendance (18-34 years, adjusted OR 1.4, 95% CI 1.1-1.7, 35-44 years, OR 1.4, 95% CI 1.2-1.7) [111].

Level of education

Most of the studies mentioned the association between level of education and DRS uptake. For PwDM having more than high school education vs less than ninth grade education (OR 1.5, 95% CI 1.0-2.1) was associated with higher likelihood of having a dilated eye examination [90]. The reasons for non-adherence mentioned in another study was education less than high school (OR 1.5, 95% CI 1.1-2.1) [81]. It was observed that the odds of past eye care use dropped with the decrease in number of years of educational attainment (<10 years, OR 0.4, 95% CI 0.2-0.9, p<0.05) [79].

In addition, education up to high school or more was a predictor of knowledge that uncontrolled diabetes could cause eye disease (OR 2.4, 95%CI 1.5-4.0, P<0.05) [73]. Xiong et al., (2015) also showed that higher awareness of DR was seen among the more educated people (OR 1.8, 95% CI 0. 98-3.44, p=0.0000) [54]. Islam et al., (2018) reported that having secondary or higher education was associated with improved DRS uptake (OR 11.8 (95% CI 4.02-34.7) [48].

Disease factors associated with uptake of screening

Higher level of glycosylated haemoglobin was associated with non-compliance with screening (>9%, OR 1.7, 95% CI 1.1-2.6) [81].

Diabetes / Eye care education

One study mentioned that those without DM education (OR 0.4, 95%CI 0.2-0.6) are less likely to undergo screening [50]. Hwang et al., (2015) in Canada showed that increased eye screening was associated with health professional discussing DM complications with PwDM (OR 2.0, 95% CI 1.3-3.2, p=0.00) [62]. Persons having attended a DM education class (OR 1.5, 95% CI 1.2-1.9) had higher likelihood of having a dilated eye examination [90].

A study done in USA showed that eye care education (OR 1.6, 95% CI 1.2-2.1) was associated with receipt of dilated eye examination [98]. No formal DM education (OR 1.3, 95% CI 1.1-1.6) and less practical knowledge on DM (OR 1.6, 95% CI 1.2-2.1) were associated with non-adherence [88]. Those who had attended a DM education class had higher odds of having a dilated eye examination in the past year (OR 1.5, 95% CI 1.2-1.9) [90]. It is shown that when there has not been any education on DM, patients are less likely to visit an ophthalmologist on a regular basis (OR 0.39, 95% CI 0.24-0.65) [50].

Personnel who conducted the last eye examination

The described reasons for non-adherence to DRS included, the type of personnel that conducted the last eye examination. It is shown that non-adherence was high when last examination had been conducted by non-ophthalmologist personnel (OR 4.3, 95% CI 2.3-6.2) [88].

Duration of diabetes

The duration of DM was a predictor of having DR. Those who have had DM for a shorter duration (<5 years, OR 0.04, 95% CI 0.01-0.10) were less likely to be having DR [42]. One study mentioned that PwDM who were <5 years (OR 0.4, 95% CI 0.3-0.8) of duration after diagnosis are less likely to undergo screening [50].

Hwang et al., (2015) in Canada showed that duration of DM longer than 10 years (OR 1.5, 95% CI 1.04-2.25, p=0.03)] was associated with increased eye screening [62]. Similarly Saadine et al., (2008) mentioned that when the DM duration was longer (>15 years , OR 1.9, 95%CI 1.4-2.6, p<0.0001) those PwDM were more likely to attend follow up [84].

A factor positively correlating with eye care use was, time since diagnosis of DM (20 years, OR 2.7, 95% CI 1.2-5.9, p=0.041) [79]. In contrast to other studies one research showed that when the duration of DM goes up, the likelihood of not attending screening also increases (5 to 9 years, OR 1.9, 95% CI 1.6-2.2), (>20 years , OR 3.4, 95% CI 2.7-4.2) [111].

Type of diabetes treatment

Eye care use by PwDM was higher when the treatment is with oral antidiabetics and insulin (OR 2.8, 95% CI 1.1-7.4, p=0.161) [79].

Regularity of clinic visits

It was observed that the odds of using eye care in the past year decreased with those who are in the younger age categories (age 20-39 years, OR 0.09, 95% CI 0.01-0.70, p<0.05), and having lesser number of years in educational attainment (<10 years, OR 0.37, 95% CI 0.16-0.88, p<0.05) [79]. Further noncompliance was associated with those who had no routine physical examination > 1 year ago (OR 1.8, 95% CI 1.3-2.5) [81].

Mukamel et al., (2016) showed that patients who visit their primary care physicians more often (OR 1.3, 0.001<p<0.01) had higher probability of attending screening in the past 12 month period [72].

Marital status

It was observed that past eye care use as being lower in those who were never married (OR 0.14, 95% CI 0.03-0.76, p<0.05) [79].

Unemployment

Unemployment was inversely associated with eye care use (OR 0.5, 95% CI 0.2-1.1, p=0.091) [79].

Alcohol intake

Heavy alcohol consumption was inversely associated with eye care use (OR 0.3, 95% CI 0.1-0.7, p=0.003) [79].

Having other complications of diabetes

Factors inversely associated with eye care use was having diabetic foot disease (OR 0.4, 95% CI 0.2-0.9, p=0.35) [79]. In contrast a study conducted by Bennet et al., (2018) found that having non-ocular complications of DM increased DRS attendance (OR 2.7, 95% CI 1.1 to 6.4) [99].

Physician recommendation

Physician recommendation is a predictor of having regular eye examinations as mentioned in one study done in Ireland (OR 1.3, 95% CI 1.1-1.6) [108]. Van-EijK et al., (2011) showed that recommendation by the care provider was a strong incentive for undergoing DRS (OR 341, 95% CI 164-715) [93]. A similar association has been mentioned by the Wang et al., (2010) (OR 2.2, 95% CI 1.5-3.3, P<0.001) [53]. Being referred for eye examination was a strong predictor of high uptake in a study conducted in Kenya (OR 20.5, 95% CI 10.2–40.9, p < 0.001) [49].

Having other eye diseases and visual impairment

Those who have other eye diseases (OR 1.2, 95% CI 1.1-1.6) and those who think that eye examinations are needed every 6 months (OR 1.2, 95% CI 1.1-1.4) showed higher odds of DRS uptake [108]. Study by Moss et al., (1995) showed that history of cataract (OR 2.9, 95%CI 1.9-4.4, p<0.0001) was associated with previous dilated eye examination [71]. Hwang et al., (2015) in Canada showed that increased eye screening was associated with having visual impairment (OR 2.6, 95% CI 1.7-3.9, p=0.00) [62].

Social deprivation

Even in HIC people living in deprived areas failed to attend DRS (OR 2.3, 95% CI 1.9-2.8) [66]. One study stated that people living in most deprived areas (OR 1.2, 95% CI 1.2-1.3) were more likely to

not adhere with screening recommendations [77]. A study done in UK showed the factors associated with non-attendance following an invitation for screening in a sample of 31,484 diabetics in a DRS program. In this study social deprivation (adjusted OR 1.4, 95% CI 1.2-1.6, p<0.001) was associated with non-attendance [111].

Another study done in South Korea by Rim et al., (2013) showed that those who lived in urban areas (OR 1.5, 95% 1.2-1.8, p<0.01) and those in the highest monthly income quintile (OR 1.4, 95% CI 1.1-1.8, p<0.01) had higher odds of undergoing screening [83]. Scanlon et al., (2008) mentioned that with each increasing quintile of socioeconomic deprivation the probability of having been screened for DR decreased (OR 1.1, 95%CI 1.1-1.2, P<0.001) [85].

Risk of development of DR among non-attendees

The relative risk of having DR was higher in non-attendees for screening, as shown in one study conducted in Yemen (Relative risk of having DR 1.5, 95% CI 1.2-2.2), (bilateral blindness 4.0 , 95% CI 1.4-11.6) (low vision disability 2.4, 95% CI 1.8-3.5) [42]. Saadine et al., (2008) mentioned that those who have moderate or worse retinopathy (OR 2.2, 95%CI 1.6-2.9, p<0.0001) were more likely to attend follow ups [84].

Discussion

We assessed the barriers and enablers to access and provision of DRS services in various country level income settings. This is the first systematic review to explore consumer, provider and health system barriers / enablers, and to understand these in the context of country income level. Knowing the barriers / enablers by country income setting is useful to identify and streamline interventions for the impeders in advance. Though the potential benefits to PwDM are widely known, attendance is at a sub-optimal level in DRS programs even in HIC settings [117]. DRS has been shown to be cost effective in terms of sight years preserved [118]. In most parts of the world DRS remains non-systematic. The findings from this narrative review will be useful to emphasise the barriers faced by consumers

and providers in a DRS program. This will be helpful to explore the avenues for successful implementation of a DRS program in a country and how to conduct a program conveniently for both users and providers. We assumed that identification of secondary factors associated with uptake will be useful in efficiently continuing the programs and to identify the risk groups in advance.

We identified that knowledge and awareness among PwDM as the main barrier to access in all income settings. A recent review has also emphasised that lack of knowledge and awareness among PwDM as a major barrier to improve uptake [30]. Under the knowledge theme we identified many subthemes that would be useful for development of health educational interventions. Few such subthemes are asymptomatic nature of DR and knowledge on frequency of DRS. This aspect has been described in a recent review as behavioural economics to improve access [119]. Therefore, we could assume that health educational interventions may improve uptake of services. However, the uptake of DRS services can be affected by various socio-economic factors as well, as observed in the review outcomes.

In our review, we identified that in the HIC most of the barriers to access were related to processes of DRS while in LIC and LMIC they were related to major system factors such as unavailability of services, lack of human resources and infrastructure. Most of the HIC settings provide population-based DRS using digital retinal imaging. Therefore, the barriers / enablers of HICs described in our review were attuned to the processes of DRS using imaging. However, most of the low-income settings still do not have systematic DRS and it is done as an opportunistic intervention only. Moreover, mode of DRS in low income settings were based on bio-microscopy / ophthalmoscopy. At the provider level in LIC and LMIC settings, lack of skilled human resources and lack of DRS infrastructure were the main barriers, while in UMIC and HIC it was lack of training and poor coordination between physicians / general practitioners and screeners. In addition, the LIC and LMIC ophthalmologists are overburdened with most prevalent blinding conditions such as cataract. This reflected in most of the studies as

a barrier, stating the lack of and maldistribution of ophthalmologists. On the other hand, it has led to increased waiting time for PwDM, which hindered uptake of services.

Synthesis of existing evidence helped to narrow down barriers to identify modifiable themes. In general, knowledge appeared as the main modifiable barrier to access, from the user side. However, in a paid healthcare system, low income and financial constrains had been mentioned frequently. We identified financial barriers as a recurrent theme in the harvest plots. In addition, most frequently mentioned (i.e., frequency of studies with the theme) barrier by consumers was asymptomatic nature of DR as shown in harvest plot in Figure 2. Therefore, the need to undergo regular screening even without visual symptoms should be an aspect that should be emphasised. Complementary to these outcomes, the most common incentives mentioned in included studies were better knowledge on DR / DRS, higher level of education, presence of symptoms and higher level of income as shown in Figure 3. When considering the most frequently cited barriers by providers, deficiencies in educating users on DR / DRS, issues in accessibility when making appointments, and long waiting time at eye clinics emerged as the main barriers (Figure 4). The main enablers for providers were educating users on regular eye examination and providing better access for PwDM (Figure 5).

Strengths and Limitations

This review included 77 articles from diverse settings. We used a comprehensive approach to capture all possible articles on this review question. Inclusion of studies without restricting the study design allowed us to derive a wide range of themes. We used narrative synthesis of data due to high heterogeneity among the studies. Further we attempted to provide wide range of barrier and enabler themes by all income settings, incorporating both qualitative and descriptive quantitative studies, without restricting to any study design or income setting.

In order to maintain the homogeneity among the included studies, we divided the studies according to the income setting. Further we explored whether there were differences in barriers and enablers between different income settings.

A majority of the studies were focused on the perspectives of the users when describing the barriers. Almost none of the studies explored the perspectives of the policy makers or program planners. Therefore, this review lacks several aspects of stakeholder perspectives.

We did not look at the community level programs which may take place outside of a medical or eye care centre. We did not specifically assess the reach or availability of DRS programs, which could be an important component in access.

The included studies reflected the barriers in a cross section of time. All the studies used diagnosed PwDM at institutional level as their study samples. There were no studies that used long term sociological and ethnographic approaches to study barriers to access in their natural environment over time.

Many of the barriers or enablers identified in this review were peculiar to modality of screening in the local context. We used a reductionistic approach in this narrative synthesis without further synthesis of new themes. Another aspect is that the barriers or enablers were assessed in different health systems which may have different socio-cultural and economic back grounds. Therefore, we could not assess the interactions between each of the themes we derived. Though we simplified and de-contextualised the barriers themes, generalizability may depend on the context.

One of the limitations of this review is lack of eligible randomised controlled trials on the review question and primary outcomes were described as explained by the authors. Considering the paucity of systematic reviews under this topic, we found it is difficult to compare and comment in contrast on our findings.

Implications and public health significance of the findings

The narrative synthesis by country income level supported by quantitative data would be helpful to identify potential strategies to overcome barriers in each setting. We observed that most important factor to define barriers is the setting. Therefore, we recommend carrying out an assessment of barriers and enablers in each context before making recommendations for a DRS program.

Diabetic retinopathy screening program implementation involves a high capital expenditure. There will be a high level of financial risk when implementing a program for the first time. By knowing the potential barriers, the risks can be minimised, and access can be improved by implementing interventions to overcome potential barriers.

The outcomes of the current review will be useful to identify the modifiable barriers which could be further explored in a local context before implementing costly DRS programs and interventions. Assessment of user and provider perspectives together enables the identification and subsequent catering to needs from the demand side as well as the supply side of DRS.

The results of this review show that there are modifiable barriers such as lack of knowledge on DRS among the PwDM which could be addressed in the development of health promotional strategies.

This review highlights the gaps in evidence on this topic in LIC and LMIC. Further there was limited evidence on system factors and perspectives of stakeholders.

Conclusion

The evidence in this review clearly suggests that the barriers and enablers are different in each income setting. The most consistent barrier across different income settings was lack of knowledge and awareness on DR and DRS among the users. In providers point of view, lack of skilled human resources and screening infrastructure was the main barrier. Knowing the modifiable barriers in a specific context would be helpful to identify the risk groups early and to improve DRS uptake among institutional PwDM. A main recommendation of this review is to carry out an assessment of barriers and enablers in each context before implementing a DRS program. The consumer-based health educational interventions and provider-based skills and DRS infrastructure development would improve the access to DRS especially in low income settings.

Additional files in Appendix 5 (numbered as per journal guidelines)

S1 Table. PRISMA check list

S2 Table. Search strategy of barriers to access systematic review

S3 Tables. Methodological quality and applicability assessment of the included studies

S4 Table. Participants' characteristics of included articles

S5 Tables. Themes tables by country income setting

S6 Table. Quantitative Data Synthesis - Factors associated with DR screening uptake and regular follow up

References cited in submitted manuscript (Chapter 7)

1. International Diabetes Federation - Diabetes Atlas Eighth Edition 2017 [Internet]. 2017. Available from: http://www.diabetesatlas.org/resources/2017-atlas.html. Cited 15 January 2018.

2. Hall M, Felton A. The St Vincent Declaration 20 years on - defeating diabetes in the 21st century. Primary Care Diabetes. 2009;3(2):127-128. https://doi.org/10.1016/j.pcd.2009.06.003

3. Klein R, Klein BEK. The Epidemiology of Diabetic Retinopathy [Internet]. Fifth Edit. Vols. 2–3, Retina: Fourth Edition. Elsevier Inc.; 2005. 1503-1521 p. Available from: http://dx.doi.org/10.1016/B978-1-4557-0737-9.00045-X. Cited 15 Aug 2017.

4. Fernandes De RJ, Ogurtsova K, Linnenkamp U, Guariguata L, Seuring T, Zhang P, et al. IDF Diabetes Atlas estimates of 2014 global health expenditures on diabetes. Diabetes Res Clin Pract. 2016;117:48–54. PMID:27329022 DOI: 10.1016/j.diabres.2016.04.016

5. Penchansky R, Thomas J. The concept of access-Definition and relationship to consumer satisfaction. Med Care. 1981;19(2):127–40. PMID:7206846

6. Gulliford M, Morgan M. What does 'access to health care' mean. J Health Serv Res Policy. 2002;7(3):186-8. PMID: 12171751 DOI: 10.1258/135581902760082517

7. Andersen RM, McCutcheon A, Aday L a, Chiu GY, Bell R. Exploring dimensions of access to medical care. Health Serv Res. 1983;18(1):49–74. PMCID: PMC1068709

8. Donabedian A. Aspects of medical care administration: specifying requirements for health care. In: Cambridge MA, Harvard University Press. 1973.

9. Taylor DJ, Scoyoc L Van, Hawley S. Health Insurance and Mammography: Would a Medi Care buy-in Take Us to Universal Screening. Health Serv Res. 2002;37(6):1469–86. PMID: 12546282

10. Hofer T, Katz S. Healthy Behaviours Among Women in the United States and Ontarion: The Effect on Use of Preventive Care. Am J Public Health. 1996;86(12):1775–9.

11. Kliner M, Fell G, Gibbons C, Dhothar M, Mookhtiar M, Cassels-Brown A. Diabetic retinopathy equity profile in a multi-ethnic, deprived population in Northern England. Eye (Lond). 2012;26(5):671–7. doi: 10.1038/eye.2012.3 PMID: 22302063

12. Jacobs B, Ir P, Bigdeli M, Annear PL, Damme W Van. Addressing access barriers to health services: an analytical framework for selecting appropriate interventions in low-income Asian countries. Health Policy Plan. 2012;27(4):288-30 doi: 10.1093/heapol/czr038.0 PMID: 21565939

13. Elam AR, Lee PP. High-Risk Populations for Vision Loss and Eye Care Underutilization: A Review of the Literature and Ideas on Moving Forward. Surv Ophthalmol. 2013;58(4):348–58. DOI: 10.1016/j.survophthal.2012.07.005 PMID: 23664105

14. Taylor SP, Nicolle C, Maguire M. Cross-cultural communication barriers in health care. Nurs Stand. 2013;27(31):35-43 PMID: 23641636

15. Betancourt J., Green AR, Carrillo JE. Cultural Competence in Health Care: Emerging Frameworks and Practical Approaches. Weil Med Coll Cornell Univeristy [Internet]. 2002;(576):1–24. Available from:

http://www.commonwealthfund.org/usr_doc/betancourt_culturalcompetence_576.pdf. Cited 15 Jan 2017.

16. The Diabetes Control and Complications Trial Research Group. The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med. 1993;329(14):977–86. DOI: 10.1056/NEJM199309303291401 PMID: 8366922

17. Kohner EM, Aldington SJ, Stratton IM, Manley SE, Holman RR, Mathews DR, et al. United Kingdom Prospective Diabetes Study, 30: diabetic retinopathy at diagnosis of non-insulin-dependent diabetes mellitus and associated risk factors. Arch Ophthalmol. 1998;116(3):297–303. PMID: 9514482

18. The Diabetic Retinopathy Study Research Group. Photocoagulation Treatment of Proliferative Diabetic Retinopathy. Second Report of Diabetic Retinopathy Study Findings. Ophthalmology 1978;85(1):82-106. https://doi.org/10.1016/S0161-6420(78)35693-1 PMID: 345173

19. The Diabetic Retinopathy Study Research Group. Indications for photocoagulation treatment of diabetic retinopathy: Diabetic Retinopathy Study Report no. 14. The Diabetic Retinopathy Study Research Group. Int Ophthalmol Clin. 1987;(27) 4:239-253 PMID: 2447027

20. The Diabetic Retinopathy Vitrectomy Study Research Group. Early Vitrectomy for Severe Proliferative Diabetic Retinopathy in Eyes with Useful Vision. Results of a randomized trial--Diabetic Retinopathy Vitrectomy Study Report 3. Ophthalmology.1988;95(10):1307–20. https://doi.org/10.1016/S0161-6420(88)33015-0 PMID: 2465517.

21. Lewis K, Patel D, Yorston D, Charteris D. A qualitative study in the United Kingdom of factors influencing attendance by patients with diabetes at ophthalmic outpatient clinics. Ophthalmic Epidemiol. 2007;14(6):375–80. DOI: 10.1080/09286580701375195 PMID: 18161611

22. Drainoni M, Lee-hood E, Tobias C, Andrew J. Cross-Disability Experiences of Barriers to

Health-Care Access Consumer Perspectives. Journal of Disability Policy Studies. 2006;101–16. https://doi.org/10.1177/10442073060170020101

23. Walker EA, Basch CE, Howard C, Zybert PA, Kromholz WN, Shamoon H. Incentives and Barriers to Retinopathy Screening Among African-Amer&an/ With Diabetes. J Diabet Complications. 1997 Sep-Oct;11(5):298-306 PMID: 9424171

24. Donnell OO. Access to health care in developing countries: breaking down demand side barriers Acess. Cad Saude Publica 2007;23(12):2820–34. http://dx.doi.org/10.1590/S0102-311X2007001200003 PMID: 18157324

25. Whitehead D. A social cognitive model for health education/health promotion practice. J Adv Nurs. 2001;36(3):417–25. PMID: 11686756

26. Bandura A. Toward a unifying theory of behavioural change [Internet]. Vol. 84, Psychological Review. 1977. p. 191–215. Available from: http://www.apa.org/pubs/journals/rev/. Cited on 15 Jan 2017.

27. Bandura A. Social cognitive theory: an agentic perspective. Annu Rev psychol. 2001;52:1-26. DOI: 10.1146/annurev.psych.52.1.1 PMID: 11148297.

28. Zhang X, Norris SL, Saadine J, Chowdhury FM, Horsley T, Kanjilal S, et al. Effectiveness of Interventions to Promote Screening for Diabetic Retinopathy. Am J Prev Med. 2007;33(4):318–35. DOI: 10.1016/j.amepre.2007.05.002 PMID: 17888859

29. Lawrenson JG, Graham-Rowe E, Lorencatto F, Presseau J, Burr J, Ivers N, et al. Interventions to increase attendance for diabetic retinopathy screening. Cochrane Database Syst Rev. 2018; (1):CD012054. DOI: 10.1002/14651858.CD012054.pub2.

30. Graham-Rowe E, Lorencatto F, Lawrenson J, Burr J, Grimshaw J, Ivers N, et al. Barriers to and enablers of diabetic retinopathy screening attendance: a systematic review of published and greay literature. Diabet Med. 2018;35(10):1308–1319. doi: 10.1111/dme.13686. PMID:

29790594.

31. Kashim RM, Newton P, Ojo O. Diabetic Retinopathy Screening: A Systematic Review on Patients' Non-Attendance. Int J Environ Res Public Health. 2018;15(157):1–12 doi:10.3390/ijerph15010157.

32. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. PLoS Med. 2007;4(10): e296. https://doi.org/10.1371/journal.pmed.0040296

33. Critical Appraisal Skills Program - CASP Check Lists [Internet]. CASP UK. Available from: http://www.casp-uk.net/casp-tools-checklists Cited 15 January 2016

34. National Institute of Health - USA. Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies [Internet]. NIH QAT. Available from: https://www.nhlbi.nih.gov/health-pro/guidelines/in-develop/cardiovascular-risk-reduction/tools/cohort. Cited 15 January 2016.

35. Burgess PI, Msukwa G, Beare NA V. Diabetic retinopathy in sub-Saharan Africa: meeting the challenges of an emerging epidemic. BMC Med. 2013;11(1):157. DOI: 10.1186/1741-7015-11-157 PMID: 23819888

36. Khandekar R. Screening and public health strategies for diabetic retinopathy in the Eastern Mediterranean Region. Middle East Afr J Ophthalmol. 2012;19(2):178. DOI: 10.4103/0974-9233.95245 PMID: 22623855

37. Thapa R, Paudyal G, Maharjan N, Bernstein P. Demographics and awareness of diabetic retinopathy among diabetic patients attending the vitreo-retinal service at a tertiary eye care center in Nepal. Nepal J Ophthalmol. 2012;4(1):10–6. doi: 10.3126/nepjoph.v4i1.5844. PMID: 22343990

38. Mumba M, Hall A, Lewellen S. Compliance with Eye Screening Examinations among Diabetic Patients at a Tanzanian Referral Hospital. Ophthalmic Epidemiol. 2007; 14:306–10. DOI: 10.1080/09286580701272079 PMID: 17994440

39. Adriono G, Wang D, Octavianus C, Congdon N. Use of eye care services among diabetic patients in urban Indonesia. Arch Ophthalmol (Chicago, Ill 1960). 2011;129(7):930–5. DOI: 10.1001/archophthalmol.2011.147 PMID: 21746983

40. Agarwal S, Mahajan S, Kumari Rani P, Raman R, Paul PG, Kumaramanickavel G, et al. How High is the Non-Response Rate of Patients Referred for Eye Examination from Diabetic Screening Camps? Ophthalmic Epidemiol. 2005;12(6):393–4. DOI:10.1080/09286580500278418

41. Srinivasan N, John D, Rebekah G, Kujur E, Paul P, John S. Diabetes and Diabetic Retinopathy: Knowledge, Attitude, Practice (KAP) among Diabetic Patients in A Tertiary Eye Care Centre. J Clin Diagn Res. 2017;11(7):1–7 DOI: 10.7860/JCDR/2017/27027.10174 PMID: 28892947

42. Bamashmus MA, Gunaid AA, Khandekar R. Regular Visits to a Diabetes Clinic Were Associated with Lower Magnitude of Visual Disability and Diabetic Retinopathy - A Hospital-Based Historical Cohort Study in Yemen. Diabetes Technology and Therapeutics. 2009;11(1):45-50. DOI: 10.1089/dia.2007.0299 PMID: 19132855

43. Kurji K, Kiage D, Rudnisky CJ, Damj KF. Improving Diabetic Retinopathy Screening in Africa: Patient Satisfaction with Tele-Ophthalmology Versus Ophthalmologist Based Screening. Middle East Afr J Ophthalmol. 2013;20(1):56–60. PMCID: PMC3617530 DOI: 10.4103/0974-9233.106388

44. Muecke JS, Newland HS, Ryan P, Ramsay E, Aung M, Myint S, et al. Awareness of diabetic eye disease among general practitioners and diabetic patients in Yango, Myanmar. Clin Exp Ophthalmol. 2008;(February):265–73. DOI: 10.1111/j.1442-9071.2008.01724.x PMID:

18412597

45. Namperumalsamy P, Kim R, Kaliaperumal K, Sekar A, Karthika A, Nirmalan PK. A pilot study on awareness of diabetic retinopathy among non-medical persons in South India. The challenge for eye care programmes in the region. Indian J Ophthalmol. 2004; 52:247–51. PMID: 15510470

46. Onakpoya OH, Adeoye AO, Kolawole BA. Determinants of previous dilated eye examination among type II diabetics in Southwestern Nigeria. Eur J Intern Med. 2010;21(3):176–9. DOI: https://doi.org/10.1016/j.ejim.2010.01.009

47. Abdulsalam S, Ibrahim A, Saidu H, Muazu M, Aliyu U, Umar H. Knowledge, Attitude, and Practice of Diabetic Retinopathy among Physicians in Northwestern Nigeria. Niger J Clin Pr. 2018; 21:478–83.

48. Islam F, Kawasaki R, Finger R. Factors associated with participation in a diabetic retinopathy screening program in a rural district in Bangladesh. Diabetes Res Clin Pract. 2018;144:111–117 DOI: 10.1016/j.diabres.2018. PMID: 30142363

49. Mwangi N, Macleod D, Gichuhi S, Muthami L, Moorman C, Bascaran C, et al. Predictors of uptake of eye examination in people living with diabetes mellitus in three counties of Kenya. Tropical Medicine and Health; 2017;45(41):1–10 DOI: 10.1186/s41182-017-0080-7 PMID: 29299019

50. Çetin EN, Zencir M, Fenkçi S, Akin F, Yildirim C. Assessment of awareness of diabetic retinopathy and utilization of eye care services among Turkish diabetic patients. Prim Care Diabetes. 2013;7(4):297–302. PMID: 23639610 DOI: 10.1016/j.pcd.2013.04.002

51. Hazavehei SMM, Jeihooni AK, Hasanzadeh A, Amini S. The Effect of Educational Program Based on BASNF Model for Eye Care in Non-insulin Dependent Diabetic Patients. J Heal Serv Res. 2010;10(2):81–90. PMID: 22911929

52. Khandekar R, Lawati J Al, Barakat N. A Retrieval System for Patients with Avoidable Blindness Due to Diabetic Retinopathy who do not Present for Ophthalmic Assessment in Oman. Middle East Afr J Ophthalmol. 2011;18(2):93–7. doi: 10.4103/0974-9233.80694 PMID: 21731317

53. Wang D, Ding X, He M, Yan L, Kuang J, Geng Q, et al. Use of eye care services among diabetic patients in Urban and Rural China. Ophthalmology. 2010;117(9):1755–62. DOI: 10.1016/j.ophtha.2010.01.019 PMID: 20471689

54. Xiong Y, Liu L, Chen Y, Zhao J. Survey on the awareness of diabetic retinopathy among people with diabetes in the Songnan community of Shanghai. Int Eye Sci. 2015;15(7):1117-21.

55. Katibeh M, Ahmadieh H, Beiranvand R, Soleimanizad R, Javadi M. Awareness of the Necessity of Regular Eye Examinations among Diabetics: The Yazd Eye Study. Int J Prev Med. 2017;4(8):49 DOI: 10.4103/ijpvm.IJPVM_218_15 PMID: 28757926

56. Katibeh M, Kalantarion M, Mariotti S, Safi S, Shahraz S, Kalestrup P, et al. A Stakeholder Perspective on Diabetes Mellitus and Diabetic Retinopathy Care in Iran; A Qualitative Study. Arch Iran Med. 2017;20(5):288–294 DOI: 0172005/AIM.006 PMID: 28510464

57. Anderson S, Broadbent DM, Swain JYS, Vora JP, Harding SP. Ambulatory photographic screening for diabetic retinopathy in nursing homes. Eye (Lond). 2003;17(6):711–6. DOI: 10.1038/sj.eye.6700487 PMID: 12928682

58. Hartnett ME, Key IJ, Loyacano NM, Horswell LR, DeSalvo KB. Perceived Barriers to Diabetic Eye Care-Qualitative study of patients and physicians. Arch Ophthalmol. 2005;123:387–91. DOI: 10.1001/archopht.123.3.387 PMID: 15767483

59. Harvey JN, Craney L, Nagendran S, Ng CS. Towards comprehensive population-based screening for diabetic retinopathy: operation of the North Wales diabetic retinopathy screening programme using a central patient register and various screening methods. J Med Screen. 2006;13(2):87–92. DOI: 10.1258/096914106777589669 PMID: 16792832

60. Hipwell AE, Sturt J, Lindenmeyer A, Stratton I, Gadsby R, Hare PO. Attitudes, access and anguish: a qualitative interview study of staff and patients' experiences of diabetic retinopathy screening. BMJ Open 2014;4:e005498. doi:10.1136/bmjopen-2014-005498

61. Huang OS, Tay WT, Tai ES, Chb MB, Wang JJ, Saw S, et al. Lack of Awareness amongst Community Patients with Diabetes and Diabetic Retinopathy: The Singapore Malay Eye Study. Ann Acad Med Singapore. 2009;(38)12:1048–55. PMID: 20052439

62. Hwang J, Rudnisky C, Bowen S, Johnson JA. Socioeconomic factors associated with visual impairment and ophthalmic care utilization in patients with type II diabetes. Can J Ophthalmol. 2015;50(2):119–26. DOI: 10.1016/j.jcjo.2014.11.014. PMID: 25863851

63. Khandekar R, Shah S, Al Lawatti J. Retinal examination of diabetic patients: Knowledge, attitudes and practices of physicians in Oman. East Mediterr Heal J. 2008;14(4):850–7. PMID: 19166168

64. Lane M, Mathewson PA, Sharma HE, Palmer H, Shah P, Nightingale P, et al. Social deprivation as a risk factor for late presentation of proliferative diabetic retinopathy. Clin Ophthalmol. 2015;347–52. PMID: 25733801 DOI: 10.2147/OPTH.S73272

65. Lee PP, Meredith LS, Whitcup SM, Spritzer K, Hays RD. A Comparison of Self-Reported Utilization of Ophthalmic Care for Diabetes in Managed Care Versus Fee-For-Service. Retina. 1998;18:356–9. PMID: 9730180

66. Leese GP, Boyle P, Feng Z, Emslie-Smith A, Ellis JD. Screening Uptake in a Well-Established Diabetic Retinopathy Screening Program. Diabetes Care. 2008;31(11):2131–5. PMID: 18728235 DOI: 10.2337/dc08-1098

67. Lian JX, McGhee SM, Gangwani RA, Hedley AJ, Lam CLK, Yap MKH, et al. Screening for diabetic retinopathy with or without a copayment in a randomized controlled trial: Influence of the inverse care law. Ophthalmology. 2013;120(6):1247–53. DOI: 10.1016/j.ophtha.2012.11.024 PMID: 23583166

68. Shamoon H, Zybert P, Basch C, Walker E, Howard C. The Effect of Health Education on the rate of ophthalmic examinations among African Americans with diabetes mellitus. Am J Public Health. 1999;89(12). PMID: 10589324

69. Lindenmeyer A, Sturt JA, Hipwell A, Stratton IM, Al-Athamneh N, Gadsby R, et al. Influence of primary care practices on patients' uptake of diabetic retinopathy screening: A qualitative case study. Br J Gen Pract. 2014;64(625):484–92. PMID: 25071061 DOI: 10.3399/bjgp14X680965

70. Maberley DAL, Koushik A, Cruess AF, Cruess AF. Factors Associated with Missed with Diabetes Eye Examinations in a Cohort. Can J Public Heal. 2002;93(3):229–32. PMID: 12050993

71. Moss SE, Klein R, Klein BE. Factors associated with having eye examinations in persons with diabetes. Arch Fam Med. 1995;4:529–34. PMID: 7773429

72. Mukamel BD, Bresnick HG, Wang Q, Dickey FC, Mukamel BD, Bresnick HG, et al. Barriers to compliance with screening guidelines for diabetic retinopathy. Ophthalmic Epidemiol. 1999;(6)1:61-72 http://dx.doi.org/10.1076/opep.6.1.61.1563 PMID: 10384685

73. Munoz B, O'Leary M, Fonseca-Becker F, Rosario E, Burguess I, Anguilar M, et al. Knowledge of Diabetic Eye Disease and Vision Care Guidelines Among Hispanic Individuals in Baltimore With and Without Diabetes. Arch Ophthalmol. 2008;126(7):968–74. doi:10.1001/archopht.126.7.968 PMID: 18625945

74. Murgatroyd H, MacEwen C, Leese G. Patients' attitude towards mydriasis for diabetic eye disease screening. Scott Med J. 2006;51(4):341–5. DOI: 10.1258/RSMSMJ.51.4.35 PMID: 17137147

75. Newcomb PA, Klein R. Factors Associated with Compliance Following Diabetic Eye Screening. J Diabet Complications. 1990;4(1):8-14. https://doi.org/10.1016/0891-6632(90)90058-D PMID: 2141844

76. Newcomb PA, Klein R, Massoth KM. Education to Increase Ophthalmologic Care in Older Onset Diabetes Patients: Indications from the Wisconsin Epidemiologic Study of Diabetic Retinopathy. J Diabet Complications. 1992;6(4):211–7. PMID: 1482778

77. Orton E, Forbes-Haley A, Tunbridge L, Cohen S. Equity of uptake of a diabetic retinopathy screening programme in a geographically and socio-economically diverse population. Public Health. 2013;127(9):814–21. DOI: 10.1016/j.puhe.2013.04.015 PMID: 23973045

78. Paksin-hall A, Dent ML, Dong F, Ablah E, Dent ML, Dong F, et al. Factors Contributing to Diabetes Patients Not Receiving Annual Dilated Eye Examinations. Ophthalmic Epidemiol. 2013;20(5):281–7. https://doi.org/10.3109/09286586.2013.789531

79. Baumeister SE, Schomerus G, Andersen RM, Tost F, Markus MRP. Trends of barriers to eye care among adults with diagnosed diabetes in Germany, 1997 e 2012. Nutr Metab Cardiovasc Dis. 2015;25(10):906–15. DOI: 10.1016/j.numecd.2015.07.003 PMID: 26298427

80. Pasagian-macaulay A, Basch CE, Zybert P, Wylie-rosett J. Ophthalmic Knowledge and Beliefs Among Women with Diabetes. Diabetes Educ. 1997;23(4):433–7. https://doi.org/10.1177/014572179702300408

81. Paz SH, Varma R, Klein R, Wu J, Azen SP. Noncompliance with Vision Care Guidelines in Latinos with Type 2 Diabetes Mellitus. The Los Angeles Latino Eye Study. Ophthalmology. 2006;113(8):1372–7. PMID: 16769120 DOI: 10.1016/j.ophtha.2006.04.018

82. Puent B, Nichols K. Patients perspectives on noncompliance with diabetic retinopathy standard of care guidelines. Optometry. 2004;75:709–16. PMID: 15597813

83. Rim TH, Byun IH, Kim HS, Lee SY, Yoon JS. Factors Associated with Diabetic Retinopathy and Nephropathy Screening in Korea: The Third and Fourth Korea National Health and Nutrition Examination Survey (KNHANES III and IV). J Korean Med Sci. 2013;(6):814–20. DOI: 10.3346/jkms.2013.28.6.814 PMID: 23772143

84. Saadine JB, Fong DS, Yao J. Factors Associated with Follow-up Eye Examinations Among Persons with Diabetes. Retina. 2008;28:195–200. DOI: 10.1097/IAE.0b013e318115169a PMID: 18301023

85. Scanlon PH, Carter SC, Foy C, Husband RFA, Abbas J, Bachmann MO. Diabetic retinopathy and socioeconomic deprivation in Gloucestershire. J Med Screen. 2008;15(3):118–21. DOI: 10.1258/jms.2008.008013 PMID: 18927093

86. Scanlon PH, Stratton IM, Leese GP, Bachmann MO, Land M, Jones C. et al. Screening attendance, age group and diabetic retinopathy level at first screen. Diabet Med. 2016;33(7):904-11. DOI: 10.1111/dme.12957 PMID: 26337435

87. Schmid KL, Schmid LM, Pedersen C. Knowledge of the ocular effects of diabetes among the general population of Australia and the members of. Clin Exp Optom. 2003;86(2):91–103. PMID: 12643805

88. Schoenfeld ER, Greene JM, Wu SY, Leske MC. Patterns of Adherence to Diabetes Vision Care Guidelines Baseline Findings from the Diabetic Retinopathy. Ophthalmology. 2001;108(3):563–71. PMID: 11237912

89. Sheppler CR, Lambert WE, Gardiner SK, Becker TM, Mansberger SL. Predicting adherence to diabetic eye examinations: Development of the compliance with annual diabetic eye exams survey. Ophthalmology. 2014;121(6):1212–9. DOI:10.1016/j.ophtha.2013.12.016 PMID: 24518614

90. Brechner RJ, Cowie CC, Howie LJ, Herman WH, Will JC, Harris MI. Ophthalmic examination among adults with diagnosed diabetes mellitus. JAMA. 1993;270(14):1714–8. PMID: 8411502

91. Shih HC, Chou P, Chen S-J, Liu J-H, Lee F-L, Liu CM, et al. A Community Based Study of the Willingness to pay associated with Screening for Diabetic Retinopathy among Type 2 Diabetes in Kinmen, Taiwan. J Epidemiol. 2007;17(6):186–95.

https://doi.org/10.2188/jea.17.186 PMID: 18094517

92. Trento M, Bajardi M, Borgo E, Passera P, Maurino M, Gibbins R, et al. Perceptions of Diabetic Retinopathy and Screening Procedures Among Diabetic People. Diabet Med. 2002;19:810–3. https://doi.org/10.1046/j.1464-5491.2002.00784.x

93. van Eijk KND, Blom JW, Gussekloo J, Polak BCP, Groeneveld Y. Diabetic retinopathy screening in patients with diabetes mellitus in primary care: Incentives and barriers to screening attendance. Diabetes Res Clin Pract. 2011;96(1):10–6. DOI: 10.1016/j.diabres.2011.11.003 PMID: 22137363

94. Storey PP, Murchinson AP, Pizzi LT, Hark LA, Dai Y, Leiby BE, et al. Impact of Physician Communication on Diabetic Eye Examination Adherence: Results from a Retrospective Cohort Analysis. Retina. 2016; 36:20–7. DOI: 10.1097/IAE.0000000000000652 PMID: 26098386

95. Walker EA, Basch CE, Howard C, Zybert PA, Kromholz WN, Shamoon H. Incentives and Barriers to Retinopathy Screening Among African-American With Diabetes. J Diabet Complications. 1997;11(5)298-306 PMID: 9424171

96. Yeo ST, Edwards RT, Fargher EA, Luzio SD, Thomas RL, Owens DR. Preferences of people with diabetes for diabetic retinopathy screening: A discrete choice experiment. Diabet Med. 2012;29(7):869–77 DOI: 10.1111/j.1464-5491.2012.03636.x PMID: 22414336

97. Yeo ST, Edwards RT, Luzio SD, Charles JM, Thomas RL, Peters JM, et al. Diabetic retinopathy screening: Perspectives of people with diabetes, screening intervals and costs of attending screening. Diabet Med. 2012;29(7):878–85. DOI: 10.1111/j.1464-5491.2012.03637.x PMID: 22414383

98. Zhang X, Williams DE, Beckles GL, Gregg EW, Barker L, Luo H, et al. Diabetic retinopathy, dilated eye examination, and eye care education among African Americans, 1997 and 2004. J Natl Med Assoc. 2009;101(10):1015–21. PMID: 19860301

99. Bennett G, Tuthill A. Investigating the Barriers to the Uptake of Diabetic Retina Screen. Ir Med J. 2017;110(9):628–29 PMID: 29372943.

100. Foreman J, Keel S, Xie J, Wijngaarden P, Taylor H, Dirani M. Adherence to diabetic eye examination Health Survey. Med J Aust. 2017;206(9):402–406 doi: 10.5694/mja16.00989.

101. Creuzot-garcher C, Martin-phipps T, Beynat J. Effectiveness of a Mobile Diabetic Retinopathy Screening Campaign to Encourage Diabetics to Undergo Regular Ophthalmic Follow-Up. Ophthalmic Res. 2014;52(4):206-11. DOI: 10.1159/000363326 PMID: 25402747

102. Glasson N, Larkins S, Crossland L. What do patients with diabetes and providers think of an innovative Australian model of remote diabetic retinopathy screening? A qualitative study. BMC Health Serv Res. 2017;17(1):158 DOI: 10.1186/s12913-017-2045-2 PMID: 28222770

103. Kreft D, Mcguinness M, Doblhammer G, Finger R. Diabetic retinopathy screening in incident diabetes mellitus type 2 in Germany between 2004 and 2013 - A prospective cohort study based on health claims data. PLoS One. 2018;13(4):e0195426. https://doi.org/10.1371/journal.pone.019.

104. Lake A, Browne J, Rees G, Speight J. What factors influence uptake of retinal screening among young adults with type 2 diabetes? A qualitative study informed by the theoretical domains framework. J Diabet Complications. 2017;31(6):997–1006 DOI: 10.1016/j.jdiacomp.20. PMID: 28363730

105. Lian J, Mcghee S, Gangwani R, Lam C, Yap M, Wong D. Awareness of diabetic retinopathy and its association with attendance for systematic screening at the public primary care setting: a cross-sectional study in Hong Kong. BMJ Open. 2018;8:e019989. doi: 10.1136/bmjopen-2017-019989.

106. Liu Y, Zupan N, Shiyanbola O, Swearingen R, Carlson J, Jacobson N, et al. Factors influencing patient adherence with diabetic eye screening in rural communities: A qualitative study. PLoS One. 2018;13(11): e0206742. https://doi.org/10.1371/journal.pone.020.

107. Moreton P, Stratton I, Chave S, Lipinski H, Scanlon P. Factors determining uptake of diabetic retinopathy screening in Oxfordshire. Diabet Med. 2017;34(7):993–999 DOI: 10.1111/dme.13350 PMID: 28295529

108. Dervan E, Lillis D, Flynn L, Staines A, O'Shea D. Factors that influence the patient uptake of diabetic retinopathy screening. Ir J Med Sci. 2008;177:303–8. DOI: 10.1007/s11845-008-0192-5 PMID: 18641918

109. Eiser JR, Eiser C, Riazi A. Screening for diabetic retinopathy is well received by patients and may improve self-management intentions. Diabet Med. 2001 Oct;18(10):835-41. PMID: 11678975

110. Gillibrand WP, Broadbent DM, Swain JY, Harding SP, Vora JP. Knowledge levels of diabetic eye disease in people with diabetes: results of a descriptive survey Knowledge levels of diabetic eye disease in people with diabetes: results of a descriptive survey. Int J Health Promot Educ. 2014;38(4):141-144. DOI:10.1080/14635240.2000.10806169

111. Gulliford MC, Dodhia H, Chamley M, Mccormick K, Mohamed M, Naithani S, et al. Socio-economic and ethnic inequalities in diabetes retinal screening. Diabet Med. 2010; 27:282–8. DOI: 10.1111/j.1464-5491.2010.02946.x

112. Hartnett ME, Key IJ, Loyacano NM, Horswell LR, DeSalvo KB. Perceived Barriers to Diabetic Eye Care-Qualitative study of patients and physicians. Arch Ophthalmol. 2005;123:387–91. DOI: 10.1001/archopht.123.3.387 PMID: 15767483

113. Lewis K, Patel D, Yorston D, Charteris D. A qualitative study in the United Kingdom of factors influencing attendance by patients with diabetes at ophthalmic outpatient clinics. Ophthalmic Epidemiol. 2007;14(6):375–80. DOI: 10.1080/09286580701375195 PMID: 18161611

114. Legorreta A, Hassan M, Peters A, Pelletier K, Leung K. An Intervention for Enhancing Compliance With Screening Recommendations for Diabetic Retinopathy. Diabetes Care.

1997;20(4):520–3. PMID: 9096973

115. Huang OS, Zheng Y, Tay WT, Chiang PP, Lamoureux EL, Wong TY, et al. Lack of Awareness of Common Eye Conditions in the Community. Ophthalmic Epidmiol. 2013;20(1):52–60. https://doi.org/10.3109/09286586.2012.751429

116. Jones HL, Walker EA, Schechter CB, Blanco E. Vision is Preciuos: A successful behavioral inetervention to increase the rate of screening for diabetic retinopathy for inner city adults. Diabetes Educ. 2010;36(1):118–26. doi: 10.1177/0145721709356116 PMID: 20044537

117. Scanlon PH. The English National Screening Programme for diabetic retinopathy 2003–2016. Acta Diabetol. 2017;54(6):515–25. DOI: 10.1007/s00592-017-0974-1 PMID: 28224275

118. Jones S, Edwards R. Diabetic retinopathy screening: a systematic review of the economic evidence. Diabet Med. 2010;27(3):249–56. DOI: 10.1111/j.1464-5491.2009.02870.x PMID: 20536486

119. Williams A, Liu P, Muir K, Waxman E. Behavioural economics and diabetic eye exams. Prev Med (Baltim). 2018;112(March):76–87. DOI: 10.1016/j.ypmed.2018.04.006 PMID: 29626555

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
E: registry@lshtm.ac.uk

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Mapa Mudiyanselage Prabhath Nishantha Piyasena
Principal Supervisor	Prof.G.V.S.Murthy
Thesis Title	A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	N/A		
When was the work published?	N/A		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	**Yes**

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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Bio-Med Central - Tropical Medicine and Health (Open source)
Please list the paper's authors in the intended authorship order:	Piyasena MMPN, Gudlavalleti VSM, Yip JLY, Gilbert C, Peto T, Premarathne M, Zuurmond M.
Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceived the concept of this formative qulitative research study, designed the study, prepared the methods and conducted the focus group discussions in the Western province of Sri Lanka. I recruited and trained a local team of sociologists, research

	assistants and translators to conduct this study in local languages. All focus groups were conducted by my self with the help from sociologists, especially in Tamil medium. Afterwards, transcripts were prepared with the support from the research team. The qualitative data analysis was conducted under supervision of a local lead sociologists and an adviser from LSHTM. The interpretation of the themes, preparation of the manuscripts were done under supervision of the main supervisor and a qualitative research adviser. Supervisors and advisers revised the manucsipt before submission to the journal. This article was initially submitted to the BMC Endcrine Disorders journal and it was withdrawn due to the delays in review process and submitted to BMC-Tropical Medicine and Health. The reviewers comments received in March/2019 and manuscript has been revised.

Student Signature: [redacted] **Date:** 27/ 03/ 2019.

Supervisor Signature: [redacted] **Date:** 27/03/2019

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Tropical Medicine and Health

RESEARCH Open Access

A qualitative study on barriers and enablers to uptake of diabetic retinopathy screening by people with diabetes in the Western Province of Sri Lanka

Mapa Mudiyanselage Prabhath Nishantha Piyasena[1*], Gudlavalleti Venkata S. Murthy[1], Jennifer L. Y. Yip[1], Clare Gilbert[1], Tunde Peto[2], Mahesh Premarathna[3] and Maria Zuurmond[4]

Abstract

Background: Blindness and visual impairment from diabetic retinopathy (DR) are avoidable through early detection and timely treatment. The Western Province of Sri Lanka has the highest prevalence of diabetes mellitus (DM) (18.6%) in the country. A situational analysis identified a significant gap in DR screening services (DRSS) uptake in this region. Barriers that hinder people with DM (PwDM) from attending DRSS are poorly understood. The purpose of this study is to understand the factors which influence the uptake of DRSS and follow-up to inform health promotion strategies and improve the uptake of these services.

Methods: Eleven focus group discussions (FGDs) were conducted with PwDM who presented to medical, general eye and vitreoretinal services in three public sector institutions (two tertiary and one secondary level) in the Western Province between October 2016 and March 2017. We enrolled six groups (four Sinhala speaking, two Tamil) of women and five groups (three Sinhala and two Tamil) of men representing ethnicity and gender. We performed a thematic analysis and described the main themes and subthemes using the socio-ecological model as a framework.

Results: We identified lack of knowledge of both the condition and the need for screening as key barriers to access DRSS. Socio-cultural factors in the family environment, economic reasons and institutional factors were also important barriers. Additional reasons include long waiting time at eye clinics and poor referrals exacerbated by the lack of a systematic DRSS. In addition, attitudes to DRSS such as fear of discomfort from the procedure and the need for accompaniment following mydriasis were also deterrents to follow-up screening.

Conclusion: This study has shown that there are inter-related user, family, and institutional factors which affect the uptake of DRSS. Understanding how DR is conceptualised by PwDM in this region is essential to refine strategies to improve access to DRSS. Strategies to improve knowledge need to be more culturally acceptable and relevant to PwDM and their families, with increased availability of DRSS at convenient locations may increase timely uptake of screening.

Keywords: Barriers, Diabetes mellitus, Diabetic retinopathy, Screening, Sri Lanka

* Correspondence: prabhath.piyasena@lshtm.ac.uk
[1]Clinical Research Department, Department of Infectious and Tropical Diseases, International Centre for Eye Health, London School of Hygiene and Tropical Medicine, London WC1E 7HT, UK
Full list of author information is available at the end of the article

Chapter 8

A Qualitative Study on Barriers and Enablers to Uptake of Diabetic Retinopathy Screening by People with Diabetes in the Western Province of Sri Lanka

Piyasena MMPN, Murthy GVS, Yip JYL, Gilbert C, Peto T, Premarathne M, Zuurmond M. A Qualitative Study on Barriers and Enablers to Uptake of Diabetic Retinopathy Screening by People with Diabetes in the Western Province of Sri Lanka. Trop Med Health. 2019 May 17;47:34. doi: 10.1186/s41182-019-0160-y. PMID: 31139011

Abstract

Background

Blindness and visual impairment from diabetic retinopathy (DR) are avoidable through early detection and timely treatment. The Western province of Sri Lanka has the highest prevalence of diabetes mellitus (DM) (18.6%) in the country. A situational analysis identified a significant gap in DR screening services (DRSS) uptake in this region. Barriers that hinder people with DM (PwDM) from attending DRSS are poorly understood. The purpose of this study is to understand the factors which influence uptake of DRSS and follow up to inform health promotion strategies and improve uptake of these services.

Methods

Eleven focus group discussions (FGDs) were conducted with PwDM who presented to medical, general eye and vitreo-retinal services in three public sector institutions (two tertiary and one secondary level) in the Western province between October 2016 and March 2017. We enrolled six groups (4 Sinhala speaking, 2 Tamil) of women and five groups (3 Sinhala and 2 Tamil) of men representing ethnicity and gender. We performed a thematic analysis and described the main themes and subthemes using the socio-ecological model as a framework.

Results

We identified lack of knowledge of both, the condition and the need for screening as key barriers to access DRSS. Socio-cultural factors in the family environment, economic reasons and institutional factors were also important barriers. Additional reasons include long waiting time at eye clinics and poor referrals exacerbated by the lack of a systematic DRSS. In addition, attitudes to DRSS such as fear of discomfort from the procedure and the need for accompaniment following mydriasis were also deterrents to follow up screening.

Conclusion

This study has shown that there are inter-related user, family and institutional factors which affect the uptake of DRSS. Understanding how DR is conceptualised by PwDM in this region is essential to refine strategies to improve access to DRSS. Strategies to improve knowledge need to be more culturally acceptable and relevant to PwDM and their families, with increased availability of DRSS at convenient locations may increase timely uptake of screening.

Keywords

Barriers, Diabetes mellitus, Diabetic Retinopathy, Screening, Sri Lanka.

Background

Diabetes mellitus (DM) is an emerging global epidemic. The International Diabetes Federation estimated that there will be 629 million people with diabetes (PwDM) by the year 2045 [1]. Diabetic retinopathy (DR) is a common microvascular complication of DM potentially leading to visual impairment and blindness. DR has an asymptomatic stage that can go unnoticed until it affects vision leading to blindness [2]. Several studies have shown that good control of blood glucose levels and hypertension, DR screening, with timely identification and treatment of significant retinal changes reduce the progression of sight threatening DR [3-7]. However, delivering an effective screening programme with a high level of coverage is difficult even in high income settings [8].

Sri Lanka is a lower middle-income country which has a distinctive and sustainable health system. Sri Lanka has achieved a remarkable development in health indicators compatible with the millennium development goals and a high literacy rate (>10 years of age, males 96.9%, females 94.6%) compared to neighbouring countries in the region [9,10]. The country has a population of 20.2 million (2012), 5.82 million (28.7%) of whom live in the Western province [10]. This province has three districts namely, Colombo, Gampaha and Kalutara, with several different ethnic groups. Colombo is the most densely populated city in Sri Lanka with 3428 persons/km^2 [10]. Health care in Sri Lanka is provided at the point of delivery in the public sector, without needing a referral from a general practitioner and eye care is free. Individuals of middle or high socio-economic status tend to favour the private sector, including for DM management and eye care.

The crude prevalence of DM in Sri Lanka was estimated at 12.6% (age >20 years) as reported in a national level survey with the highest prevalence (18.6%, 95% CI 15.8-21.5%, age >20 years) in the Western province [11]. The prevalence of any DR among PwDM ranged from 18.1% (mean age 37.1 years) to 27.4% (mean age 56.4 years) [12,13]. A situational analysis of the Western province in 2014 indicated a wide gap between the background need and screening provision for DR, with an estimated

additional 670,970 DR screening visits and 110,690 laser procedures which need to be performed to prevent sight loss due to DR per year to address the unmet need [14]. Sri Lanka does not have a systematic screening program for DR, but PwDM who attend out-patient medical care are given a referral letter for an annual retinal examination at the nearest eye clinic [14]. Clinicians in the Western province report significant numbers presenting with more severe stages of DR, leading to costly eye surgeries and poorer outcomes. This is a burden to the health system, leading to long waiting time for surgeries, extending beyond 1-2 years.

Access to health care depends on a complex interaction of various factors. The availability of screening services will inevitably influence uptake [15]. Studies that explored eye health seeking behaviour and barriers to access of DR screening services (DRSS) by PwDM have identified a range of socio-cultural factors which are likely to be context specific. Barriers including low economic status [16,17], low level of literacy [18] and other socio-economic inequities in access [19] affect the uptake of eye care services [20,21]. Low levels of awareness and knowledge among the PwDM about DR and its screening is another common barrier [22–25]. However, there are no known studies which have looked at the specific barriers in the Sri Lankan context and this study addresses this gap.

Methods

Aim

The aim of this study was to explore why PwDM do not take-up referral for free eye examinations in the Western province of Sri Lanka, from the patients' perspectives. We were interested in identifying the barriers in the care pathway in this local context. This study was conducted as part of a larger feasibility study, to develop an integrated DRSS program in Sri Lanka. We assumed that identifying barriers for PwDM will enable us to make recommendations for a systematic DRSS strategy in Sri Lanka and to inform the development of health education interventions to facilitate access.

Conceptual Framework

We used the *"Socio-Ecological Model"* framework to analyse the study. This model describes dynamic interactions amongst and between various personal and environmental factors and their impact on an intended outcome [26,27]. We used this model to develop our understanding of the multi-faceted interactions between individuals (PwDM) and their environment and therefore explain patients' behaviour in relation to access of DRSS. This model was also used for examining barriers within the different layers of the individual, family and society, including interactions with the service providers (see Figure 1) [28,29].

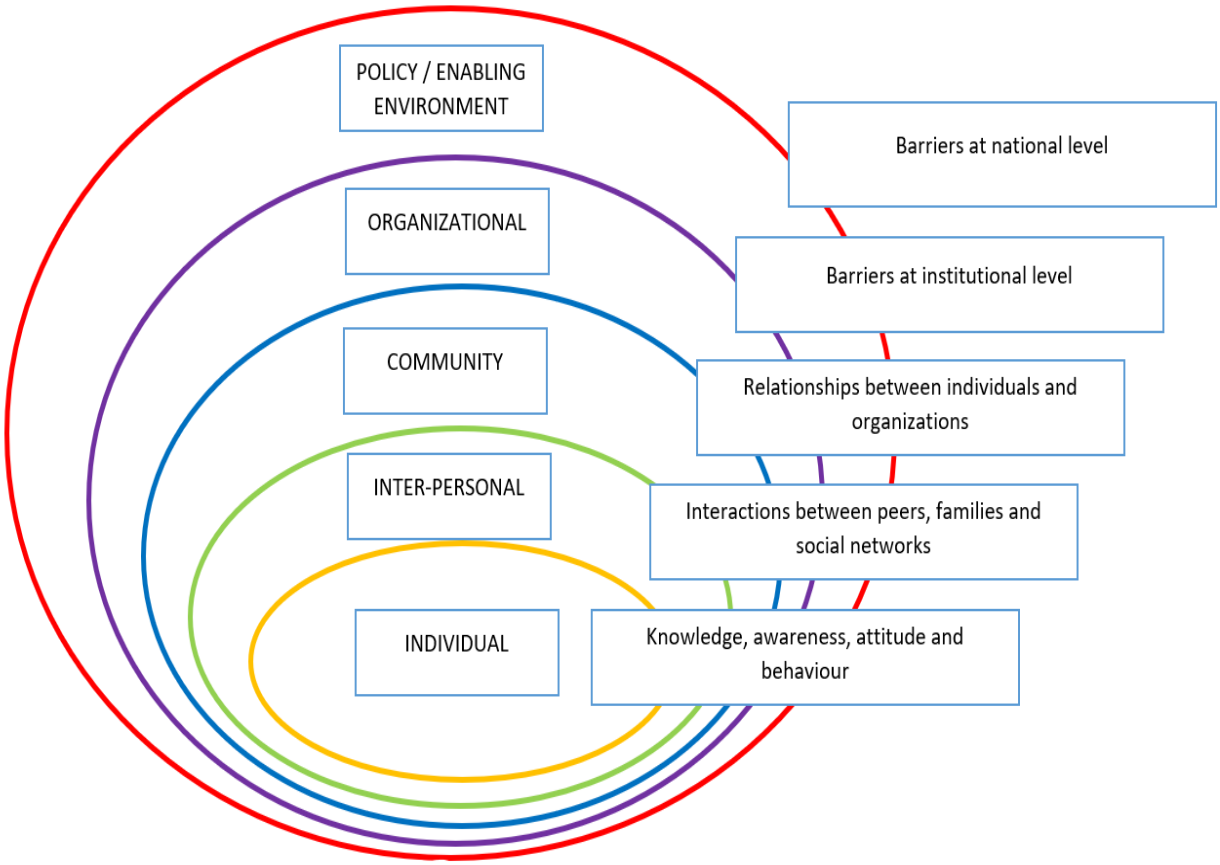

Figure 1. Illustration of socio-ecological model to understand interactions of PwDM and environment depicting barriers at each level

Research team and reflexivity

The team of investigators comprised the lead investigator (MMPNP), four moderators (three males and one female) and two research assistants (one male and one female). The moderators were all experienced Sri Lankan sociologists and each of them were fluent in either Sinhala or Tamil language. The research team spent a few hours at a study centre observing the clinics before conducting FGDs. The objective of non-participatory observations was to identify the processes involved in manging a PwDM and for the sociologists to familiarize themselves with the context. The FGDs were conducted in a closed room of the hospital to maintain privacy. Each FGD lasted between 45-90 minutes (The topic guide available as Additional file 1 in Appendix 6).

The topic guide for FGDs was informed by a literature review, translated into the two key languages, pilot tested and then revised. It explored knowledge, awareness, socio-economic and cultural factors that could affect the DRSS health seeking behaviour of a PwDM.

Study sites

We purposefully selected urban public sector clinic settings in two districts of the Western province; two tertiary care institutions (one multi-speciality and one eye hospital in Colombo district) and one secondary level institution (a general hospital in Gampaha district). These clinics are all attended by a large number of people every day, most commonly those with chronic disease and lower socio-economic position and are in urban settings [30].

Participant selection

Potential participants at the out-patient clinics were asked to complete a short questionnaire by study research assistants, whilst waiting for their consultation. We used the completed questionnaires to purposively sample participants >18 years of age to ensure representation from different ethnic groups (Sinhala, Tamil and Moor), men and women, different economic and educational backgrounds and at different stages of care or different stages of diabetic eye disease, ranging from no DR to those already receiving treatment for DR. DM and DR status were determined by referring to the medical

records and socio-economic position was assessed using the house-hold income categories of the population census. Eleven FGDs were held with a total of 87 participants. These FGD were conducted separately according to the gender and ethnicity and language. The Moor minority ethnic group speak the Tamil language and were combined these FGD due to pragmatic reasons. Seven FGDs in Sinhala and four in Tamil were conducted (see Table 1).

Table 1. Composition of focus groups

<table>
<tr><th colspan="2">Medium of discussion - Sinhala language</th><th colspan="2">Medium of discussion - Tamil language</th></tr>
<tr><th>Female</th><th>Male</th><th>Female</th><th>Male</th></tr>
<tr><td>Group 1: In medical care
N=9</td><td>Group 5: In medical care
N=7</td><td>Group 8: In medical care
N=5</td><td>Group 10: In medical care
N=9</td></tr>
<tr><td>Group 2: In medical care
N=9</td><td rowspan="2">Group 6: Had been referred to an eye clinic
N=10</td><td rowspan="3">Group 9: Mixed group: had been referred to an eye clinic or who had previous DR treatment and major surgery
N=5</td><td rowspan="3">Group 11: Mixed group: Had been referred to an eye clinic or who had previous DR treatment and major surgery
N=6</td></tr>
<tr><td>Group 3: Had been referred to an eye clinic
N=6</td></tr>
<tr><td>Group 4: Had previous DR treatment and major surgery
N=12</td><td>Group 7: Had previous DR treatment and major surgery
N=9</td></tr>
</table>

Analysis

A thematic analysis was conducted in the two main local languages. Audio records were transcribed into local languages, and two separate researchers coded (in Sinhala and Tamil) data after familiarising themselves with the content. Afterwards the coding was cross checked by a sociologist (MP) and experienced qualitative researcher. All data under a theme were further analysed in detail and categorised into subthemes and tabulated. Further triangulation of data was conducted by a 2nd reviewer

(MMPNP). The main themes, sub-themes and relevant quotations that emerged were translated into English for this paper.

Results

Description of the sample

Eighty three percent of the participants were >50 years of age (mean 58.7 years ±1.12), all had type 2 DM (mean duration of DM 9.5 years ±0.75, mean age at DM diagnosis 48.8 years ±1.39), 68% were from lower socio-economic background, as identified through the house-hold income level. Ninety-two percent had education up to primary and above. Fifty two percent were women, 72.4% were Sinhalese which reflects the proportion in Western province and a mix of those from urban (48.3%) and rural areas (51.7%). On average participants lived between 10-20 km away from the hospital. Twenty four percent of the participants had not had any previous examination. Approximately one fifth (18.3%) presented late and were found to have more severe late stage of DR (Tractional retinal detachments) and had previously received major eye surgeries (see Table 2).

Table 2. Participants' characteristics

Variables	Data
Gender	Male n=42 (48.3%) Female n=45 (51.7%)
Age (years)	Mean 58.7 years Range (26 - 79) years
Duration of diabetes (years)	Mean 9.6 years Range (1 - 28) years
Age at diagnosis of diabetes	Mean 48.9 years Range (20 - 70) years
Ethnic group	Sinhalese n=63 (72.4%) Tamil n=18 (20.7%) Moors n=5 (5.8%) Other n=1 (1.1%)

Main language	Sinhala n=61 (70.11%) Tamil n=26 (29.89%)
Level of education	No School n=7 (8.1%) Primary n=26 (30.2%) Secondary n=12 (13.9%) GCE n=39 (45.3%) Degree and above n=2 (2.3%)
Income (per month)	LKR <39,220 n=31 (35.6%) LKR (39,220 – 69,880) n=28 (32.2%) LKR >69,880 n=28 (32.2%)

Knowledge and awareness

One of the main barriers to accessing DRSS was a lack of awareness and knowledge about DR amongst PwDM. This included low levels of knowledge that DM could lead to loss of vision including blindness and a lack of understanding among those who has vision loss that visual impairment was attributable to DM. Although most participants had a vague idea that DM could affect the eyes, their knowledge of DR blindness was basic.

> *"I do not know how diabetes causes loss of vision. I do not know how to tell more about it" (FGD 1, female (F), Sinhala speaking(S))*

Most PwDM understood that DM was a disorder of the blood and they generally called diabetes *"sugar"* in the local language. However, there was limited understanding of the causal link between *"blood sugar"* levels and how this could lead to vision problems.

It was more common in the Sinhala FGDs for the reduced vision to be explained by a weakness in the small blood vessels, "*nahara" (tubes)* in local language. The Sinhalese often correlated diseases of any organ as weakness in blood vessels. In contrast, it was more common in the Tamil FGDs for the loss of vision to be attributed to God as illustrated in the following quotation.

> *"God will decide what will be given to us, If God has thought that it is better not to give diseases to this person….that is His decision. If god has given an illness to you, you cannot*

refuse it. You will have to ask from the god to take it back… So we have to pray to the God to heal the disease". (FGD 8, F, Tamil speaking (T))

Vision problems were frequently explained as being caused by cataracts, the need for glasses or glaucoma; all of which are 'conditions' familiar to the local population. Therefore, many PwDM thought that undergoing cataract surgery and wearing spectacles would solve their eye problems. We detected considerable confusion around the different types of eye conditions; some Sinhala participants mistakenly conflated DR with glaucoma, mentioning the word *"glucose"*. We also found poor understanding of different structures within the eye, such as the retina, which are not visible, and which further impeded their understanding of the disease.

"I got to know that when diabetes increased you get glaucoma. I think glaucoma means increased glucose in your blood. Because of that you become blind". (FGD 5, Male (M)-S)

In contrast, FGDs conducted with PwDM in the vitreo-retinal clinics, who had already experienced sight loss and treatment had better comprehension of the condition. They generally indicated that their awareness grew after experiencing symptoms and treatment, as illustrated by a 54 years old man who recently received surgery.

"After you lose sight, it is very difficult to restore, whatever you do. The reduced vision will remain for ever. Even if you put a lens (intra ocular lens implantation) you cannot take back your previous good vision. I underwent a big surgery recently, as there was blood inside my eye-ball. Now I know it is difficult to cure". (FGD 7, M-S)

Poor understanding of asymptomatic early stages of DR was a related sub-theme. Participants described suffering from other illnesses, lack of visual symptoms or discomfort in their eyes affected their DRSS uptake, illustrated in one of the female FGDs; *"I do not want to rush to check my eyes since I do not feel any problems in my eyes".* Participants were reluctant to take actions when there was no immediate threat to life, and health seeking behaviour was influenced by personal experiences of visual symptoms in the past, such as reduced vision or vision loss. They were not aware of treatment options available to manage DR.

"When you say chest pain, you are scared….When you say kidney problem, you are scared. When you say you would get reduced sight, you would try to correct it with glasses and any how try to see. If you can see with the glasses, you would not have much concern about it". (FGD 2, F-S)

Socio-cultural and economic factors

The socio-cultural environment also impacted upon decision-making to access services. The sub-themes included responsibilities of looking after family members, domestic work and the patriarchal role of other male family members in determining women's access to eye clinic / the hospital. There were considerable gender differences, reflecting societal and gender norms in Sri Lanka.

Data collected in female FGDs revealed societal values as barriers to attending DRSS. There was evidence that the traditional patriarchy dictated decisions on activities and spend by family members. Women were further subordinated by their own perceptions as they commonly stated that they did not like to be a burden on other family members, even for health matters; because their role was to serve the family. Further, they were commonly not in a position to prioritise their own health care, when there were many responsibilities at their home environment, a theme that did not emerge in the male FGDs.

"Though I have an appointment date [to check eyes], I was not able to go due to some reason, mainly problems at home. … suddenly children get ill….or children say there is a parents' meeting at school". (FGD 2, F-S)

"Because of problems and day to day work load at home, I couldn't go [to the eye clinic]. When we are ploughing the paddy field, I have to prepare meals for the workers, also I have to accompany my son to the school. Because of this and that reason I could not go". (FGD 9, F-T)

In contrast, it was more common for the male FGDs to offer economic reasons as a barrier, citing financial constraints. They saw their family role as a breadwinner. Under these circumstances financial

constraints, difficulties in obtaining leave from work and loss of daily earning were the main barriers to attending DRSS. The fact that they had to attend the clinic at least two or three times to complete a full eye examination, often with long waiting queues, further exacerbated the loss of earnings. In this work priority environment, men prioritised income generation over accessing DRSS especially given the asymptomatic nature of early DR.

> *"I have a small tea kiosk in Pettah (Colombo)…I cannot close it even for a single day. It is a very small income. However, I would lose that amount also if I close the stall. Therefore, I do not have much time to attend a clinic." (FGD 11, M-T)*

> *"When my father died, I was eleven. Since the age of 11, I worked and looked after my family members… So, I have to earn my expenses to look after them….Therefore, I could not care much about my health. I am a mason and I work 24x7 continuously. I did not have time to go to check my eyes. (FGD 7, M-S)*

Institutional factors

Patient experience in clinics and hospitals also shaped people's willingness to take up referrals. One sub-theme was the poor organization of care; including very long waiting times, some even waiting a whole day without eating, crowded and uncomfortable waiting areas with limited seating and confusing appointment systems which impeded efforts to rebook a missed appointment.

> *"I went to check my eyes at X hospital. I came back without checking my eyes after seeing the large crowd there". (FGD 8, F-T)*

> *"There are long queues. So, it is very difficult to find a place to sit as there are many people. Also, there are no chairs to sit. There is no proper canteen to have a meal. We have to bring our own water bottle". (FGD 3, F-S)*

Other sub-themes related to their experience with the doctors at medical/eye clinics. Participants reported very limited time for consultation, poor referrals and limited counselling for how to follow up

their screening test. PwDM showed poor appreciation of the value of regular screening, especially when the screening outcome was negative.

> *"I was asked to go to Y hospital and checked my eyes. So, I went there once, and they checked everything and told me that nothing was wrong with my eyes. Afterwards they gave me a letter to come back, But I did not go back, I thought, there was no need to check again, since they told me that my eyes were alright" (FGD 7, M-S)*

Poor experience of previous eye examination such as discomfort of the dilating eye drops and reduced vision after dilating, in particular the resulting need for a companion to the clinic appeared to be another hurdle which they had to negotiate within the family that may prevent them from attending again.

> *"It is very difficult after putting the drops and very difficult to see when you go back home under bright sunlight… it is really blurring…..I usually do not go for checking if there is no one to accompany. You cannot do this and come alone afterwards." (FGD 3, F-S)*

Overall participants described various inter-related factors which contributed to their decision to decline or to delay attending screening services. We found evidence of an interplay of societal, institutional and personal and inter-personal factors that contribute to poor attendance of DRSS.

Discussion

This study explored barriers to access of DRSS by PwDM in the Western province of Sri Lanka, which revealed barriers at the individual, family and institutional levels. We found that lack of knowledge and awareness, socio-cultural, economic and institutional factors were the main domains of detected barriers. Individual-level barriers identified include poor understanding of DR characteristics which resulted in low uptake of screening as well as poor follow-up. Other studies have also shown that lack of knowledge and awareness about DR form a barrier to uptake of DRSS in low and middle income countries [22,23] and high income countries [32–34]. The 'St Vincent

declaration' states that plans for the prevention, identification and treatment of DM and its complications should be implemented as it is a growing problem [31]. However these targets were not achieved in most of the low and middle income countries.

We observed that the absence of colloquial words for "diabetic retinopathy" and "retina" in local languages, and common use without understanding of bio-medical jargon contributed to patients' misunderstanding, further aggravated by the short consultation time in clinics, and the use of English language terms by the doctors, without taking time to explain. Providers were reported have used the English term of "diabetic retinopathy" when describing the condition. Some PwDM confused "diabetic retinopathy" with "glaucoma"; possibly due to the homophonic syllables in "glucose" and "glaucoma". The confusion between the terms could also be attributed to health promotion activities on glaucoma in this region. The perceived disconnect between DM, sugar levels and the effects on the eye may be a key target to improving the knowledge of the PwDM on DR.

The misconceptions on how and why a screening programme is delivered and deterred access have been observed in other studies. One UK study found some PwDM confused DRS with retinal photographs taken during routine eye examinations at optometrists [32]. The reason for annual eye examinations was also reported to be poorly understood in other studies [35,36]. The particular challenge of understanding the importance of regular checkups in the asymptomatic stage is also not new, and has been shown in several other studies in low income [24,37–39] as well as in high income countries [40–43]. The early asymptomatic phase has similary been observed as a barrier to access services in the eye condition of glaucoma [44,45]. It is a challenge for the providers to convince an apparently healthy person to participate in routine screening programmes in the absence of a perceived threat to sight. The asymtomatic nature of DR was shown to be an important element in health promotional material [46]. An individual's better understanding of their susceptibility to vision loss may increase motivation to attend a screening examination.

Our study showed that people with advanced proliferative DR, such as tractional retinal detachment and who had undergone treatment had, perhaps not surprisingly, a better understanding of the link between DM and vision loss. Symptoms form triggers for action in participants, as observed in other studies [37,39,47]. A qualitative study with PwDM in a high income setting found that fear of blindness was an incentive to attend DR screening [35] but few of the participants in our study knew that DR was asymptomatic and could lead to blindness.

The importance of understanding the patient within the context of their family, and how this influences patients' decission-making and actions has also been observed in the uptake of cataract services in Tanzania. This study showed that the perceived need and mobilisation of resources for cataract surgery was dependent on the family and wider social context [48]. Some studies have also examined the role of the family in DRSS uptake, such as marital status [43], requirement of a person to accompany [49] and household finances [35]. Sri Lanka has a 'collectivistic' society and family system, where needs of the family or a group is considered as a priority over individual needs, as seen in other South Asian countries. Though public health services are free, women defer to men prior to access. Patriarchal norms dictate that the father, husband or the eldest male member plays the central role in earning and decision making [50,51]. Older people also rely on family members for addresssing their health needs, since there are limited social protection mechanisms [52]. The wider social norms interacts with family roles and influences an individual's health care seeking behaviuor.

Women lack power and authority to attend healthcare services. Previous studies have shown that older women are less motivated to seek eye care, unwilling to use limited family income, and reluctant to be a burden on others. This combined with a lack of decision making power form significant barriers to access healthcare [53–55]. Family issues such as child care and family attitudes have also formed deterents to uptake of DRSS in both low income [24,25,37,56] and high income countries [35,42]. So whilst women play a primary role in looking after family health, their own health needs are ancillary.

Women's perceptions of their own needs reinforce the men's authority in the household. We did not detect any differences in this theme between ethnic groups.

Though men have greater power and independence within the household, our study shows that male PwDM also did not attend screening. Work was a priority and absence from work formed an opportunity cost in an economy where, many participants were earning daily wages, reflecting the lower socioeconomic position of the public clinic patients. The economic role of men in this society contributes to both men and women's ability to attend healthcare services. Again, the asymptomatic nature of the condition may also contribute to low engagement with screening. Work commitments has been observed in other studies [32]. A study from Hipwell, A.E. et al set in UK found that family attitude and work commitments hinder access [32]. Walker, E.A. et al also showed prioritisation of work as a barrier to access [57]. Our sample was drawn from public sector institutes, which provides service for poorer communities, and is consistent with studies where socio-economic position are also determinants of healthcare access [16,19,58]. The Western province has highly a dynamic and industrial economy with significant competition for employment making attendance at work more important than attendance at a screening examination.

This study highlighted a number of institutional-level barriers previously shown in other settings. The eye care services lack capacity in this region and the clinics are overcrowded. Our participants did not attend an organised screening program and their appointments were interspersed with other clinic commitments. Consequently, PwDM faced many obstacles and developed negative perceptions about the providers in their experience of DRSS. As described above, economic and family factors suggest that patients would intend to spend a minimum time for DRSS. Most of the participants stated that long waiting times without food was a deterrent for screening attendance. This was a significant concern for PwDM on anti-diabetic medications such as insulin injections with a risk of hypoglycaemia. Similar concerns were raised in a study from the UK [59]. Other institutional barriers such as weak

appointment systems [43,60,61], time constraints in examination [35,37,42], inability to cope with large number of PwDM, [38] less space in screening clinics [62] have also been reported in elsewhere. Discomfort following instillation of pupil dilating eye drops also discourages attendance at DRSS, in the Western province and elsewhere [59,63,64]. These findings imply that a DRSS should consider using more patient-centred and culturally sensitive strategies.

Access to health care has multiple components beyond healthcare utilisation [65]. Studies have advocated for relevent and culturally competent care delivered to a diverse patient community [20,66]. The services should be expanded in a way of able to provide universal eye care to PwDM with diverse values, beliefs and behaviours; reducing the disparity. The identification of social norms and other barriers to access DRSS by the PwDM in the Western province of Sri Lanka highlights both challenges and areas for development. The socio-ecological model enabled us to understand the interactive effects of personal and environmental factors that determined patient access to DRSS [27]. Building on this work, we can use these insights to inform interventions designed ot improve uptake of DRSS In this region.

Limitations

We sampled participants from urban areas attending secondary and tertiary care clinics and these views do not represent those living in rural areas and attending primary care. The Sri Lankan public health system mainly provides for people from a lower socio-economic background. Therefore, more affluent PwDM are not represented in this study. Since this is a cross section of PwDM population, temporal patterns and seasonal factors may not be reflected. We also recruited low numbers of people from Tamil and Moor ethnic groups, and this may have biased the results and over-represented views from the Sinhala ethnic group. Further exploration with different ethnic groups would be useful to gauge their views in greater depth. Our FGDs were conducted in hospital settings and not in the participants' own home environment, which may have influenced what participants were willing to say.

We selected people attending clinics, and we did not include PwDM who failed to access services completely. However, our sample did capture those who had delayed seeking DRSS and treatment.

Conclusion

Understanding how DR is conceptualised in this region and responded by the PwDM is essential to define strategies to improve uptake of DRSS. This study shows that there are modifiable barriers to DRSS access in the Western province of Sri Lanka. These are inter-connected personal, inter-personal, institutional, organizational and environmental barriers which hinder the uptake of DRSS. Availability of DRSS at a convenient location using methods acceptable, culturally and gender sensitive and relevant to PwDM together with strategies to improve the knowledge and awareness among the PwDM may facilitate uptake of screening services in this province.

Recommendations

Implementation of strategies to improve service availability through a health system approach may be helpful to expand DRSS in this province. There is an urgent need to expand the DRSS in this province with focus on improving waiting times, lengthening consultation periods, and developing an organized referral pathway. To address workforce issues, task-shifting or sharing may improve capacity limitations, and allow more time for counselling in the busy hospital and clinic settings and reduce waiting times. Our findings indicate health promotion strategies should be focused on engaging with the families of PwDM and their nested environment, in addition to efforts targeted at individual level. Health educational interventions should be gender sensitive, and in local languages. A work-based mobile screening approach, i.e., using telemedicine or mobile health (m-health) possibly for larger employers in this region and outreach screening may also improve coverage of DRSS.

Additional files in Appendix 6

6.1 - Additional File 1 - Topic guides of the FGDs

References cited in submitted manuscripts (Chapter 8)

1. IDF. International Diabetes Federation Diabetes Atlas Eighth Edition 2017: http://www.diabetesatlas.org/resources/2017-atlas.html. Accessed 15 Jan 2018.
2. Klein R, Klein BEK. The Epidemiology of Diabetic Retinopathy. Fifth Edit. Vols. 2–3, Retina: Fourth Edition. Elsevier Inc.; 2005. 1503-1521 p. doi.org/10.1016/B978-1-4557-0737-9.00045-X
3. The Diabetes Control and Complications Trial Research Group. The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med 1993;329:977–86. PMID: 8366922 DOI: 10.1056/NEJM199309303291401
4. Kohner EM, Aldington SJ, Stratton IM, Manley SE, Holman RR, Mathews DR, Turner RC. United Kingdom Prospective Diabetes Study, 30: diabetic retinopathy at diagnosis of non-insulin-dependent diabetes mellitus and associated risk factors. Arch Ophthalmol 1998;116(3):297–303. PMID: 9514482
5. The Diabetic Retinopathy Study Research Group. Photocoagulation Treatment of Proliferative Diabetic Retinopathy. Clinical Application of Diabetic Retinopathy Study Findings, DRS Report Number 8 Ophthalmology. Ophthalmology 1981;88:583-600. PMID: 7196564
6. Indications for photocoagulation treatment of diabetic retinopathy: Diabetic Retinopathy Study Report no. 14. The Diabetic Retinopathy Study Research Group. Inl Ophthalmol Clin 1987; 27(4):239-53. PMID: 2447027
7. The Diabetic Retinopathy Vitrectomy Study Research Group. Early Vitrectomy for Severe Proliferative Diabetic Retinopathy in Eyes with Useful Vision. Results of a randomized trail--Diabetic Retinopathy Vitrectomy Study Report 3. Ophthalmology 1988;95(10):1307–20. PMID: 2465517
8. Millett C, Dodhia H. Diabetic Retinopathy Screening: Audit of equity in participation and selected outcomes in South East London. J Med Screen 2006;13(3):152–5. PMID: 17007657 DOI: 10.1258/096914106778440608

9. UNDPs role and leadership in achieving the MDG in Sri Lanka - About Sri Lanka. 2014. http://www.lk.undp.org/content/srilanka/en/home/countryinfo/. Accessed 18 Jan 2018.
10. Census of Population and Housing 2012. Department of Census and Statistics of Sri Lanka. 2012. http://www.statistics.gov.lk/PopHouSat/CPH2012Visualization/htdocs/index.php?usecase=indicator&action=Data&indId=. Accessed 20 Dec 2017.
11. Katulanda P, Rathnapala D, Sheriff R, Matthews D. Province and ethnic specific prevalence of diabetes among Sri Lankan adults. Sri Lanka J Diabetes Endocrinol Metab 2012;1(1):2–7. doi.org/10.4038/sjdem.v1i1.4180/
12. Katulanda P, Ranasinghe P, Jayawardena R. Prevalence of retinopathy among adults with self-reported diabetes mellitus: the Sri Lanka diabetes and Cardiovascular Study. BMC Ophthalmol 2014;14(1):100. doi.org/10.1186/1471-2415-14-100
13. Katulanda P, Waniganayake YC, Ranasinghe P, Udai WM, Wijetunga A, Jayaweera M, et al. Retinopathy among young adults with Diabetes Mellitus from a tertiary care setting in Sri Lanka. BMC Endocr Disord 2014;14(1):1–8. doi:10.1186/1472-6823-14-20
14. Piyasena PN, Murthy GVS. A situation analysis of diabetic eye care service delivery in health care institutions of the Western Province of Sri Lanka. Ceylon Med J. 2017;62:205–6. doi.org/10.4038/cmj.v62i3.8527
15. Levesque JF, Harris MF, Russell G. Patient-centred access to health care: Conceptualising access at the interface of health systems and populations. Int J Equity Health 2013;12(1):1. doi:10.1186/1475-9276-12-18.
16. Baumeister SE, Schomerus G, Andersen RM, Tost F, Markus MRP. Trends of barriers to eye care among adults with diagnosed diabetes in Germany, 1997 e 2012. Nutr Metab Cardiovasc Dis. 2015;25(10):906–15. doi.org/10.1016/j.numecd.2015.07.003
17. Brechner RJ, Cowie CC, Howie LJ, Herman WH, Will JC, Harris MI. Ophthalmic examination among adults with diagnosed diabetes mellitus. JAMA 1993;270(14):1714–8. PMID: 8411502
18. Shamoon H, Zybert P, Basch C, Walker E, Howard C. The Effect of Health Education on the

rate of ophthalmic examinations among African Americans with diabetes mellitus. Am J Public Health 1999;89(12):1878–1882. PMID: 10589324

19. Gulliford MC, Dodhia H, Chamley M, Mccormick K, Mohamed M, Naithani S, et al. Socio-economic and ethnic inequalities in diabetes retinal screening. Diabet Med 2010;27(3):282-8. doi: 10.1111/j.1464-5491.2010.02946.x.

20. Betancourt J., Green AR, Carrillo JE. Cultural Competence in Health Care: Emerging Frameworks and Practical Approaches. Field Report Weil Med Coll Cornell University 2002;(576):1–24. http://www.etn.leeds.ac.uk/document/resources/betancourtcultural%20competence.pdf. Accessed 15 April 2018.

21. Donnell OO. Access to health care in developing countries: breaking down demand side barriers. Cad Saude Publica 2007;23(12):2820–34. doi.org/10.1590/S0102-311X2007001200003.

22. Mumba M, Hall A, Lewellen S. Compliance with Eye Screening Examinations among Diabetic Patients at a Tanzanian Referral Hospital. Ophthalmic Epidemiol 2007;14:306–10. PMID: 17994440 DOI: 10.1080/09286580701272079

23. Thapa R, Paudyal G, Maharjan N, Bernstein P. Demographics and awareness of diabetic retinopathy among diabetic patients attending the vitreo-retinal service at a tertiary eye care center in Nepal. Nepal J Ophthalmol 2012;4(1):10–6. PMID: 22343990 DOI: 10.3126/nepjoph.v4i1.5844

24. Adriono G, Wang D, Octavianus C, Congdon N. Use of eye care services among diabetic patients in urban Indonesia. Arch Ophthalmol 2011;129(7):930–5. PMID: 21746983 DOI: 10.1001/archophthalmol.2011.147

25. Agarwal S, Mahajan S, Kumari Rani P, Raman R, Paul PG, Kumaramanickavel G, et al. How High is the Non-Response Rate of Patients Referred for Eye Examination from Diabetic Screening Camps? Ophthalmic Epidemiol 2005;12(6):393–4. PMID: 16283991 DOI: 10.1080/09286580500278418

26. Centre for Diseases Control USA. The Social Ecological Model: A Framework for Violence

Prevention. Division of Violence Prevention. 2015. p. e0148343. https://www.cdc.gov/violenceprevention/pdf/sem_framewrk-a.pdf. Accessed on 15 May 2016

27. UNICEF. Understanding the Social Ecological Model (SEM) and Communication for Development_Module 1. 2015. Available from: https://www.unicef.org/earlychildhood/files/Module_1_-_MNCHN_C4D_Guide.docx. Accessed on 15 June 2016.
28. Brofenbrenner U. The Ecology of Human Development - Experiments by Nature and Design USA: Harvard University Press; 1979. 1-10 p. https://khoerulanwarbk.files.wordpress.com/2015/08/urie_bronfenbrenner_the_ecology_of_human_developbokos-z1.pdf. Accessed on 18 July 2016.
29. Gombachika B.C, Heidi F, Chirwa E, Sundby J, Malata A, Maluwa A. A Social Ecological Approach to Exploring Barriers to Accessing Sexual and Reproductive Health Services among Couples Living with HIV in Southern Malawi. ISRN Public Health 2012;2012:1–13. doi.org/10.5402/2012/825459
30. Pallegedara A, Grimm M. Demand for private healthcare in a universal public healthcare system: Empirical evidence from Sri Lanka. Health Policy Plan 2017;32(9):1267–84. PMID: 28981660 DOI: 10.1093/heapol/czx085
31. The Saint Vincent Declaration. Acta Ophthalmol Scand. 1997;75(S223):63. http://onlinelibrary.wiley.com/doi/10.1111/j.1600-0420.1997.tb00440.x/pdf. Accessed on 20 Sept 2016
32. Hipwell AE, Sturt J, Lindenmeyer A, Stratton I, Gadsby R, O'Hare P, et al. Attitudes, access and anguish: a qualitative interview study of staff and patients' experiences of diabetic retinopathy screening. BMJ Open 2014;4(12):e005498. doi.org/10.1136/bmjopen-2014-005498
33. Schmid KL, Schmid LM, Pedersen C. Knowledge of the ocular effects of diabetes among the general population of Australia and the members of. Clin Exp Optom 2003;86(2):91–103. PMID: 12643805
34. Trento M, Bajardi M, Borgo E, Passera P, Maurino M, Gibbins R, et al. Perceptions of diabetic

retinopathy and screening procedures among diabetic people. Diabet Med 2002;19(10):810–3. PMID: 12358866

35. Hartnett ME, Key IJ, Loyacano NM, Horswell LR, DeSalvo KB. Perceived Barriers to Diabetic Eye Care-Qualitative study of patients and physicians. Arch Ophthalmol 2005;123:387–91. PMID: 15767483 DOI: 10.1001/archopht.123.3.387

36. Puent B, Nichols K. Patients' perspectives on noncompliance with diabetic retinopathy standard of care guidelines. Optometry 2004;75:709–16. PMID: 15597813

37. Muecke JS, Newland HS, Ryan P, Ramsay E, Aung M, Myint S, Esmail-Zadeh R, Zborowska B, Selva D. Awareness of diabetic eye disease among general practitioners and diabetic patients in Yangon, Myanmar. Clin Exp Ophthalmol 2008; 36(3):265–73. doi:10.1111/j.1442-9071.2008.01724.x.

38. Wang D, Ding X, He M, Yan L, Kuang J, Geng Q, et al. Use of eye care services among diabetic patients in urban and rural China. Ophthalmology 2010;117(9):1755–62. doi.org/10.1016/j.ophtha.2010.01.019

39. Xiong Y, Liu L, Chen Y, Zhao J. Survey on the awareness of diabetic retinopathy among people with diabetes in the Songnan community of Shanghai. Int Eye Sci 2015;15(7):1117-22

40. Creuzot-garcher C, Martin-phipps T, Beynat J. Effectiveness of a Mobile Diabetic Retinopathy Screening Campaign to Encourage Diabetics to Undergo Regular Ophthalmic Follow-Up. Ophthalmic Res 2014;52(4)206–11. doi:10.1159/000363326

41. Gillibrand WP, Broadbent DM, Swain JY, Harding SP, Vora JP. Knowledge levels of diabetic eye disease in people with diabetes: results of a descriptive survey. Int J Health Promot Educ 2000;38(4):141-144. doi.org/10.1080/14635240.2000.10806169

42. Lewis K, Patel D, Yorston D, Charteris D. A qualitative study in the United Kingdom of factors influencing attendance by patients with diabetes at ophthalmic outpatient clinics. Ophthalmic Epidemiol 2007;14(6):375–80. doi:10.1080/09286580701375195

43. Moss SE, Klein R, Klein BE. Factors associated with having eye examinations in persons with diabetes. Arch Fam Med 1995;4:529–34. PMID: 7773429

44. Green J, Siddall H, Murdoch I. Learning to live with glaucoma: a qualitative study of

diagnosis and the impact of sight loss. Soc Sci Med 2002;55(2):257–67. PMID: 12144140

45. Crabb DP, Smith ND, Glen FC, Burton R, Garway-Heath DF. How does glaucoma look?: Patient perception of visual field loss. Ophthalmology 2013;120(6):1120–6. doi.org/10.1016/j.ophtha.2012.11.043

46. Livingston PM, McCarty CA, Wood CA, Harper AC, Keeffe JE, Taylor HR. Use of focus groups to identify health promotion strategies for the early detection of diabetic retinopathy. Aust N Z J Public Health 1998;22(2):220–2. PMID: 9744180

47. Onakpoya OH, Adeoye AO, Kolawole BA. Determinants of previous dilated eye examination among type II diabetics in Southwestern Nigeria. Eur J Intern Med 2010;21(3):176–9. doi.org/10.1016/j.ejim.2010.01.009

48. Geneau R, Lewallen S, Bronsard A, Paul I, Courtright P. The social and family dynamics behind the uptake of cataract surgery: Findings from Kilimanjaro region, Tanzania. Br J Ophthalmol 2005;89(11):1399–402. PMID: 16234438 DOI: 10.1136/bjo.2005.075572

49. Van-Eijk KND, Blom JW, Gussekloo J, Polak BCP, Groeneveld Y. Diabetic retinopathy screening in patients with diabetes mellitus in primary care: Incentives and barriers to screening attendance. Diabetes Res Clin Pract 2011;96(1):10–6. doi.org/10.1016/j.diabres.2011.11.003

50. Greenwood RA, George R, Madero S. An Exploration of Cross-Cultural and Gender Differences in East Asia, South Asia and Southeast Asia. 2016; https://pdfs.semanticscholar.org/5961/c31b3f163f4c18a6842dab7fc3b083b7a3a6.pdf. Accessed on 10 Feb 2018.

51. Fikree FF. Role of gender in health disparity: The South Asian context. Bmj 2004;328(7443):823–6. doi/10.1136/bmj.328.7443.823

52. Kaluthanthri KDMS. Ageing and the changing role of the family in Sri Lanka. University of Adelaide; 2014. https://digital.library.adelaide.edu.au/dspace/bitstream/2440/93498/3/02whole.pdf. Accessed on 18 Feb 2018.

53. Jennifer E. Eye care for older people. Community Eye Heal J 2008;21(66):21–3.

54. Nkumbe H. Helping older people get the eye care they need. Community Eye Heal J 2008;21(66):26–8.

55. Wormald R. Delivery of eye care to the elderly: Practical considerations. Community Eye Heal J 1999;12(29):6–7.

56. Namperumalsamy P, Kim R, Kaliaperumal K, Sekar A, Karthika A, Nirmalan PK. A pilot study on awareness of diabetic retinopathy among non-medical persons in South India. The challenge for eye care programmes in the region. Indian J Ophthalmol 2004;52:247–51. PMID: 15510470

57. Walker EA, Basch CE, Howard C, Zybert PA, Kromholz WN, Shamoon H. Incentives and Barriers to Retinopathy Screening Among African-American with Diabetes. J Diabet Complications 1997;(11) 5:298-306. PMID: 9424171

58. Lane M, Mathewson PA, Sharma HE, Palmer H, Shah P, Nightingale P, et al. Social deprivation as a risk factor for late presentation of proliferative diabetic retinopathy. Clin Ophthalmol 2015; 9:347–52. doi:10.2147/OPTH.S73272

59. Hipwell AE, Sturt J, Lindenmeyer A, Stratton I, Gadsby R, Hare PO. Attitudes, access and anguish: a qualitative interview study of staff and patients' experiences of diabetic retinopathy screening. Bmj Open. 2014;1–9. doi.org/10.1136/bmjopen-2014-005498

60. Burgess PI, Msukwa G, Beare NA V. Diabetic retinopathy in sub-Saharan Africa: meeting the challenges of an emerging epidemic. BMC Med 2013;11(1):157. doi.org/10.1186/1741-7015-11-157

61. Dervan E, Lillis D, Flynn L, Staines A, O'Shea D. Factors that influence the patient uptake of diabetic retinopathy screening. Ir J Med Sci 2008;177(4):303–8. PMID: 18641918 DOI: 10.1007/s11845-008-0192-5

62. Lindenmeyer A, Sturt JA, Hipwell A, Stratton IM, Al-Athamneh N, Gadsby R, et al. Influence of primary care practices on patients' uptake of diabetic retinopathy screening: A qualitative case study. Br J Gen Pract 2014;64(625):484–92. PMID: 25071061 DOI:10.3399/bjgp14X680965

63. Murgatroyd H, MacEwen C, Leese G. Patients' attitude towards mydriasis for diabetic eye

disease screening. Scott Med J 2006;51(4):341–5. PMID: 17137147 DOI: 10.1258/RSMSMJ.51.4.35

64. Yeo ST, Edwards RT, Luzio SD, Charles JM, Thomas RL, Peters JM, et al. Diabetic retinopathy screening: Perspectives of people with diabetes, screening intervals and costs of attending screening. Diabet Med 2012;29(7):878–85. PMID: 22414383 DOI: 10.1111/j.1464-5491.2012.03637.x

65. Penchansky R, Thomas J. The concept of access-Definition and relationship to consumer satisfaction. Med Care 1981;19(2):127–40. PMID: 7206846

66. Taylor SP, Nicolle C, Maguire M. Cross-cultural communication barriers in health care. Nurs Stand 2013;27(31):35-43. PMID: 23641636

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
E: registry@lshtm.ac.uk

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Mapa Mudiyanselage Prabhath Nishantha Piyasena
Principal Supervisor	Prof.G.V.S.Murthy
Thesis Title	A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	N/A		
When was the work published?	N/A		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Bio Med Central (BMC) Health Services Research - Open Source
Please list the paper's authors in the intended authorship order:	Piyasena MMPN, Gudlavalleti VSM, Yip JLY, Gilbert C, Zuurmond M.
Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceived the concept of this formative qualitative research study, prepared the methodology and conducted interviews with the service providers in the Western province of Sri Lanka. I recruited and trained a local team of sociologists, research assistants and translators to conduct this study. All the semi-

	structured interviews were conducted by my self with the help from sociologists. Afterwards, transcripts were prepared with the support from the research team. The qualitative data analysis was conducted under supervision of a local lead sociologists and an adviser from LSHTM. The interpretation of the results and preparation of the manuscripts were done my self, under supervision of the main supervisor and qualitative research adviser. Supervisors and advisers revised the manucript before submission to the journal.This article has been reviewed by the BMC Health Services Reseach journal reviewers in Oct/2018 and revised version submitted in Nov/2018. The 2nd revision comments received in Jan/2019 and revised version re-submitted.

Student Signature: [redacted] **Date:** 27/03/2019.

Supervisor Signature: [redacted] **Date:** 27/03/2019

Chapter 9

Service Providers' Perspectives on Barriers and Enablers to Provision of Diabetic Retinopathy Screening Services in the Western Province of Sri Lanka

Piyasena MMPN, Murthy GVS, Yip JYL, Gilbert C, Zuurmond M. Service Providers' Perspectives on Barriers and Enablers to Provision of Diabetic Retinopathy Screening Services in the Western Province of Sri Lanka. Submitted to BMC-Health Services Research and reviewed.

Abstract

Background

Diabetic retinopathy (DR) is a common microvascular complication of diabetes mellitus (DM) that can lead to sight loss. It significantly impacts health systems. The highest prevalence of DM (18.6%) in Sri Lanka is in the Western province where there is no systematic DR screening. People with DM undergo free opportunistic screening in the public-sector, with overall poor uptake of services. This study aimed to explore barriers to services perceived by health care providers.

Methods

This study was a formative research component of a larger feasibility study to develop an integrated DR screening program. A purposive selection of a wide range of providers were sought at a national and provincial level in the free public health care system. Semi-structured interviews were conducted with 27 providers: clinicians, mid-level personnel, hospital administrators and national level policy makers and planning staff. A thematic analysis was undertaken, using the framework of the World Health Organization health system building blocks.

Results

Lack of skilled human resources and infrastructure for DR screening were the main challenges identified. The majority stated that poor availability of screening services and lack of an organised

referral system hinder uptake. Providers suggested that DR screening should take place in medical clinics where most people with DM present regularly, using a method such as fundus photography. Limited knowledge and awareness about DR among people with DM was also perceived as a major barrier.

Conclusion

This study highlights that in order to improve provision of DR screening, there is a need to consider task sharing and training of non-ophthalmic mid-level human resources, such as medical officers on primary DR screening. In addition, screening instruments should be reformed using local adaptable innovative technologies. Primary screening of people with DM when they present for medical care, incorporated with health educational interventions to improve knowledge and awareness would be an appropriate strategy to improve access.

Key words

Access, Diabetic retinopathy, Health systems, Health care providers, Qualitative research, Sri Lanka.

Background

The diabetes epidemic is increasing globally, with an estimated 425 million people with diabetes mellitus (DM) in the world in 2017 which is projected to increase to 629 million by 2045 [1]. Diabetic retinopathy (DR) is a common microvascular complication of DM that can lead to sight loss. It significantly impacts health systems. It is estimated that globally, 28 million people with DM may currently have sight threatening DR [2]. Sight loss due to DR can be prevented by early screening and treatment. One of the main aspects of development of cost-effective strategies to control DR blindness depends on the organizational structure of screening and service delivery [3].

Annual screening is currently recommended to prevent sight loss from DR [4]. However, the screening interval can be extended, based on level of risk of the people with DM at baseline. Biennial screening is recommended for low risk people with DM [5] which is a more pragmatic approach for resource poor settings. However, achieving a recommended level of DR screening coverage is a challenge in any setting. A range of user, provider and system factors affect uptake of screening and understanding these is crucial to the development of services [6,7]. Providers' perceptions on barriers and enablers are explored in this study.

Sri Lanka is a lower-middle income country which has achieved remarkable development in health status compared to other countries in South Asia. Free government health care is provided for all aspects of eye care. However, eye care is only available at tertiary and secondary levels of service delivery. The national prevention of blindness program, mostly overlaps with the VISION 2020 country program under the Ministry of Health provides ad hoc free screening and preventive eye care services through mobile campaigns, in addition to facility-based services. In addition, there is a national plan for DR, to refer all the people with DM present at health care facilities to the nearest eye clinic to screen for DR. Yet, despite free services, visual impairment and blindness due to DR is emerging as a major public health issue. The Western province, where the capital city Colombo is

located has the highest estimated prevalence of DM of 18.6% (95% CI 15.8-21.5%) in the country [8]. Despite the high prevalence, there is no national screening program [9]. People with DM undergo opportunistic DR screening, following referral by a general physician, or when they present at an eye clinic. A situational analysis conducted in the Western province showed a gap between the numbers screened and treated, and the expected number requiring treatment [9].

This study is one of the formative components of a wider project on assessment of feasibility of development of an integrated DR screening program in the Western province of Sri Lanka. In the current study we aimed to assess the views of a range of health service providers on barriers and enablers to service uptake and their recommendations to improve DR screening services available in the public health system. Services are mostly delivered by the medical officers who are qualified medical graduates, under supervision of a specialist and assisted by a team of para-medical staff. Our focus was on how to improve uptake at the tertiary and higher secondary institutional level, as an initial step. A separate study which looks at service user perspectives is described in a separate article (under review of BMC Tropical Medicine and Health). In order to provide more in depth understanding of the barriers in this local context, we have incorporated relevant user perspectives in the discussion.

Conceptual Framework

This study was a formative research component of a larger feasibility study to develop an integrated DR screening program. The World Health Organization (WHO) describes six essential building blocks in a health system and this was used as a guiding framework to explore barriers/enablers related to provision of DR services [10]. This analytical approach would allow specific recommendations to be made on how different components of the health system would need to be strengthened or modified to deliver DR screening.

Methods

A qualitative research design was adopted, in order to explore in greater depth, the views of a range of service providers. Individual face to face semi-structured interviews were conducted with 27 providers in their workplace, ideally in a closed room to afford privacy. Interviews were conducted in Sinhala, Tamil or English and the average duration was 45 minutes. The interviews were audio recorded, or where permission was not given for recording, detailed notes were taken. On several occasions, (4/27, 14.8%) interviews required 2-3 sessions, due to the busy schedules of the providers. The main investigator of the project (MMPNP) conducted all interviews, whilst two research assistants and two local sociologists assisted with taking field notes, transcribing, translating, and analysing.

The interview guide covered the following key areas, in line with the WHO health system building blocks; i.e., leadership, finances, medical supplies (mainly DR screening equipment), human resources, health information systems and service delivery [10] (see Additional File 1 in Appendix 7 for details). We formulated the topic guide to explore the current challenges faced by the providers and enablers identified by them in the local context, in relation to development of a DR screening programme.

Participant selection

A purposive selection was made to include a range of providers, from the policy and planning level through to front-line clinical staff, at both the national and provincial level. All were public sector providers at the national level or working in the Western province of Sri Lanka. Service providers were recruited from two tertiary level public sector hospitals in Colombo district (one multi-speciality and one eye hospital) and one secondary level hospital in Gampaha district (see Table 1 and 2). These hospitals were selected because they have potential to develop a DR screening program as they have a high daily attendance of people with DM, and facilities are available to treat DR.

Table 1. Hospital level providers participated in the study (clinical staff and administrators)

Public sector – health care institutions		
Tertiary level (Eye Care)	**Tertiary level (General)**	**Secondary level (General)**
Institutional Administrators: -Head of the institution	*Administrator* - Head of the institution	*Administrator* -Head of the institution -Matron (Administrator of nursing staff)
Specialists -General physician -Ophthalmologists -Vitreo-retinal surgeon	*Specialists* -General physician -Ophthalmologists (visiting)	*Specialists* -General physician -Ophthalmologists
Mid-level cadres -Medical officer-eye care -Medical officer-medical care -Nursing officer-eye care (imaging)	*Mid-level cadres* -Medical officer-eye care -Medical officer-medical care -Nursing officer-medical care -Resident (physician)	*Mid-level cadres* -Medical officer-eye care -Medical officer-medical care
Number of institutions n=1 Number of interviews n= 7	Number of institutions n=1 Number of interviews n=7	Number of institutions n=1 Number of interviews n= 6

Table 2. Providers participated in the study with national level program planning capacity

Ministry of Health, Sri Lanka	**Professional bodies engage in DR screening program development**	**Professional bodies of eye care related paramedical staff**
National blindness prevention program VISION 2020 National program	College of Ophthalmologists of Sri Lanka Association of Vitreo-retina Specialists of Sri Lanka	School of Ophthalmic Technologists of Sri Lanka School of Nursing

VISION 2020 Diabetic retinopathy blindness prevention program	Ceylon College of Physicians College of Endocrinologists of Sri Lanka	Sri Lanka Optometric Association

Twenty interviews were conducted with clinicians which included physicians, ophthalmologists, including retina specialists and other clinical staff, i.e., medical officers and nursing officers. Criteria for their selection was having active involvement in DR blindness prevention programme planning and clinical management of people with DM. Seven interviews were conducted with staff at a policy, planning and advisory level. At the national level, programme planners were selected from the Ministry of Health and representatives of professional bodies. At the institutional level hospital administrators i.e., head of the same selected hospital were selected. Details of the providers are described in Tables 1 and 2.

Analysis

A thematic analysis was undertaken. Interviews conducted in local language were translated into English. Two stages of the analysis were conducted. All scripts were read by the lead sociologist who identified the key themes and then a second sociologist reviewed the coding, and in further discussion with the main investigator final themes and sub-themes were agreed upon. The derived themes were categorised according to the WHO health system building blocks and additional themes were categorised separately and considered for inclusion in relevance to development of an integrated DR screening programme in the Western province.

Ethics

Ethical approval was obtained from both ethics review committees of the National Eye Hospital-Sri Lanka and the London School of Hygiene & Tropical Medicine-United Kingdom. Written informed

consent was obtained from the providers after explaining study objectives. Consent was obtained for participation, audio recording and for the use of anonymous quotes in publications.

Results

Providers characteristics

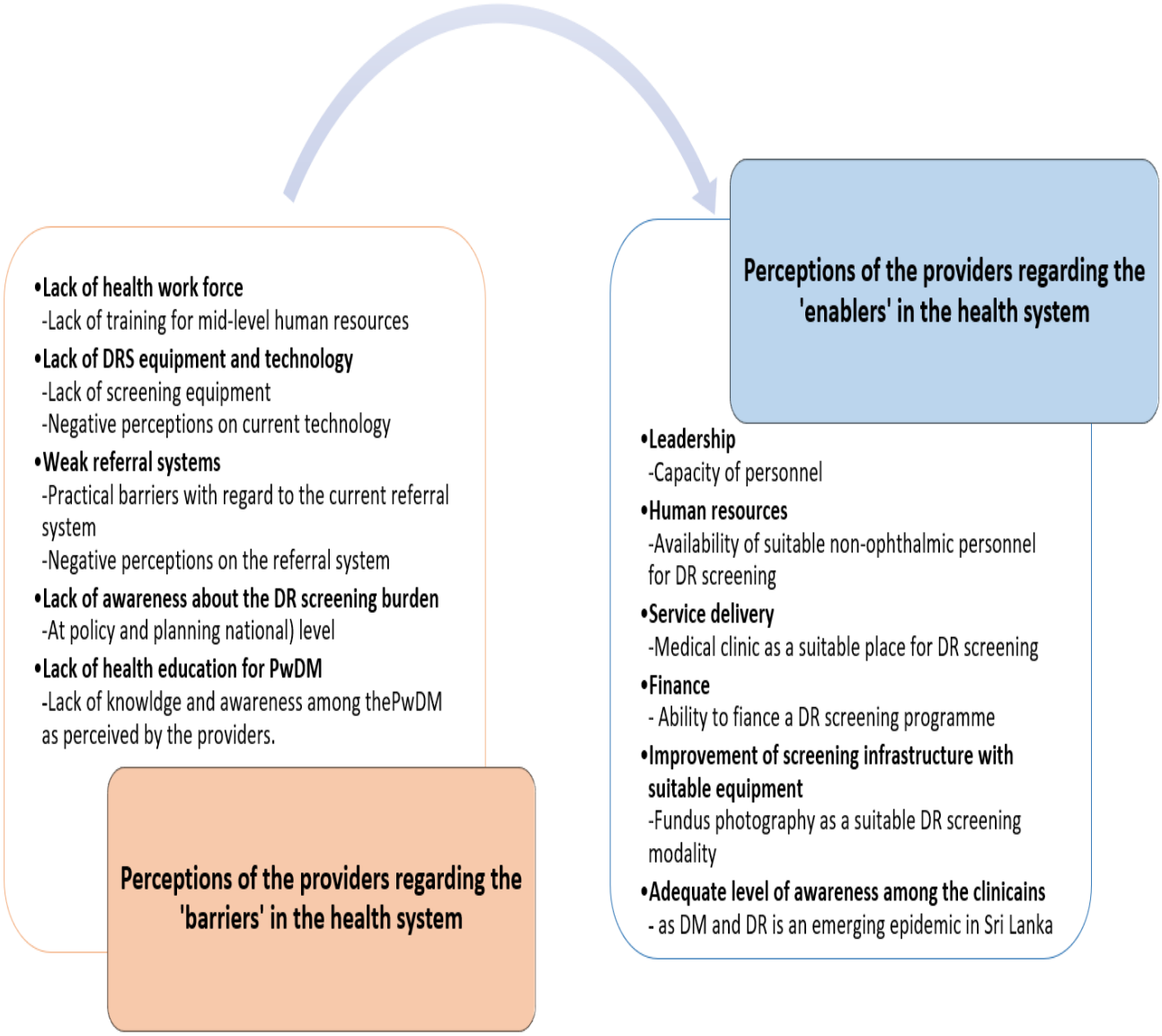
Fifty two percent (14/27) of the service providers were male. Eleven (11/27, 40%) were program planners or policy makers at national or institutional level (representatives from the national blindness prevention program, representatives of professional bodies, heads of the institutions and a nursing administrator). The other 16 providers consisted of clinical staff, including seven specialists (from internal medicine, endocrinology, general ophthalmology and sub-speciality of vitreo-retina). The overall educational level of participants was high with 78% (21/27) having completed tertiary level medical training and the remainder had a diploma in nursing or optometry. On average, the providers had worked for 20 years in government health services including 14 years in diabetes care / eye care. Over half of the providers (16/27, 60%) were senior officials working in the Ministry of Health at national level or under the Regional Director of Health Services.

Perceptions of the providers

The main themes and subthemes identified were overall provider knowledge and awareness of the current load of DR screening i.e., what is being done by the clinicians as well as what needs to be done, lack of a systematic approach for referrals, limited skilled human resources (HR) and poor DR screening infrastructure to deliver including equipment and technology.

In addition, providers described their perception of the barriers faced by people with DM when accessing screening services. The barriers, enablers and providers' suggestions to implement a program are described in Figure 1 (see Additional File 2 in Appendix 7 for full details).

Figure 1. Schematic representation of provider perceptions



Overall provider awareness on current DR screening situation

Overall there was good awareness about the current prevalence of DR in the region amongst all levels of providers and recognition that DR is an important emerging health problem. It was common for clinicians to reflect on their very high workload, as described here by a retinologist, *"It is a burden. So exactly I don't have the figures, but I am getting a lot of patients"*.

Hospital administrators generally reflected on the broader social and economic implications, "*It is really an emerging issue. It is a challenge for us, economically, socially and psychologically" (Hospital*

administrator, 3ry level). Despite gaps in service delivery, and burden on clinicians, there was poorer knowledge at the policy level about the availability of screening services.

Barriers to systematic DR screening

Health work force

Mid-level cadres of staff, such as the medical officers, reported that training on DR screening was not available for them, which commonly resulted in referring all people with DM to the next level of already over-subscribed ophthalmologist's clinic. They pointed out that the relevant skills were not acquired in general medical training, and that unless a medical officer underwent residency in ophthalmology, they would not have been trained in DR screening and treatment.

> *"You know in current setting; one patient coming with an eye problem is seen by several doctors. This is happening because nobody has proper training on DR screening on their career other than consultant ophthalmologists or vitreo-retinal surgeons". (Medical officer, 3ry level)*

In contrast, program planners were more likely to express their concern that introducing DR screening training may destabilize the existing system, and that it would be difficult to find someone who would be willing to take on the responsibility of training on DR screening. *"It is like a 'ball passing game'. Identifying personnel with genuine interest in this problem is the biggest challenge, in the development of a screening program"*.

Poor DR screening equipment and technology

Medical officers in general medical clinics currently screen for DR using direct ophthalmoscopy without dilating the pupils. They described lack of suitable equipment and poor diagnostic services in their clinics as a limiting factor, which generally resulted in all people with DM being referred to eye clinics. This has implication for people with DM who had to make yet another hospital visit, as well as adding to the workload on specialist eye clinics, as illustrated by one medical officer. *"Generally, we do un-dilated direct ophthalmoscopy as the DR screening intervention at medical clinics. You know…*

you can hardly see anything. Therefore, we refer all the patients to specialist's eye clinic". (Medical officer, 2ry level).

In addition, some medical officers at secondary level hospitals highlighted the lack of DR screening equipment as another challenge they faced,-*"We don't have the needed gadgets like even the simple ophthalmoscopes" (Medical officer, 2ry level).* Clinicians' knowledge was also poor about the process of procurement and purchase of medical supplies related to DR screening at the clinic level. Similarly, knowledge about the equipment requirements for screening was limited at the programme planning level. Overall most providers recommended the need to develop and assess the feasibility of DR screening using fundus photography, recognising that only retinologists currently have adequate technical knowledge to do this.

Referral systems

Weak referral systems from medical clinic to eye clinic, as a key barrier was a major recurrent theme. The lack of a register of people with DM at any level was the main challenge highlighted by clinicians: *"One of the issues is, we don't have a proper referral system in this country, any patient can walk into our clinics at any time, whether private sector or public". (General Ophthalmologist, 3ry level).* The clinicians further elaborated that there was no coordination between medical and eye clinics, and a system for follow up, and that this contributed to drop out after referral. In addition, medical officers at medical clinics stated that current referral system is very inconvenient for people with DM including those with disabilities due to long waiting time at the specialist eye clinic. Non-ophthalmic providers had a view that only the dedicated eye care hospitals should provide DR screening services. Therefore, they referred most of the people with DM to one institution, without referring to the nearest specialist eye clinic.

> *"Only those who are coming to the XX Hospital are undergoing DR screening at that occasion. It is not a regular thing. I think only about half of the diabetics in this region undergo screening" (Physician, 2ry level).*

In contrast, ophthalmologists provided a different view stating that they screen all the people with DM attending an out-patient department irrespective of the availability of a referral letter, "*We identify the*

all diagnosed diabetics at OPD (out-patient department) level and in my unit, I have advised the juniors (doctors) to screen all the diabetics on the same day". (Ophthalmologist, 3ry level). In addition, physicians stated electronic or manual record system like diabetic patients' register would enable tracking for follow-up.

Lack of health education

Low levels of knowledge and awareness of DR among people with DM was another identified subtheme, and a reason given for poor uptake of treatment. Providers emphasised that this is due to lack of health educational interventions on DR in hospitals or clinics level: *"We don't have a proper health education system in our hospitals. The health education on DR, educating the patients about the gravity, follow up should be tackled at primary care levels, may be by physicians or medical officers". (Ophthalmologist, 2ry level).*

Enablers to develop a DR screening program

Capacity of personnel in leadership

There were two main contrasting views about who should lead the development and implementation of a DR screening program. Most of the specialist clinicians thought that implementation of a DR screening program, should be under the leadership of an ophthalmologist i.e., as a head of a campaign while senior administrators with decision making capacity suggested that leadership and governance of a program should be by a medical administrator in the Ministry of Health.

Suitable non-ophthalmic personnel for DR screening

For the first line of screening, all levels of providers agreed that this should be undertaken by medical officers in the medical clinics i.e., where people with DM receive care for their diabetes. Some providers were of the view that screening should be provided wherever they come into contact with health care personnel, suggesting that this be done by non-ophthalmic personnel in medical clinics, general practitioners' clinics and sub-speciality clinics such as endocrinology clinics; "*The doctor*

who treat diabetes could be a GP (general practitioner), or maybe a physician, maybe an endocrinologist, whoever the primary care physician who is looking after the condition (diabetes mellitus), is the ideal person". (General physician, 3ry level).

Financing

There were contrasting views about means of financing a DR screening program. Sub-themes were funding through the Ministry of Health, non-governmental funds and raising funds by a user fee or through foreign aid. Some service providers pointed out that the main difficulties lay in efficient channelling of funds for a screening program as described by a senior ophthalmologist: *"Money itself is not a problem. Most of the problems are due to administrative issues in handling and channelling the funds".*

Improvement of screening infrastructure with suitable equipment

Most providers suggested that the most suitable modality of DR screening for this region would be fundus photography. In addition, they proposed that the competency of non-ophthalmic personnel in retinal imaging should be developed rather than that of ophthalmic personnel. Ophthalmologists suggested that a comprehensive network of screening could be achieved by having peripheral screening units connected through tele-ophthalmology, *"The best modality would be digital retinal imaging with facility to transfer images for expert opinion using tele-ophthalmology". (Ophthalmologist, 3ry level).* Further, it was highlighted that this was a practical option, as this approach was already being used in the region, in private sector.

Discussion

The WHO recommends provision of patient centred care for DR by using locally adaptable strategies such as selecting the most appropriate method and personnel for DR screening [11]. However, this is often not followed in most low and middle-income countries (LMICs) for a broad range of reasons. In this study, we identified the barriers and enablers in the Sri Lanka context from the public sector

provider's perspective. This is one of several articles which are part of a larger feasibility study which inform the development of a systematic DR screening program.

There is a paucity of studies on challenges faced by those providing DR screening services in LMICs, and this is one of the first studies in Sri Lanka. Our study showed that program planners and administrators had low levels of awareness of the very high workload in clinics and hospitals resulting from the increasing number of patients with DR. Similar findings have been reported in other LMIC settings, such as India [12] and Nigeria [13]. Provider understanding on the need and current situation of services are key elements of development of a successful systematic screening program [14]. This points to the need for improve channels of communication on service level needs, as well as stronger leadership on training HR and implementing a DR screening program.

The lack of skilled HR was another key barrier in our study, which has also been reported in studies conducted in other settings; Sub-Saharan Africa [15], Kenya [16] and the Mediterranean region [17]. In the Western province this is unlikely to be due to a shortage of medical staff as this province has the highest number of health care professionals in the country [18]. Instead it points to the needs for training of a suitable cadre such as mid-level medical officers in DR screening. Task shifting has been used as a means of identifying DR in Nigeria for example, where non-ophthalmologist physicians were trained to examine the retina of PwDM, which improved uptake [13]. The potential for task sharing has been assessed in Pakistan and Cambodia showing the possibility of improving access [19,20] . To achieve task shifting, training needs to be competency based with systems for quality assurance, and screening methods with high level of validity should be used, such as retinal imaging. In addition, screening by non-ophthalmic personnel needs to be acceptable to the providers as well as those being screened, for example, a study conducted in Fiji reported that general doctors are suitable for DR screening [21]. The lack of awareness about techniques of DR screening has been observed as a barrier in various studies in both low and high income settings; a study done in Myanmar showed

lack of familiarity on techniques of fundus examination among the general practitioners [22] and the lack of training on preferred practice patterns among the physicians was a hindrance to screening uptake in a study conducted in China [23]. Further, need of prioritisation of vitreo-retina as a sub-speciality has been mentioned as a requirement to establish DR screening programs in LMICs [15].

Low levels of awareness about DR and the importance of screening amongst PwDM, combined with an absence of available health education materials were also barriers highlighted in our study. We reported a similar finding in our previous study of assessing the user perspectives using focus group discussions. Recent 'Rapid Assessment of Avoidable Blindness - DR' (RAAB-DR) studies demonstrate the need of increased awareness among the users [24]. The lack of effective communication between providers and service users has been reported in several countries [25–28] whilst the need for educational strategies for both clinicians and people with DM have been shown to improve uptake of DR screening services in various studies [22,29,30]. The previous studies showed that provision of health education by the service provider was an incentive to improve uptake [25–31]. Factors which improve uptake of screening in these studies include showing fundus images to the people with DM [32], emphasising the importance of an annual eye examination [33] and using simple language in letters inviting people for screening [34]. However, health education requires staff to have good communication skills and adequate time which appear to be lacking in the clinics in Sri Lanka, and task sharing, and training may be a way forward.

Lack of an organised systematic system for screening, including onward referral was another barrier in the Western province, which has also been reported from studies in Nigeria and Turkey [13,35]. In our previous study we reported similar barriers faced by the service users when accessing DR screening services in the Western province. Even in high income countries a weak appointment system is a barrier to access [36]. A study set in the United Kingdom showed that re-organisation of the booking systems is required to improve efficiency [37]. Service providers in the Western province

recommended that the most suitable health management information system would be an electronic system. However, considering the limited resources, a manual record system is likely to be the more pragmatic approach for this local context.

Our study showed lack of suitable equipment and lack of efficient new techniques such as digital imaging was a major barrier to uptake. This has been similarly highlighted in a RAAB-DR study conducted in Costa Rica [38]. The reports from International Agency for the Prevention of Blindness highlighted that low income countries are ill equipped to identify and manage DR [39]. However, feasibility of using imaging technologies should be assessed in the local context, as reported in a study conducted in India [40]. The medical officers identified the practical limitations of the current method of DR screening using direct ophthalmoscopy, whilst dilated eye examination method with bio-microscopic examination was only available at specialist eye clinics. In addition, facilities should be able to offer for procedures such as visual acuity checking and pupil dilation, and the feasibility of this would need to be assessed before implementing a screening program. The lack of imaging and treatment infrastructure has similarly been shown to be one of the most common barriers in studies conducted in LMICs [13,15,16,22,41].

In our study, the recommendation from the majority of providers was the need to have more effective DR screening at the level of the medical clinic where it can be integrated with general diabetic care. This also ties in recommendations in other studies [42–45]. This should be accompanied by stronger leadership in directing the program. However, DR screening in a non-ophthalmic setting would depend on the acceptance of task shifting by the physicians. Most of the providers agreed that DR screening using imaging would be the most suitable modality.

There were a range of views on how best to finance a DR screening program. Financial barriers are major barriers in implementing a DR screening program in any setting [29]. However, financing a

program through the government would be feasible in Sri Lanka according to the providers' views. Considering the health system and how the blindness prevention programs in Sri Lanka is planned, incorporating DR screening program under the administration of VISION 2020 country program would be more appropriate and sustainable. In addition, it could attract external donors for bilateral funding schemes. On the other hand, the DR screening programs run by the governments have the potential to be more sustainable and scalable because of financial assurance and ability to use existing HR and infrastructure.

Limitations

There were several limitations to this study. There may have been an element of bias in interpretation of the data as the main investigator is a male Sri Lankan ophthalmologist who has worked in this region for a long time, and his occupation may have influenced what providers were willing to say to the investigator. Cultural factors, such as the hierarchical nature of the health system, may also have influenced the interviews, and there may have also been social desirability bias from staff who were unwilling criticise the system. However, we worked closely with a team of sociologists on the analysis and key themes, and this will have gone some way to mitigate any bias. In addition, local sociologists had different views regarding the current public health system in general which may have some effects on data analysis and interpretation. Another limitation is that providers working in the non-communicable disease control programme were not interviewed, as the program is not yet well established.

Only the tertiary and higher secondary levels health settings were targeted in this research and therefore the barriers and enablers at peripheral hospitals and primary care settings may have highlighted different issues. Another limitation was that the study was in the Western province only and therefore these findings may not be generalisable to a different region.

Conclusion

This study showed a range of provider perceived barriers to DR screening and their recommendations to improve uptake. It highlights a combination of service delivery issues at the medical clinic level

which need to be addressed, as well as the need for improved understanding of the needs at national level, with need for strong leadership commitment to implement a screening program. Training of existing non-ophthalmic human resources at medical clinic level by careful task-shifting and development screening infrastructure such as imaging systems under the funding schemes of Ministry of Health would be a feasible strategy to improve screening uptake.

Recommendations

- Improve the availability of DR screening by increasing the availability of skilled HR and instruments for screening. DR screening using an imaging method where people with DM present for their routine medical care, combining with a central tele-ophthalmology reading centre may improve the access.
- Train mid-level HR in medical clinic level as a preliminary strategy to assess the feasibility of an integrated DR screening program in this region. Task shifting, and training might improve the skills of DR screening among the mid-level personnel, enabling an environment for implementing systematic screening during routine medical care.
- Robust health educational strategies to improve the knowledge and awareness on DR and DR screening among the people with DM.
- Strengthen the referral network linking the medical and nearest specialists eye clinics for further assessment and treatment.
- Explore the channels of effective communication in between medical and eye clinics for improved follow-up of people with DM. Moreover, means of communications should be developed in between clinicians and programme planners.
- Explore the possibility of financing a DR screening program through bi-lateral funding schemes.

- Further research on the assessment of provider views incorporating all levels of service delivery with a special attention at peripheral district hospitals and primary level of service delivery.

Additional files in Appendix 7

7.1 - Additional file 1 - Semi-structured interview topic guide

7.2 - Additional file 2 - Tables of main domains of barriers and enablers identified by the providers

References cited in submitted manuscript (Chapter 9)

1. Diabetes Atlas of International Diabetes Federation (IDF). Eighth Edition 2017. http://www.diabetesatlas.org/resources/2017-atlas.html. Accessed 15 March 2018.
2. Yau JWY, Rogers SL, Kawasaki R, Lamoureux EL, Kowalski JW, Bek T, et al. Global prevalence and major risk factors of diabetic retinopathy. Diabetes Care. 2012;35(3):556–64. http://dx.doi.org/10.2337/dc11-1909. PMID: 22301125.
3. Jones S, Edwards R. Diabetic retinopathy screening : a systematic review of the economic evidence. Diabet Med. 2010;27(3):249–56. doi: 10.1111/j.1464-5491.2009.02870.x. PMID: 20536486.
4. Taylor-Phillips S, Mistry H, Leslie R, Todkill D, Tsertsvadze A, Connock M, et al. Extending the diabetic retinopathy screening interval beyond 1 year: systematic review. Br J Ophthalmol 2016;100(1):105–14. http://dx.doi.org/10.1136/bjophthalmol-2014-305938.
5. Scanlon PH. Screening Intervals for Diabetic Retinopathy and Implications for Care. Current Diabetes Reports; 2017;17(96):1–8. DOI: 10.1007/s11892-017-0928-6 PMID: 28875458.
6. Levesque JF, Harris MF, Russell G. Patient-centred access to health care: Conceptualising

access at the interface of health systems and populations. Int J Equity Health. 2013;12(1):1-5. DOI: 10.1186/1475-9276-12-18. PMID: 23496984

7. Penchansky R, Thomas J. The concept of access-Definition and relationship to comsumer satisfaction. Med Care. 1981;19(2):127–40. PMID: 7206846

8. Katulanda P, Rathnapala D, Sheriff R, Matthews D. Province and ethnic specific prevalence of diabetes among Sri Lankan adults. Sri Lanka J Diabetes Endocrinol Metab. 2012;1(1):2–7. http://sjdem.sljol.info/articles/10.4038/sjdem.v1i1.4180/.

9. Piyasena PN, Murthy GVS. A situation analysis of diabetic eye care service delivery in health care institutions of the Western Province of Sri Lanka. Ceylon Med J. 2017;62(September 2016):205–6. http://doi.org/10.4038/cmj.v62i3.8527.

10. The World Health Organisation Frame Work : Health Services Development. 2017 http://www.wpro.who.int/health_services/health_systems_framework/en/. Accessed on 12 Feb 2018.

11. The World Health Organisation. Perevention of blindness from diabetes mellitus - Report of WHO Consultation in Geneva. 2005. https://www.who.int/blindness/Prevention%20of%20Blindness%20from%20Diabetes%20Mellitus-with-cover-small.pdf Accessed on 12 Feb 2018.

12. Namperumalsamy P, Kim R, Kaliaperumal K, Sekar A, Karthika A, Nirmalan PK. A pilot study on awareness of diabetic retinopathy among non-medical persons in South India. The challenge for eye care programmes in the region. Indian J Ophthalmol. 2004;52:247–51. PMID: 15510470

13. Onakpoya OH, Adeoye AO, Kolawole BA. Determinants of previous dilated eye examination among type II diabetics in Southwestern Nigeria. Eur J Intern Med. 2010;21(3):176–9. DOI: 10.1016/j.ejim.2010.01.009. PMID: 20493418

14. Foster A. Planning a programme to prevent visual loss from diabetic retinopathy. Comm Eye

Heal. 2015;28(92):s1-s5. PMID: 27418736

15. Burgess PI, Msukwa G, Beare NA V. Diabetic retinopathy in sub-Saharan Africa: meeting the challenges of an emerging epidemic. BMC Medicine 2013;11(1):157. DOI: 10.1186/1741-7015-11-157. PMID: 23819888.

16. Kurji K, Kiage D, Rudnisky CJ, Damj KF. Improving Diabetic Retinopathy Screening in Africa: Patient Satisfaction with Tele-Ophthalmology Versus Ophthalmologist Based Screening. Middle East Afr J Ophthalmol. 2013;20(1):56–60. doi: 10.4103/0974-9233.106388. PMID: 23580853

17. Khandekar R. Screening and public health strategies for diabetic retinopathy in the Eastern Mediterranean Region. Middle East Afr J Ophthalmol. 2012;19(2):178. doi: 10.4103/0974-9233.95245. PMID: 22623855.

18. Ministry f Health Sri Lanka - Medical Statistics Unit. Annual Health Bulletin Srilanka. 2017. 35-36 p. http://www.health.gov.lk/moh_final/english/public/elfinder/files/publications/AHB/2017/AHB2015.pdf. Accessed on 15 May 2018

19. Shah M, Noor A, Deverell L, Ormsby G, Harper C, et al. Task sharing in the eye care workforce: Screening, detection and management of diabetic retinopathy in Pakistan. A case study. Int J Heal Plann Manag. 2018;11. PMID: 29527739 DOI: 10.1002/hpm.2508

20. Shah M, Ormsby G, Noor A, Chakrabarthi R, Morcehn M. et al. Roles of the eye care workforce for task sharing in management of diabetic retinopathy in Cambodia. Int J ophthalmol. 2018;11(1):101-107. PMID: 29375999 doi: 10.18240/ijo.2018.01.18

21. Kool B, Webber M, McCool J. DR services in Fiji : attitudes, barriers and screening practices. Community Eye Health. 2015;28(92):s6-s11. PMID: 27418742

22. Muecke JS, Newland HS, Ryan P, Ramsay E, Aung M, Myint S, et al. Awareness of diabetic eye disease among general practitioners and diabetic patients in Yangon, Myanmar. Clin Exp

Ophthalmol. 2008 Apr;36(3):265-73. doi: 10.1111/j.1442-9071.2008.01724.x. PMID: 18412597

23. Wang D, Ding X, He M, Yan L, Kuang J, Geng Q, Congdon N. Use of Eye Care Service among Diabetic Patients in Urban and Rural China. Ophthalmology 2010;117:1755-1762 PMID: 20471689 DOI: 10.1016/j.ophtha.2010.01.019

24. Burnett A, Lee L, D'Esposito F, Wabulembo G, Cama A, Et A. Rapid assessment of avoidable blindness and diabetic retinopathy in people aged 50 years and older in the National Capital District of Papua New Guinea. Br J Ophthalmol. 2018;4. PMID: 29973367 doi:10.1136/bjophthalmol-2017-311803.

25. Xiong Y, Liu L, Chen Y, Zhao J. Survey on the awareness of diabetic retinopathy among people with diabetes in the Songnan community of Shanghai. Int Eye Sci. 2015(15);7:1117-22

26. Hartnett ME, Key IJ, Loyacano MN, Horswell RL, DeSalvo KB. Perceived Barriers to Diabetic Eye Care-Qualitative study of patinets and physicians. Arch Ophthalmol. 2005;123:387–91. DOI: 10.1001/archopht.123.3.387 PMID:15767483.

27. Huang OS, Tay WT, Tai ES, Chb MB, Wang JJ, Saw S, et al. Lack of Awareness amongst Community Patients with Diabetes and Diabetic Retinopathy : The Singapore Malay Eye Study. Ann Acad Med Singapore. 2009 Dec;38(12):1048-55. PMID: 20052439

28. Hwang J, Rudnisky C, Bowen S, Johnson JA. Socioeconomic factors associated with visual impairment and ophthalmic care utilization in patients with type II diabetes. Can J Ophthalmol 2015;50(2):119–26. DOI: 10.1016/j.jcjo.2014.11.014. PMID: 25863851.

29. Adriono G, Wang D, Octavianus C, Congdon N. Use of eye care services among diabetic patients in urban Indonesia. Arch Ophthalmol. 2011;129(7):930–5. DOI: 10.1001/archophthalmol.2011.147. PMID: 21746983.

30. Agarwal S, Mahajan S, Kumari Rani P, Raman R, Paul PG, Kumaramanickavel G, et al. How High is the Non-Response Rate of Patients Referred for Eye Examination from Diabetic

Screening Camps? Ophthalmic Epidemiol. 2005;12(6):393–4. DOI: 10.1080/09286580500278418. PMID: 16283991.

31. Hazavehei SMM, Jeihooni AK, Hasanzadeh A, Amini S. The Effect of Educational Program Based on BASNF Model for Eye Care in Non-insulin Dependent Diabetic Patients. J Heal Serv Res. 2010;10(2):81–90. PMID: 22911929

32. Eiser JR, Eiser C, Riazi A. Screening for diabetic retinopathy is well received by patients and may improve self-management intentions. Diabet Med. 2001 Oct;18(10):835-41.PMID: 11678975

33. Moss SE, Klein R, Klein BE. Factors associated with having eye examinations in persons with diabetes. Arch Fam Med. 1995;04:529–34. PMID: 7773429

34. Orton E, Forbes-Haley A, Tunbridge L, Cohen S. Equity of uptake of a diabetic retinopathy screening programme in a geographically and socio-economically diverse population. Public Health. 2013;127(9):814–21. DOI: 10.1016/j.puhe.2013.04.015. PMID:23973045.

35. Çetin EN, Zencir M, Fenkçi S, Akin F, Yildirim C. Assessment of awareness of diabetic retinopathy and utilization of eye care services among Turkish diabetic patients. Prim Care Diabetes. 2013;7(4):297–302. DOI: 10.1016/j.pcd.2013.04.002. PMID: 23639610.

36. Dervan E, Lillis D, Flynn L, Staines A, O'Shea D. Factors that influence the patient uptake of diabetic retinopathy screening. Ir J Med Sci. 2008;177:303–8. DOI: 10.1007/s11845-008-0192-5. PMID: 18641918

37. Lewis K, Patel D, Yorston D, Charteris D. A qualitative study in the United Kingdom of factors influencing attendance by patients with diabetes at ophthalmic outpatient clinics. Ophthalmic Epidemiol. 2007;14(6):375–80. DOI: 10.1080/09286580701375195. PMID:18161611.

38. Castellon R, Vargas E, Chavarria R, Vargas G. Rapid assessment of avoidable blindness and diabetic retinopathy in individuals aged 50 years or older in Costa Rica. PLoS One.

2019;42(2):e0212660. https://doi.org/10.1371/journal.pone.021.

39. Kourgialis N. Diabetic Retinopathy - Silently bllinding millions of people world wide [Internet]. IAPB Technical Report. Available from: http://atlas.iapb.org/vision-trends/diabetic-retinopathy/. Accessed on 10 April 2019.

40. Gupta V, Bansal R, Gupta A, Bhansali A. Sensitivity and specificity of nonmydriatic digital imaging in screening diabetic retinopathy in Indian eyes. Indian J Ophthalmol. 2014;62(8):851-6. doi: 10.4103/0301-4738.141039. PMID: 25230960

41. Bamashmus MA, Gunaid AA. Khandekar R. Regular Visits to a Diabetes Clinic Were Associated with Lower Magnitude of Visual Disability and Diabetic Retinopathy. A Hospital-Based Historical Cohort Study in Yemen. Diabetes Technol Ther. 2009:(11)1:45-50. DOI: 10.1089/dia.2007.0299.

42. Lindenmeyer A, Sturt JA, Hipwell A, Stratton IM, Gadsby R, Hare JPO, et al. Influence of primary care practices on patients' uptake of diabetic retinopathy screening : a qualitative case study. Br J Gen Pract. 2014 Aug;64(625):e484-92. doi: 10.3399/bjgp14X680965. PMID: 25071061.

43. Hipwell AE, Sturt J, Lindenmeyer A, Stratton I, Gadsby R, O'Hare P, et al. Attitudes, access and anguish: a qualitative interview study of staff and patients' experiences of diabetic retinopathy screening. BMJ Open. 2014;4(12):e005498. doi:10.1136/bmjopen-2014-005498

44. Lee PP, Meredith LS, Whitcup SM, Spritzer K, Hays RD. A Comparison of Self-Reported Utilization of Ophthalmic Care for Diabetes in Managed Care Versus Fee-For-Service. Retina. 1998;18:356–9. PMID: 9730180

45. Shih HCh, Chou P, Chen SJ, Liu JH, Lee FL, Liu CM, et al. A Community Based Study of the Willingness to pay associated with Screening for Diabetic Retinopathy among Type 2 Diabetes in Kinmen, Taiwan J Epidemiol. 2007;17(6):186–95. PMID: 18094517

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
E: registry@lshtm.ac.uk

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

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Student	Mapa Mudiyanselage Prabhath Nishantha Piyasena
Principal Supervisor	Prof.G.V.S.Murthy
Thesis Title	A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	Bio Med Central (BMC) - Systematic Review - Open Source		
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Student Signature: [redacted] **Date:** 27/03/2019

Supervisor Signature: [redacted] **Date:** 27/03/2019

Piyasena et al. Systematic Reviews (2018) 7:182
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Systematic Reviews

RESEARCH Open Access

Systematic review and meta-analysis of diagnostic accuracy of detection of any level of diabetic retinopathy using digital retinal imaging

Mapa Mudiyanselage Prabhath Nishantha Piyasena[1*], Gudlavalleti Venkata S. Murthy[1], Jennifer L. Y. Yip[1], Clare Gilbert[1], Tunde Peto[2], Iris Gordon[1], Suwin Hewage[3] and Sureshkumar Kamalakannan[4]

Abstract

Background: Visual impairment from diabetic retinopathy (DR) is an increasing global public health concern, which is preventable with screening and early treatment. Digital retinal imaging has become a preferred choice as it enables higher coverage of screening. The aim of this review is to evaluate how different characteristics of the DR screening (DRS) test impact on diagnostic test accuracy (DTA) and its relevance to a low-income setting.

Methods: We conducted a systematic literature search to identify clinic-based studies on DRS using digital retinal imaging of people with DM (PwDM). Summary estimates of different sub-groups were calculated using DTA values weighted according to the sample size. The DTA of each screening method was derived after exclusion of ungradable images and considering the eye as the unit of analysis. The meta-analysis included studies which measured DTA of detecting any level of DR. We also examined the effect on detection from using different combinations of retinal fields, pupil status, index test graders and setting.

Results: Six thousand six hundred forty-six titles and abstracts were retrieved, and data were extracted from 122 potentially eligible full reports. Twenty-six studies were included in the review, and 21 studies, mostly from high-income settings (18/21, 85.7%), were included in the meta-analysis. The highest sensitivity was observed in the mydriatic greater than two field strategy (92%, 95% CI 90–94%). The highest specificity was observed in greater than two field methods (94%, 95% CI 93–96%) where mydriasis did not affect specificity. Overall, there was no difference in sensitivity between non-mydriatic and mydriatic methods (86%, 95% CI 85–87) after exclusion of ungradable images. The highest DTA (sensitivity 90%, 95% CI 88–91%; specificity 95%, 95% CI 94–96%) was observed when screening was delivered at secondary/tertiary level clinics.

Conclusions: Non-mydriatic two-field strategy could be a more pragmatic approach in starting DRS programmes for facility-based PwDM in low-income settings, with dilatation of the pupils of those who have ungradable images. There was insufficient evidence in primary studies to draw firm conclusions on how graders' background influences DTA. Conducting more context-specific DRS validation studies in low-income and non-ophthalmic settings can be recommended.

Keywords: Diabetes mellitus, Diabetic retinopathy, Diagnostic test accuracy, Digital imaging, Mydriatic, Non-mydriatic, Low income, Screening

* Correspondence: prabhath.piyasena@lshtm.ac.uk
[1]Clinical Research Department, International Centre for Eye Health, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT, UK
Full list of author information is available at the end of the article

Chapter 10

Systematic Review and Meta-Analysis of Diagnostic Accuracy of Detection of Any Level of Diabetic Retinopathy Using Digital Retinal Imaging

Piyasena MMPN, Murthy GVS, Yip JYL, Gilbert C, Peto T, Gordon I, Hewage S, Kamalakannan S. Systematic review and meta-analysis of diagnostic accuracy of detection of any level of diabetic retinopathy using digital retinal imaging. BMC Systematic Reviews 2018. 7:18 https://doi.org/10.1186/s13643-018-0846-y

Abstract

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Methods

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Results

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Conclusions

Non-mydriatic 2-field strategy could be a more pragmatic approach in starting DRS programs for facility based PwDM in low-income settings, with dilatation of pupils of those who have ungradable images. There was insufficient evidence in primary studies to draw firm conclusions on how graders' background influences DTA. Conducting more context specific DRS validation studies in low-income and non-ophthalmic settings can be recommended.

Key words

Diabetes mellitus, Diabetic retinopathy, diagnostic test accuracy, digital imaging, mydriatic, nonmydriatic, low income, screening

Background

Diabetes mellitus (DM) is one of the most prevalent non-communicable diseases and has significant impacts on health systems [1]. The International Diabetes Federation (IDF) estimated that there were 425 million people with DM (PwDM) in the world in 2017 which is projected to increase to 629 million by 2045 [2]. The greatest impact affects low and middle income countries (LMIC) (overall increase 69%) due to ageing population, obesity and sedentary life style [3]. This is exacerbated by weak health systems coupled with slow economic development [4]. Diabetic retinopathy (DR) is a common microvascular complication of DM caused by chronic hyperglycaemia [5]. A pooled meta-analysis using population based studies conducted in USA, Australia, Europe and Asia showed that the prevalence of any DR in PwDM aged 20 to 70 years was 34.6% (95% CI 34.5-34.8%): proliferative DR affected 6.96% (95% CI 6.87-7.04%) and sight threatening DR (STDR) affected 10.2% (95% CI 10.1-10.3%), globally translating to approximately 28 million PwDM affected by STDR [6]. DR is a leading cause of blindness among the young and middle-aged adults in most of the high-income countries (HIC).

Many studies have shown that control of risk factors, early DR screening (DRS) and appropriate treatment can reduce the risk of blindness and visual impairment due to DR [7–12]. Digital retinal imaging has been widely practiced and an accurate method for DRS [13]. Providing appropriate training to photographers is of paramount importance, and with enough practice, high levels of competence can be achieved by those taking imaging regularly. Non-mydriatic digital imaging methods cause less discomfort and are more convenient for service providers. However poor image quality is an important limitation of digital retinal imaging, particularly if non-mydriatic systems are being used, in countries where cataract is common [14].

In current literature, a systematic review showed that dilated imaging aided by fundoscopy for ungradable images was an effective modality to screen for DR [15]. This review included studies from

1985 to 1998 when digital retinal imaging technology was not available. Shi, L. et al. concluded that accuracy of detecting presence/absence of DR by tele-medicine using digital imaging is high (pooled sensitivity 80%, 95% CI 84-88%, pooled specificity 89%, 95% CI 88-91%) [16]. Another meta-analysis concluded that dilatation of pupils did not have a bearing on the diagnostic test accuracy (DTA) for any level of DR (sensitivity: odds ratio (OR)-0.89, 95% CI 0.56–1.41, p=0.61 and specificity: OR 0.94, 95% CI 0.57-1.54, p=0.80) [17]. A limitation of this review was that results from different imaging methods (i.e., polaroid, film and digital) and clinical examination were pooled into one estimate.

A DRS modality which is suited to the health system and its context is a key factor in the success of a program [18]. A screening program requires substantial investment in infrastructure and workforce development. LMICs have low capacity to implement a population-based DRS program (DRSP) with routine call/recall and full DR patient list. Yet there is a high burden of unmet need, with higher levels of uncontrolled DM leading to higher rates of DR progression. Weak health systems require a DRSP where detection of any DR using most effective and efficient instruments would be most useful. In addition, resources are scarce, and so efficient use of both equipment and human resources are essential. The detection of clinic based PwDM, with any DR will enable identification and stratifying risk groups early and screen safely at a lower threshold at non-ophthalmic settings. Therefore, a feasible way of providing accessible services is to offer digital photographic DRS when PwDM present for routine medical care at diabetologist/physicians clinics. In a low-income setting, identification of a person with any DR / no DR would be a helpful stratification for the providers. In a practical program guideline, we would suggest performing mydriatic imaging or refer to the next level for those with ungradable images. There is also a lack of understanding among the PwDM about the benefits of mydriasis. Discomfort experienced after pupil dilatation has led to low uptake in dilated examination [19]. Therefore, it is important to understand the best method to detect any DR in non-specialist settings, that will be suited to LMICs [18].

The objectives of this review were to evaluate how using or not using pharmacological dilation of the pupil and the number of fields captured influence DTA and how well different ophthalmic and non-ophthalmologist health care professionals perform DR grading compared to 7 field image grading or mydriatic ophthalmoscopy by ophthalmologists in different clinical settings. This will inform decision making for choosing strategy in those aspects of a DRSP. This is an assessment of accuracy of instruments for a systematic clinic-based screening rather than a population-based screening tool. We plan to propose most efficient modality for provision of DRS to PwDM at non-ophthalmic settings (i.e., medical clinic, endocrinology clinic) using this evidence.

Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines were followed in reporting (The PRISMA checklist is available as Additional file 1 in Appendix 8).

Eligibility criteria and study context

We included studies of cross-sectional study designs, that aimed to evaluate the accuracy of DRS using digital imaging as the index test, in PwDM at permanent healthcare facilities. We used the Early Treatment Diabetic Retinopathy Study (ETDRS) 7-field image interpretation as the gold standard, and mydriatic bio-microscopy/ophthalmoscopy by an ophthalmologist / retinologist as the clinical reference standard where the gold standard was not performed. The primary context considered for this review was institutional DRS clinics/programs using digital imaging. We categorised the context as either primary or secondary/tertiary. We excluded studies: conducted in informal health facilities, used automated analysis systems, used non-digital imaging methods in index test, used mobile screening methods or did not report on DTA as an outcome measure.

Primary outcome

The outcome examined was sensitivity and specificity of detection of ‘any level of DR’. It is important to understand the optimal method to detect any DR in non-specialist settings, especially in

LMICs where PwDM have higher risk of progression, due to poorly controlled risk factors and irregular follow up. 'Any level' of DR was considered appropriate as we felt that such an approach would have collateral benefits like raising awareness among the providers as well as augmenting awareness of PwDM regarding the importance of regular follow up and control of the risk factors minimising the progression to STDR.

Search and study selection

We developed a comprehensive search strategy to obtain published articles by consulting an information specialist and searched MEDLINE (Ovid), Cochrane Database of Systematic reviews (CDSR) and CENTRAL in the Cochrane Library. The data bases were searched from the date of inception of the data bases to September 2016, to identify any published reviews on this topic and to see whether relevant trials where included in the CENTRAL database. The search terms and strategy are shown in Table 1 and Figure 1 respectively. Two reviewers (PN and SK) independently assessed the eligibility of the titles and abstracts, and discrepancies were solved by consulting a 3rd reviewer (GV). Full papers of the eligible articles (n=122) were obtained from the publishers/authors.

Table 1. Electronic data bases search terms

1.Exp mass screening/ 2.Exp vision tests/ 3.Exp telemedicine/ 4.Exp Photography/ 5.Exp ophthalmoscopes/ 6.Exp ophthalmoscopy/ 7.(ophthalmoscop$ or fundoscop$ or funduscop$) . ti . 8.((photo$ or imag$) adj3 fundus) . tw . 9.(Photography or retinopgraphy) . tw . 10.((mydiatric or digital or retina$ or funduc or stereoscopic) adj3 camera) . tw . 11.((mydiatric or digital or retina$ or fundus or stereoscopic) adj3 imag$) . tw . 12.Screen$. tw .	13.((eye$ or retina$ or ophthalm$) adj4 exam$).tw . 14.((eye$ or vision or ophthalmic) adj4 test$) . tw . 15.((eye$ or retina$ or ophthalm$) adj4 visit$) . tw . 16.Office visits/ 17.(telemedicine$ or telemonitor$ or telescreen$) . tw . 18. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 19. exp diabetes mellitus/ 20. exp diabetes complications/ 21. 19 or 20 22. exp diabetic retinopathy/ 23. ((diabet$ or proliferative or non-proliferative) adj4 retinopath$).tw. 24. 21 or 22 25. 18 and 21 and 24

Data collection process

A data extraction form was prepared, and data were extracted and entered into a formatted MS Excel® database. Data from all the full reports of filtered citations (n=122) were extracted. We used a modified Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cross sectional studies to identify the components to extract [20]. The modifications made were based on Cochrane guidelines on conducting systematic reviews of studies of DTA [21]. Two independent reviewers extracted the data (PN and SK) from full reports. In the piloting stage data were extracted from 10% (12/122) of the articles by two reviewers and consistency was checked (SH). Corrections to the data extraction sheets and databases were done at this stage. The data extracted of all the included articles (n=26) were checked by the co-reviewer (SK) for consistency.

Data items

The data extracted from each study included country, study design, study setting, sample size and participant characteristics (mean age with standard deviation and range, male to female ratio, number of years with DM). The next section of the extraction included study objectives, sampling strategy, methods of index test (degree of view, number of fields, pupil status and type of camera) and method of reference standard. Finally, data on DTA (sensitivity with 95% CI, specificity with 95% CI, number of true positives, true negatives, false positives and false negatives, kappa value and gradability) were extracted. Studies were categorized according to the status of pupils, number of fields in imaging, type of index test grader and type of reference standard.

Meta-analysis

Meta-analysis of the data was conducted to examine differences in outcome due to pupil status (mydriatic and non-mydriatic), number of retinal fields (1 field, 2 fields, >2 fields), type of index test grader (ophthalmologist, retinologist, retinal reader, ophthalmic registrars) and by the context (primary and secondary/tertiary). A subgroup meta-analysis was undertaken to determine the DTA of 'any level' of DR by non-ophthalmic personnel. Further sub-analyses were conducted by considering the studies which reported on DTA using the same participant imaged before and after pupil dilatation.

Risk of bias in individual studies

We assessed the variations in bias using the Quality assessment of diagnostic accuracy studies - 2nd version (QUADAS-2) framework [22]. The methodological quality and applicability of the studies was considered using signalling questions under the four domains of patient selection, index test, reference standard and flow and timing [22]. We examined the differences in reported DTA estimates based on QUADAS-2 quality assessment guidelines and given results in the meta-analysis were based on the studies identified to have low risk of bias. The methodological quality of the studies included in the review and meta-analysis are described in Table 2. All included studies were cross sectional in design as these demonstrated less bias in the QUADAS assessment. We considered the signalling questions according to the QUADAS-2 guidelines as examples, masking of the graders, inclusion of range of spectrum to reduce the spectrum bias, all participant undertaking all tests etc. when assessing the bias.

Synthesis of results

Meta-analysis was conducted using STATA/IC (version-14.1, 2015-Texas-77845-USA) after acquiring the 2x2 table (TP, FP, TN and FN) values for number of eyes screened as the unit of analysis in each method of DRS. These values were cross checked by the number of DR positives and negatives reported in classification of findings under different categories of DR. The meta-analysis was conducted using the DTA of any DR, after excluding the ungradable images. Sub-analyses were conducted using the estimates that reported DTA on same participant groups before and after pupil dilatation and by non-ophthalmic index test graders.

Heterogeneity was assessed between the studies and between different modalities in the same study. Due to differences in definitions of the ungradable image category, we decided to exclude all ungradable images to minimise heterogeneity. At a practical program level, all PwDM with ungradable images will be referred to the ophthalmologist's clinic for further assessment. However, in this study we were interested in the accuracy of the intervention to detect any DR, rather than any referable PwDM in a program model.

Results

The electronic data base search yielded 6646 titles and abstracts and 122 studies were selected to review full reports. Twenty-six studies were included in the review (Figure 1). The details of the excluded articles are available as Additional file 2 in Appendix 8. We included 26 cross sectional studies and 88% (23/26) were conducted in HICs [23–45]. The remaining studies (3/26, 11%) were conducted in South East Asian upper-middle income countries (Thailand (one) [46], China (one) [47] and Taiwan (one) [48]). There were 6 studies (10 estimates) which reported DTA in which the same participant underwent imaging before and after pupil dilatation [25,35,40,42,44,47].

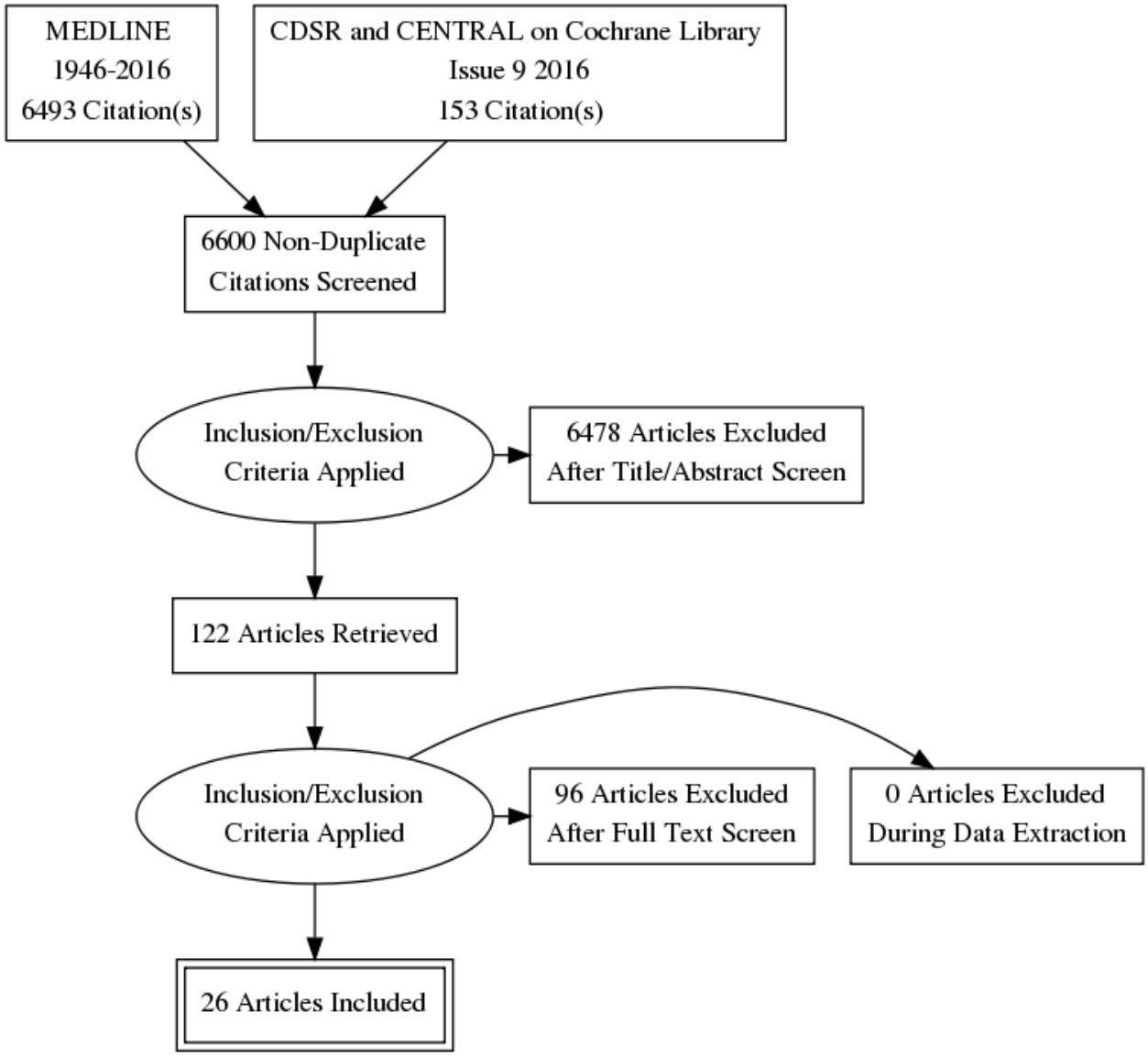


Figure 1. PRISMA flow diagram of the study selection process

The mean sample size of the studies was 316 PwDM screened (SE ± 72.3, 95% CI 166-467, range 51-1549). Thirty percent (8/26) of studies selected participants from local and regional primary care units. Other studies recruited PwDM from retinal care (5/26, 19.2%), diabetes care (4/26, 15.3%), existing DR screening programs (4/26, 15.3%), medical and ophthalmology care (1/26, 3.8%), retinal and ophthalmology care (1/26, 3.8%), ophthalmology care (1/26, 3.8%), private sector optometry network (1/26, 3.8%). One study did not report the setting (1/26, 3.8%). The mean age of participants was 57.4 years (SE ±1.52, 95% CI 54.3–60.7, range 16-89 years): the mean age of participants in nonmydriatic strategies 58.9 years and mydriatic 59.0 years. The mean duration of known diabetes among participants was 12.0 years (SE ±1.5, 95% CI 8.8-15.3 years, and 50.5% were male (SE ±2.7, 95% CI 44.8-56.3). Participants' characteristics tables of the studies included in this review are available as Additional file 3 in Appendix 8.

Meta-analysis

Of these 26 studies, 5 studies (5/26, 19.2%) were not eligible for the meta-analysis. Those were excluded from the meta-analysis due to unavailability of required 2x2 table data, very high level of bias and heterogeneity. The study conducted by Perrier M et al (2003) used the same participants as in the study by Boucher MC et al (2003) which has been included and another study was excluded due to a high likelihood of bias [33,36]. The study conducted by Schiffman RH et al (2005) was excluded as index test pupil status and number of retinal fields were not mentioned [30]. Two further studies were excluded: one only reported DTA for STDR [41] and another from Singapore (Bhargava M et al, 2012), did not provide DTA data [34].

Among 21 studies included in the meta-analysis 39 different modalities were identified in terms of pupil status, retinal field strategy and human resources involved in index test DR grading. Forty six percent (18/39 modalities) of the studies used non-mydriatic methods (13/21 studies) [25,26,29,31,35,38,40,42,44,45,47–49], 44% (17/39 modalities) used mydriatic methods (11/21 studies) [23–25,32,35,37,39,40,42,44,47] and ophthalmic personnel currently trained and practiced in DR grading had performed index test grading in these studies. In 10%, (4/21) [27,28,46,48] newer non-

ophthalmologist personnel had performed index test grading. Six studies reported mydriatic and non-mydriatic methods (6/21) [25,35,40,42,44,47]. One study reported DTA values for ophthalmic and non-ophthalmic personnel [48]. The DTA of each screening strategy is available in Additional file 4 in Appendix 8.

Table 2. Methodological quality and applicability assessment of the included studies (Using QUADAS-2 guidelines)

Domains	**Risk of bias**				**Applicability concerns**		
Study	**Patient selec-tion**	**Index test**	**Reference standard**	**Flow and timing**	**Patient selection**	**Index test**	**Reference standard**
1.Ahmed, J. et al 2006	Low	Low	Low	High	High	Low	Unclear
2.Aptel, F. et al 2008	Low	Low	Low	Unclear	Low	Low	Low
3.Baeza, M. et al 2009	High	Low	Low	Low	Low	Low	Low
4.Boucher, M. C. et al 2003	Low	Low	Low	High	High	High	Low
5.Ding, J. et al 2012	Low	Low	Low	Low	Low	High	Low
6.Hansen, A. B. et al 2004	High	Low	Low	Low	Low	Low	Low
7.Henricsson, M. et al 2000	Low	Low	Low	Unclear	Low	Low	Low
8.Herbert, H. M. et al 2003	Low	Low	Low	Low	Low	High	Low
9.Ku, J. J. et al 2013	Low	Low	Low	Unclear	High	Low	Low
10.Kuo, H. K. et al 2005	Low	Low	Low	Low	High	Low	Low
11.LopezBastida, J. et al 2007	Low	Low	Low	Unclear	Low	Unclear	Low
12.Maberley, D. et al 2002	Low	Low	Low	Low	High	High	Low
13.Massin, P. et al 2003	Unclear	Unclear	Low	Low	High	High	Low
14.Murgatroyd H et al 2003	Low	Low	Low	Low	Low	Low	Low
15.Neubauer, A. S. et al 2008	Low	Low	Low	Unclear	Low	Low	Low
16.Olson, J. A. et al 2003	Unclear	Low	Low	Unclear	Low	Low	Low
17.Phiri, R. et al 2006	Unclear	Low	Low	Low	Low	High	Low
18.Scanlon, P. H. et al 2003	Low	Low	Low	Low	High	High	Low
19.Scanlon, P. H. et al 2003 (2)	Low	Low	Low	Low	Low	High	Low
20.Suansilpong, A et al 2008	Low	Low	Low	Low	Low	Low	Low
21.Sundling, V. et al 2013	Low	Low	Low	Low	Low	Low	Low
Studies excluded in meta-analysis							
22.Bhargava, M. et al 2012	High	High	High	Unclear	Low	High	Low
23.Mizrachi, Y. et al 2014	High	High	High	High	High	High	Low
24.Perrier, M. et al 2003	High	Low	Low	High	High	High	Low
25.Schiffman, R.M. et al 2005	Low	High	High	Unclear	Low	High	High
26.Tu, K.L. et al 2004	High	High	High	Low	Low	High	Low

Studies included in secondary output analysis

Four studies were eligible for secondary output of meta-analysis of DTA of DRS as they used different non-ophthalmologist personnel [27,28,46,48]. However, there weren't adequate number of studies to meta-analyse by pupil status and field strategy. The details of these studies are described in Additional file 3 (participants' characteristics) and 4 (DTA) of Appendix 8.

Risk of bias and applicability concerns within studies

The methodological quality and applicability assessment of the included studies (Table 2) were according to the QUADAS-version 2 guidelines. In the assessment of bias, it was minimal (15.38% high risk) in conducting the index tests and reference tests. Nineteen percent of the studies showed high risk of bias in selection and 30.7% in participant flow and timing (Figure 2). In the assessment of applicability, risk was minimal in reference standard (3.8%) and 34% of the studies showed high risk in applicability with regard to patient selection and 50% in index test (Figure 3).

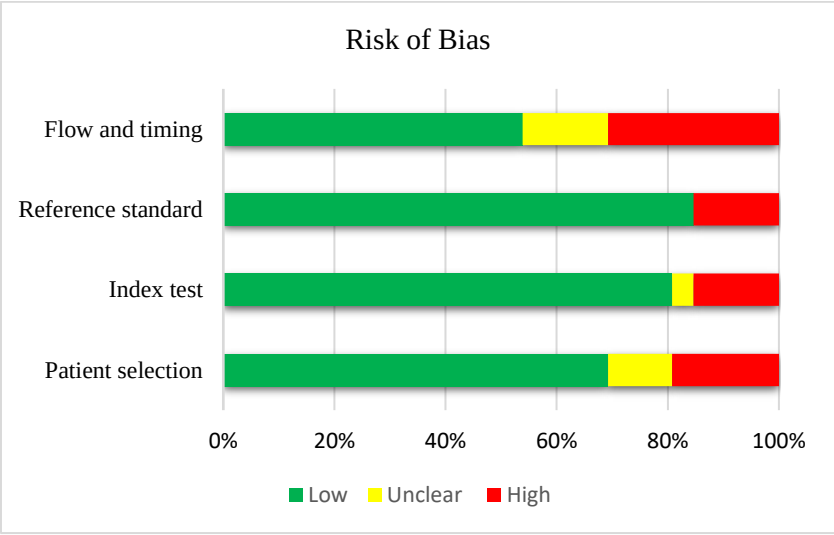


Figure 2. Proportion of included studies with a risk of bias

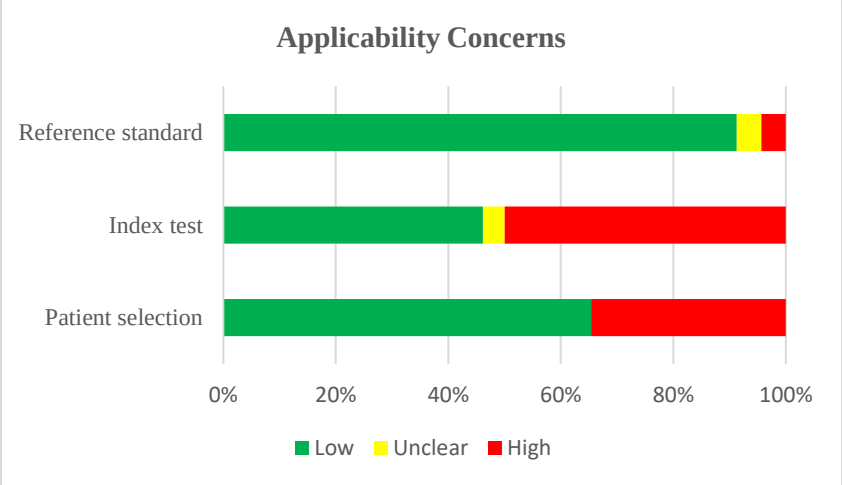


Figure 3. Proportion of included studies with applicability concerns

Risk of bias in the included studies.

There was selection bias in some studies: Baeza M et al excluded patients who had visited an ophthalmologist within 6 months of screening and those with hyper-mature cataract [44] and Boucher MC et al purposively selected participants who had a greater risk DR [31]. There were also applicability concerns when authors reported the DTA of referable level of DR [38–40,43,47]. The study conducted by Hansen AB et al, which selected people with diabetes through a record review, was weighted towards less severe retinopathy, as mentioned by the authors [25]. Two studies attempted non-mydriatic methods and ended up dilating the pupils due to high proportion of ungradable images [23,32]. In the study by Lopez-Bastida J et al, the time interval between the index and reference tests was not stated, nor whether participants with ungradable images (90/773, 10%) underwent mydriasis while performing the index test [45]. Similarly time and flow was not mentioned in the study by Ku JY et al [37]. Two studies selected indigenous populations which lead to generalizability concerns [32,37]. Furthermore, some studies were conducted in eye/retinal clinics where there was a possibility of high prevalence of advanced DR [39,43,48].

Reporting of DR was not uniform. In several studies DTAs were reported for different levels of DR leading to some heterogeneity [25,26,31,39,40,43]. In these studies, we considered results for the

detection of any level of DR. For example, Phiri, R. et al had defined DR including the macular signs which other authors had not considered and which would have an impact on the analysis [38].

Diagnostic test accuracy in non-mydriatic imaging

Among the 21 studies included in the meta-analysis, 18 used the following non-mydriatic imaging strategies: 1-field (8/18-44.4%), 2-field (4/18-22.2%) and >2 fields (6/18-22.2%). The pooled sensitivity of detection of any level of DR using non-mydriatic digital imaging was 86% (95% CI 85-87%). The 2-field strategy gave the highest estimate of sensitivity of 91% (95% CI 90-93%). The 1 and >2 field strategies gave summary estimates of sensitivity of 78% (95% CI 76-80%) and 88% (95% CI 86-91%), respectively. (Figure 4, Table 3) The mean proportion of ungradable images in non-mydriatic methods was 18.4% (SE ±2.2, 95% CI 13.6-23.3%). The summary estimate of specificity of detection of any level of DR using non-mydriatic digital imaging was highest in 2-field and >2 field strategy (94%, 2 field 95% CI 93-95%, >2 filed 95% CI 93-96%). The 1-field strategy gave pooled specificity values of 91% (95% CI 90-92%) (Figure 5 and Table 3).

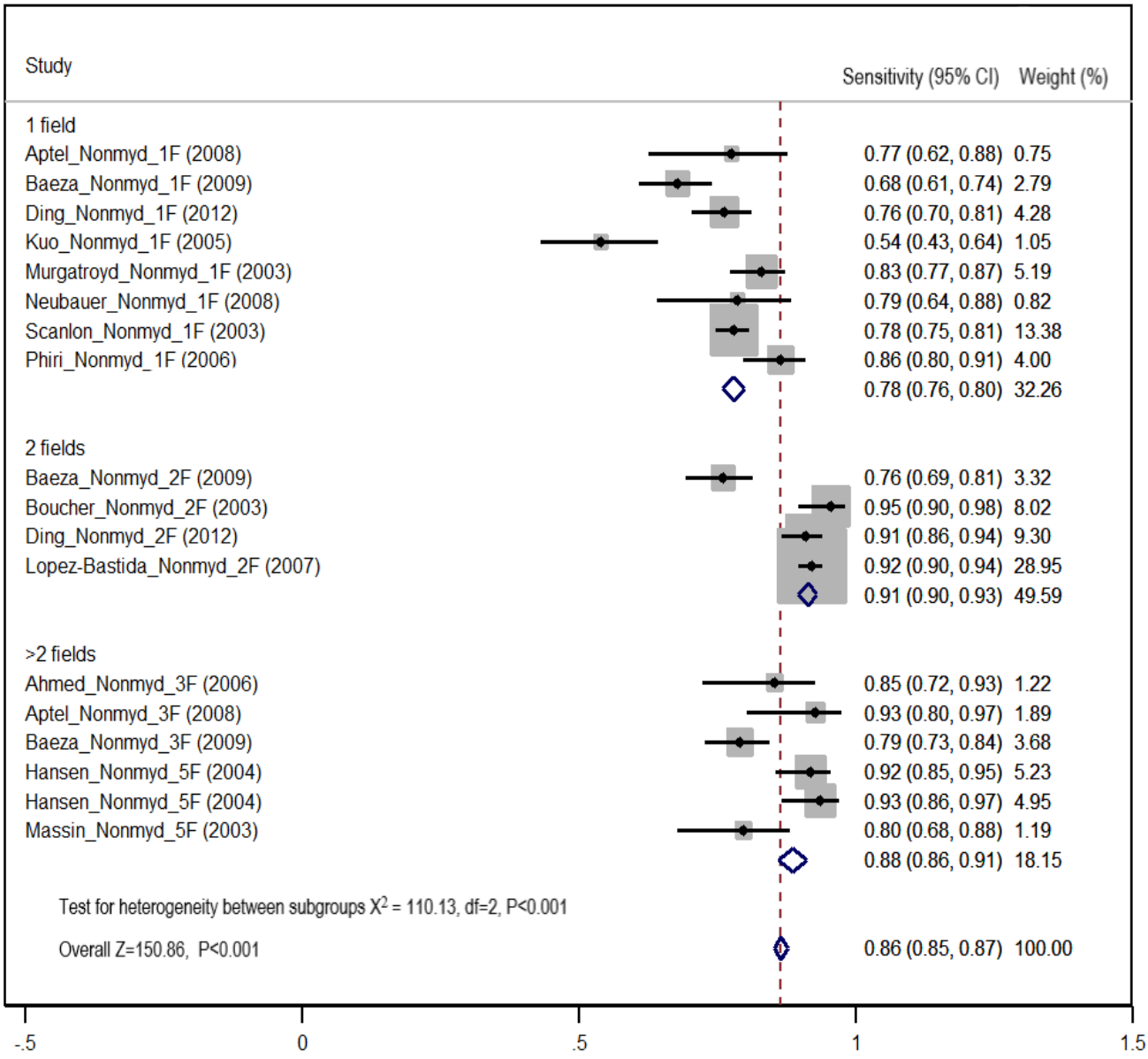


Figure 4-Forest plot of summary estimates of sensitivity of non-mydriatic imaging using different field strategies (1: 1 filed, 2: 2 fields, 3: >2 fields)

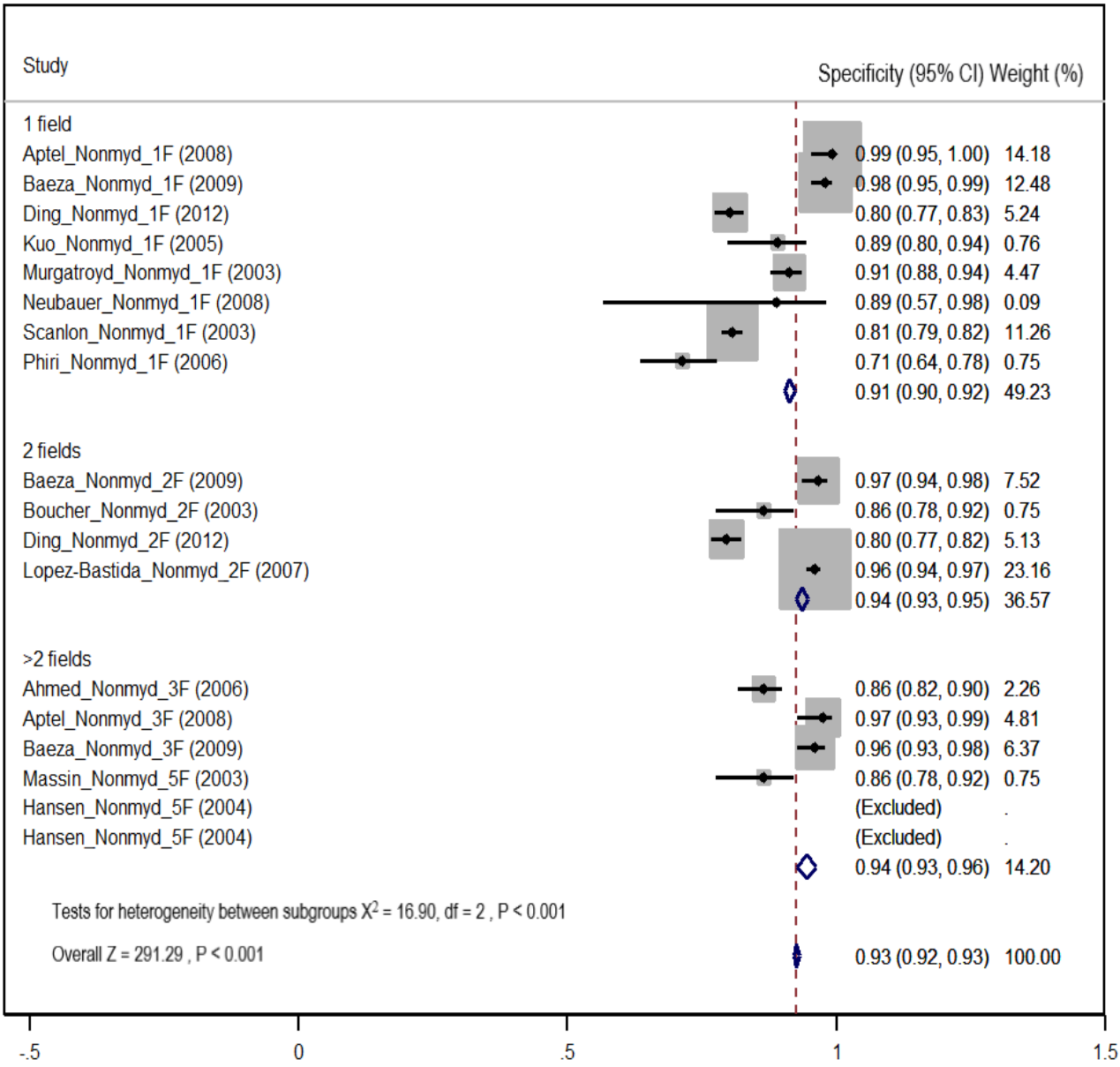


Figure 5 - Forest plot of summary estimates of specificity of non-mydriatic imaging using different field strategies (1: 1 filed, 2: 2 fields, 3: >2 fields)

Diagnostic test accuracy in mydriatic imaging

The highest pooled sensitivity of detection of any level of DR using different mydriatic digital imaging field strategies was for the >2 field strategy (92%, 95% CI 90-94%). The sensitivity of the 1-field strategy was 80% (95% CI 77-82%) and it was 85% (95% CI 84-87%) for the 2-field strategy (Figure

6, Table 3). The mean proportion of ungradable images for the mydriatic method was 6.2% (SE ±2.2, 95% CI 1.7-10.8%). The summary estimation of specificity in detection of any level of DR using mydriatic digital imaging was highest in >2 field strategy at 94% (95% CI 93-96%) followed by the 1 field, 93% (95% CI 92-94%) and then 2-field 82% (95% CI 81-83%) (Figure 7, Table 3).

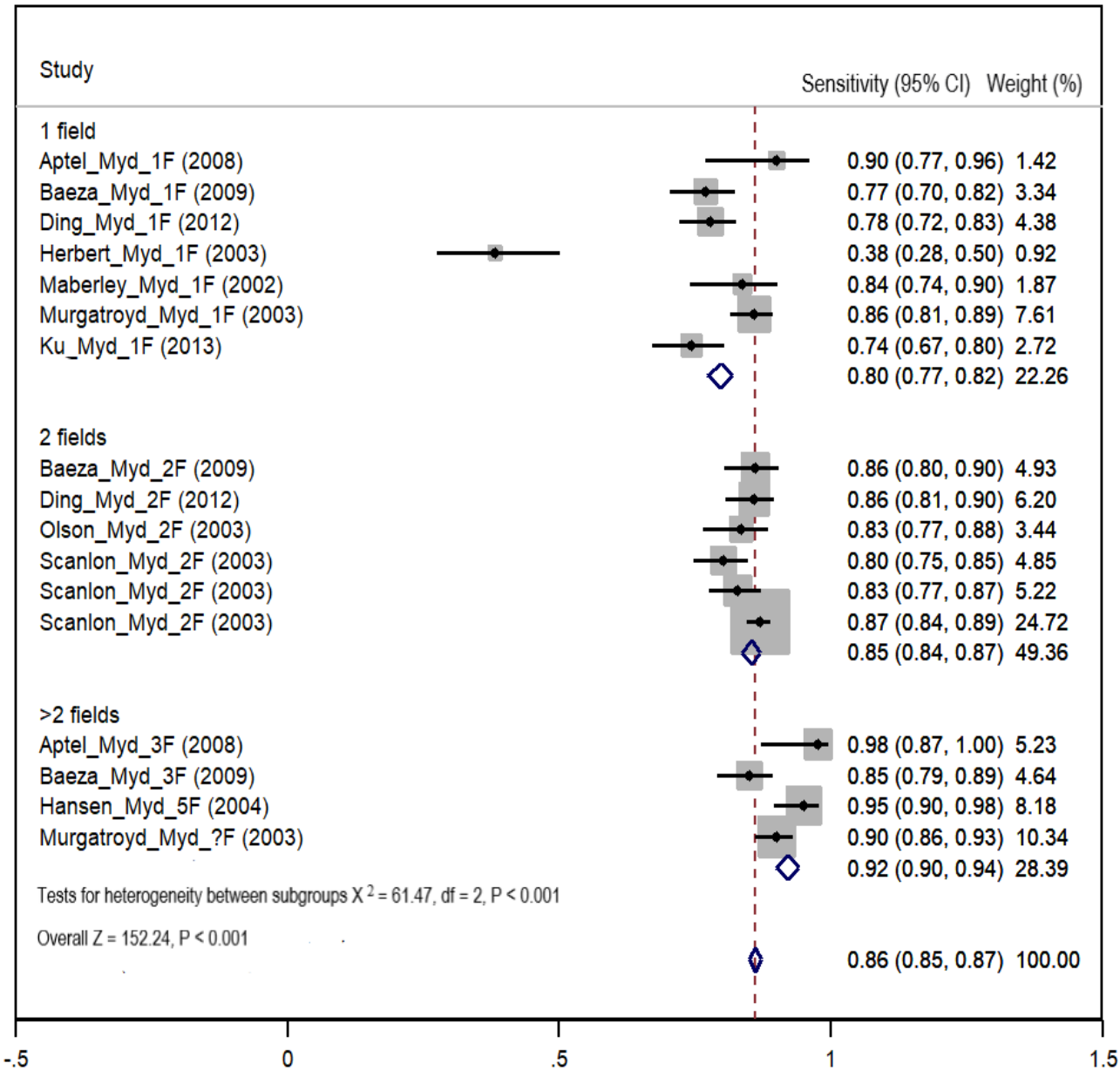


Figure 6 - Forest plot of summary estimates of sensitivity of mydriatic imaging using different field strategies (1: 1 filed, 2: 2 fields, 3: >2 fields)

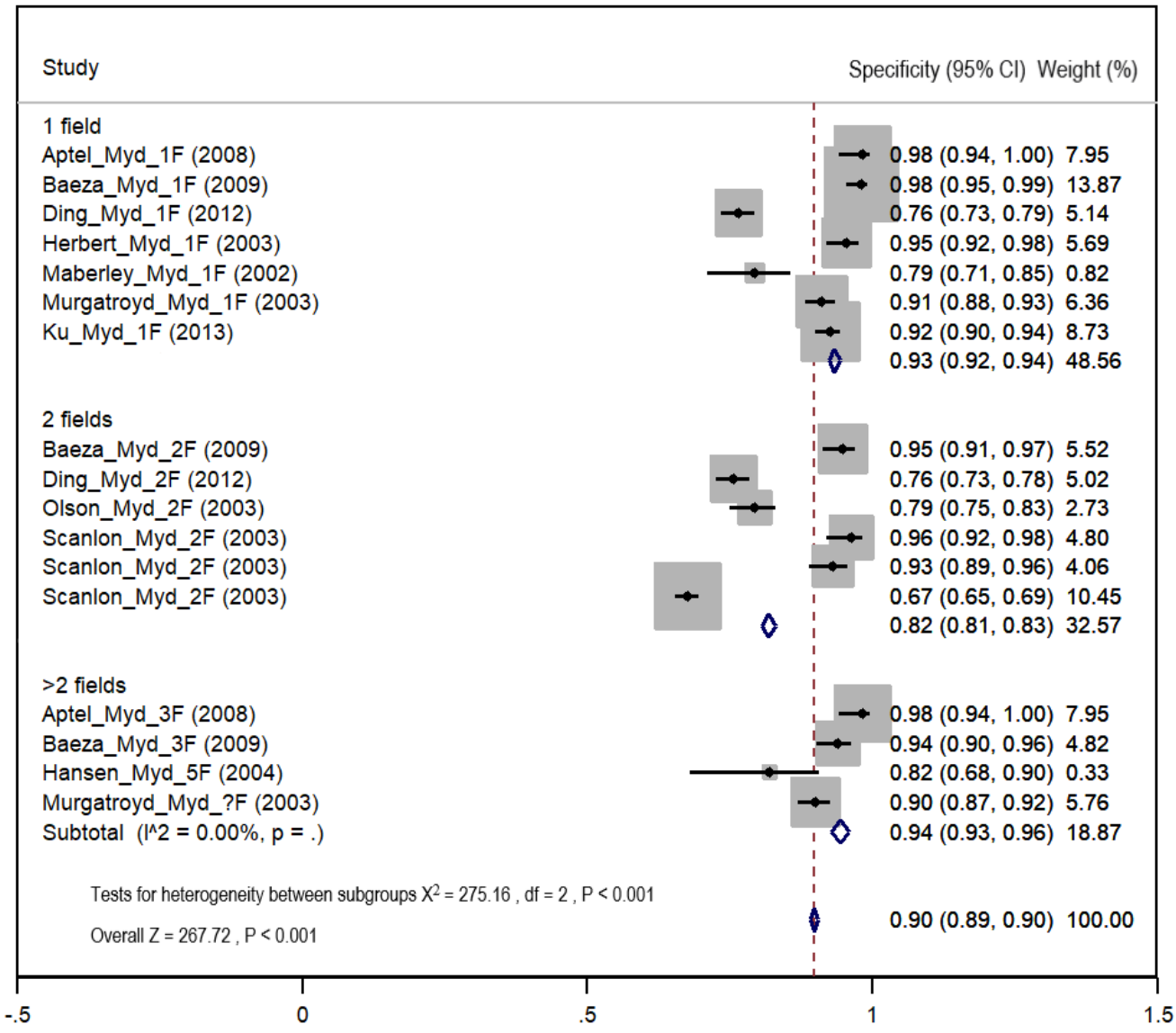


Figure 7 - Forest plot of summary estimates of specificity of mydriatic imaging using different field strategies (1: 1 filed, 2: 2 fields, 3: >2 fields)

Hierarchical summary receiver operating characteristics (HSROC) curve interpretation

Both non-mydriatic and mydriatic strategies showed very high discriminative power in ruling out presence or absence of any level of DR with the diagnostic odds ratio (DOR) of nonmydriatic strategies being 68.03 (95% CI 35.5-130.0) and positive likelihood ratio of 11.79 (SE 3.04, 95% CI 7.1-19.5) (Figure 8). Similarly, mydriatic DOR was 53.98 (95% CI 31.1-93.5) and the positive likelihood ratio was 9.5 (SE 2.1, 95% CI 6.1-14.7) (Figure 9). After adjusting for ungradable images, we

observed that the pooled sensitivity of detection of any level of DR was the same for non-mydriatic and mydriatic strategies: 86% (95% CI 85-87%) for both. The specificity of detection of any level of DR was higher using both nonmydriatic and mydriatic >2 field strategies (94%, 95% CI 93-96%) and in 2 field non-mydriatic strategy (94%, 95% CI 93-95%). The highest diagnostic odds ratio (DOR) was obtained for the >2 field strategy (nonmydriatic DOR 182.4 (SE 145.2, 95% CI 38.3-868.5), mydriatic DOR 140 (SE 76.1, 95% CI 48.2-406.7)). Therefore, we have to consider the number of fields in a DRS strategy (Figure 10 and Additional file 9 in Appendix 8).

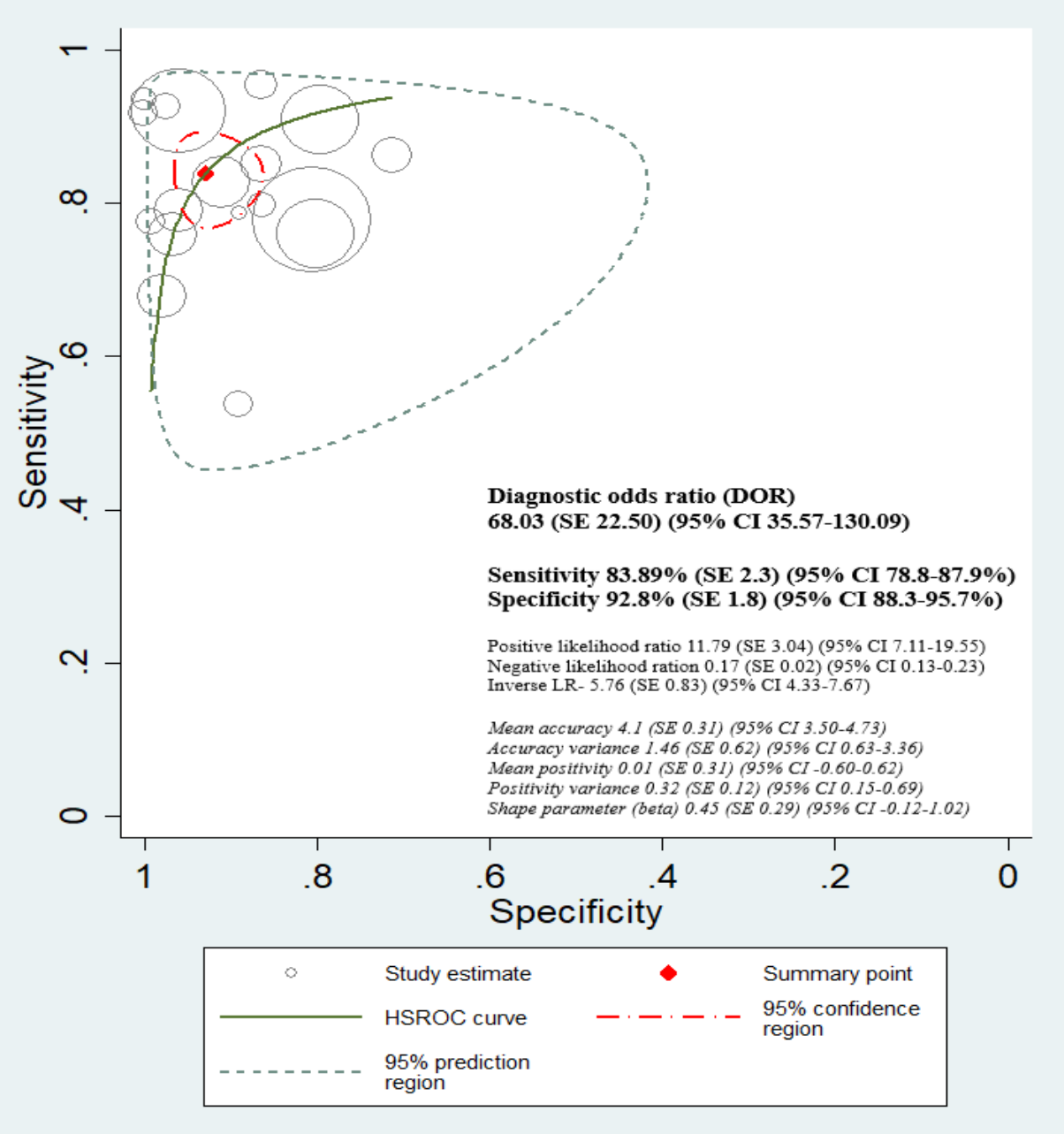


Figure 8. HSROC curve in nonmydriatic imaging strategies

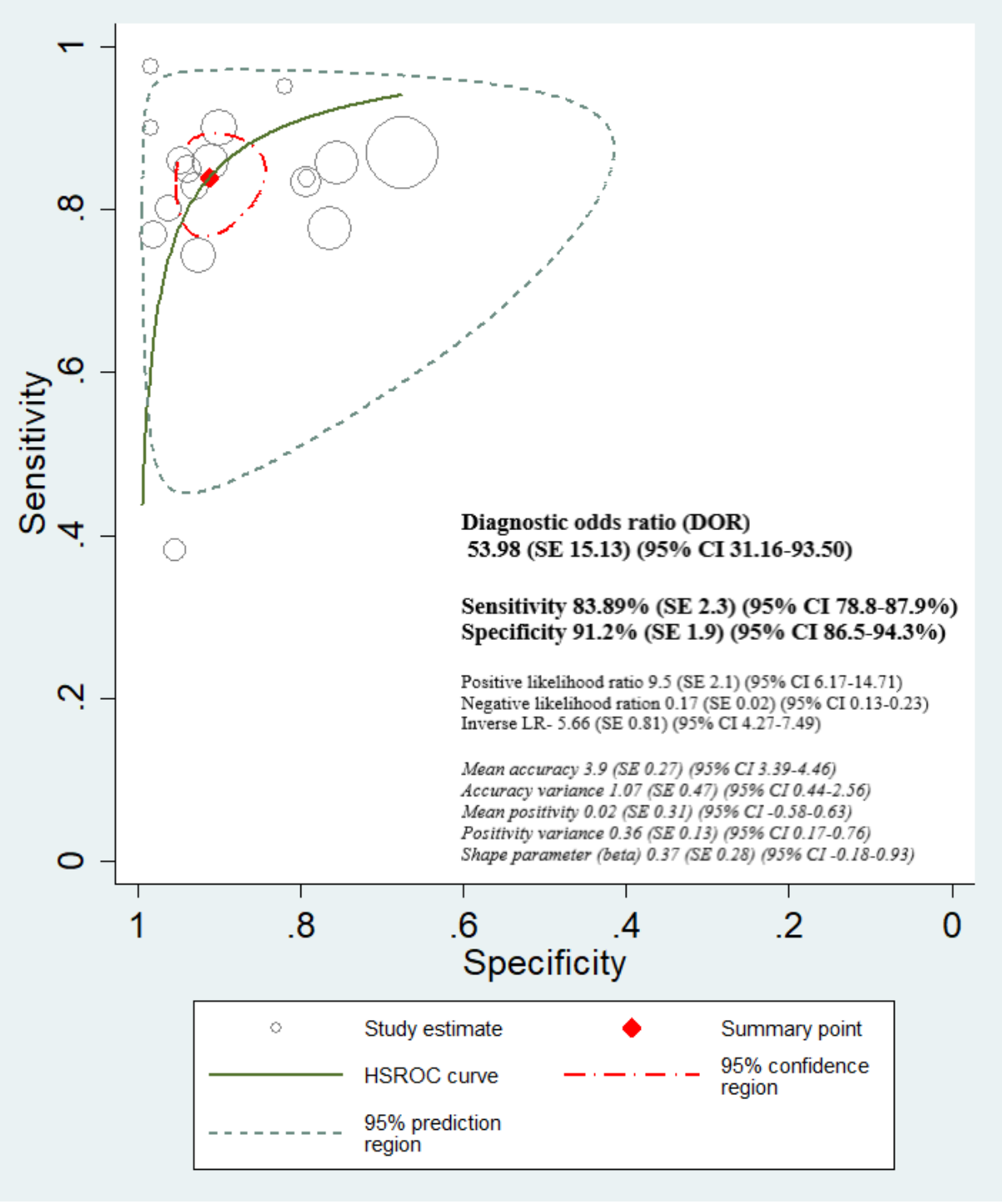
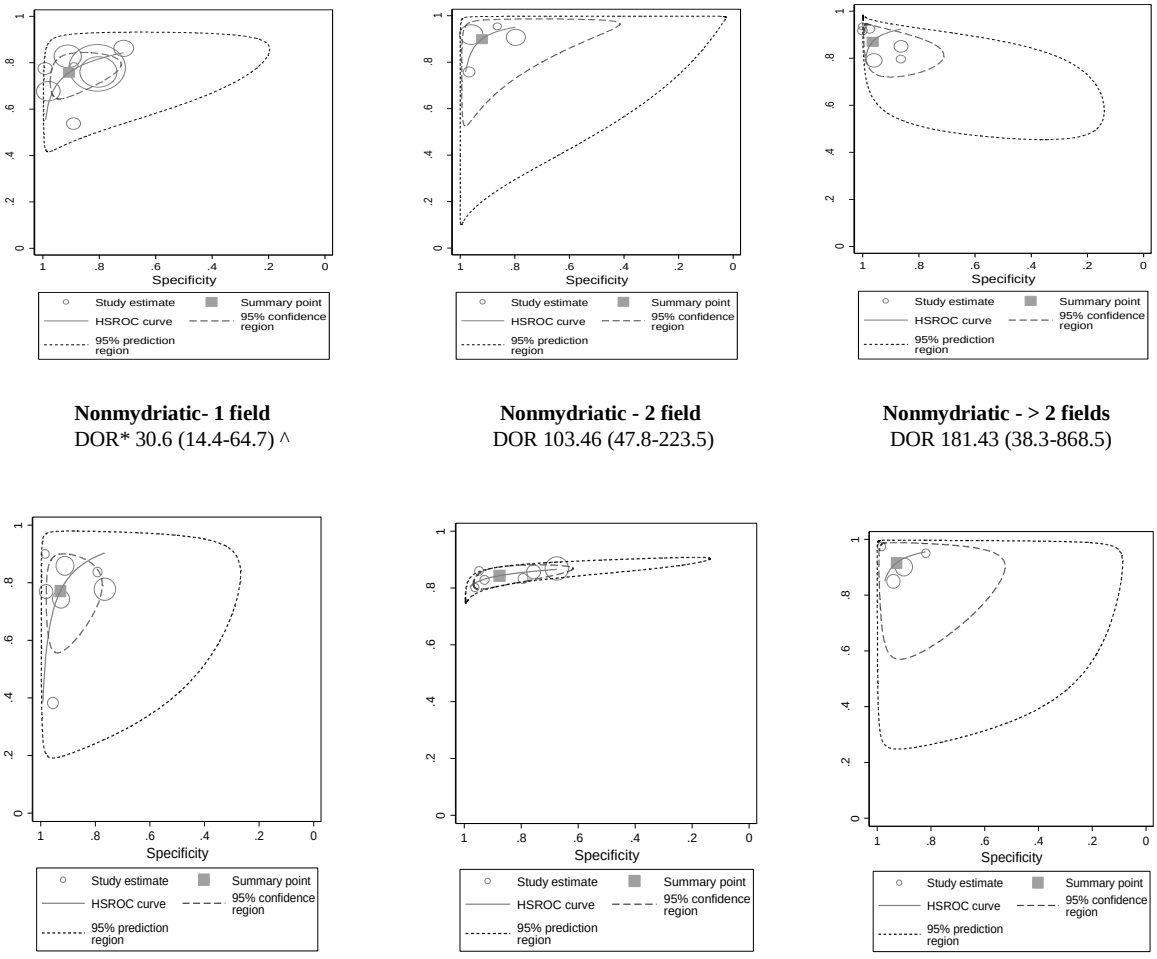


Figure 9. HSROC curve in mydriatic imaging strategies



Nonmydriatic- 1 field
DOR* 30.6 (14.4-64.7) ^

Nonmydriatic - 2 field
DOR 103.46 (47.8-223.5)

Nonmydriatic - > 2 fields
DOR 181.43 (38.3-868.5)

Mydriatic - 1 field
DOR 43.4 (17.8-105.9)

Mydriatic - 2 field
DOR (19.3-75.1)

Mydriatic - > 2 field
DOR (48.2-406.7)

**DOR-diagnostic odds ratio, ^ 95% confidence interval*

Figure 10. HSROC curves by field strategy and pupil status

Summary estimates were derived by the reference test, to assess the variability in DTA according to the reference standard. The pooled sensitivity of detection of any level of DR was higher in non-mydriatic imaging using 7-field ETDRS images as the reference than direct/indirect ophthalmoscopy: (87%, 95% CI 85-89% vs 86%, 95% CI 85-88% in mydriatic). There was no significant difference when compared with mydriatic bio-microscopic ophthalmoscopy as the reference standard

(nonmydriatic 86%, 95% CI 85-88% vs mydriatic 86%, 95% CI 85-87%). Pooled estimates of specificity were high in both nonmydriatic (96%, 95% CI 95-97%) and mydriatic (96%, 95% CI 95-97%) imaging using 7-field ETDRS images as the reference standard compared to mydriatic bio-microscopy (nonmydriatic 91%, 95% CI 91-92 vs mydriatic 87%, 95% CI 86-88%) (Table 3 and Forest plots available in Additional file 6 in Appendix 8).

In the analysis of DTA by setting, highest estimates were shown in secondary/tertiary settings using nonmydriatic imaging (sensitivity 90%, 95% CI 88-91; specificity 95%, 95% CI 94-96%) compared to mydriatic imaging (sensitivity 87%, 95% CI 86-89%; specificity 89%, 95% CI 88-90%) (Table 4 and Forest plots available in Additional file 6 in Appendix 8). However, in non-mydriatic methods, there was one study from HIC with a larger sample size, which may have attributed for a skewed result [40].

Table 3. Summary estimates of diagnostic test accuracy by field strategy and variations by reference standard

Imaging Strategy		**Nonmydriatic**				**Mydriatic**			
		Reference -7F ETDRS [b]		**Reference – DF [c] slit lamp examination**		**Reference - 7F ETDRS**		**Reference - DF slit lamp examination**	
		Sensitivity (95% CI)[d]	**Specificity (95% CI)**	**Sensitivity (95% CI)**	**Specificity (95% CI)**	**Sensitivity (95% CI)**	**Specificity (95% CI)**	**Sensitivity (95% CI)**	**Specificity (95% CI)**
Overall estimate		87% (85-89%) [a](8)	96% (95-97) (6)	86% (85-88%) (10)	91% (91-92%) (10)	86% (84-89%) (5)	96% (95-97%) (5)	86% (85-87%) (12)	87% (86-88%) (12)
Field Strategy	**1F 1 field**	79% (74-83%) (2)	96% (95-98%) (2)	78% (75-80%) (6)	89% (88-90%) (6)	77% (70-82%) (1)	96% (95-99%) (1)	80% (78-83%) (6)	91% (90-92%) (5)
	2F 2 field	90% (86-93%) (2)	96% (94-98%) (2)	92% (90-93%) (2)	93% (92-94%) (2)	83% (80-87%) (2)	95% (93-97%) (2)	86% (84-88%) (4)	75% (74-77%) (4)
	>2F >2 field	88% (85-91%) (4)	95% (93-97%) (4)	90% (83-96%) (2)	94% (92-96%) (2)	91% (88-94%) (2)	93% (90-96%) (2)	93% (90-95%) (2)	95% (93-97%) (2)

[a] Number of studies included in each estimate in meta, [b] 7F ETDRS - Early treatment diabetic retinopathy study seven field strategy, [c] DF-Dilated fundoscopy, [d] CI-Confidence intervals

Table 4. Summary estimates of diagnostic test accuracy by field strategy, by index test grader, by pupil status and by setting

Imaging Strategy		Index grader	Nonmydriatic				Mydriatic			
			Sensitivity		Specificity		Sensitivity		Specificity	
			Estimate (95% CI)	Number of studies	Estimate (95% CI)	Number of studies	Estimate (95% CI)	Number of studies	Estimate (95% CI)	Number of studies
Overall estimates			**86% (85-87%)**	**18**	**93% (92-93%)**	**18**	**86% (85-87%)**	**17**	**90% (89-90%)**	**17**
By index test grader		**Ophthalmologist**	82% (80-84%)	7	94% (94-95%)	7	87% (85-89%)	9	93% (92-94%)	9
		Retinologist	90% (89-92%)	7	94% (93-95%)	7	69% (62-75%)	2	93% (91-96%)	2
		Retinal reader	89% (86-93%)	3	91% (88-94%)	3	86% (84-88%)	4	92% (91-94%)	4
		SpR Registrar	78% (75-81%)	1	81% (79-82%)	1	86% (84-89%)	2	70% (68-72%)	2
By field strategy	**1F**	**Ophthalmologist**	73% (69-77%)	3	96% (94-97%)	3	78% (75-81%)	4	94% (92-95%)	4
		Retinologist	79% (75-84%)	3	81% (76-86%)	3	69% (62-75%)	2	93% (91-96%)	2
		Retinal reader	83% (77-87%)	1	91% (88-94%)	1	86% (81-89%)	1	91% (88-93%)	1
		SpR Registrar	78% (75-81%)	1	81% (79-82%)	1	No data	-	No data	-
	2F	**Ophthalmologist**	87% (84-90%)	2	90% (88-92%)		86% (83-89%)	2	86% (84-88%)	2
		Retinologist	93% (91-95%)	2	96% (94-97%)	2	No data		No data	
		Retinal reader	No data	-	No data	-	82% (78-85%)	2	95% (92-97%)	2
		SpR Registrar	No data	-	No data	-	86% (84-89%)	2	70% (68-72%)	2
	>2F	**Ophthalmologist**	84% (79-88%)	2	97% (95-98%)	2	93% (91-96%)	3	96% (94-98%)	2
		Retinologist	82% (75-90%)	2	86% (8-90%)	2	No data	-	No data	-
		Retinal reader	93% (89-96%)	2	No data	-	90% (86-93%)	1	90% (87-92%)	1
		SpR Registrar	No data	-	No data	-	No data	-	No data	-
By setting		**Primary**	85% (83-86%)	8	92% (91-92%)	8	82% (80-84%)	6	91% (90-92%)	6
		Other (2ry or 3ry)	90% (88-91%)	10	95% (94-96%)	10	87% (86-89%)	11	89% (88-90%)	11

Regarding the personnel involved in index test grading, for ‘any level’ of DR the highest pooled sensitivity and specificity using non-mydriatic imaging was reported by retinologists: sensitivity 90% (95% CI 89-92%) and specificity 94% (95% CI 93-95%). The highest DTA estimates in mydriatic imaging were reported by ophthalmologists. (sensitivity 87%, 95% CI 85-89%; specificity 93%, 95% CI 92-94%) (Table 4 and forest plots available in Additional file 7 in Appendix 8).

Secondary output

In the sub analysis of those studies that captured images of the same participant before and after pupil dilatation, mydriasis (1 field, 2 field, 3 field and 5 field: 6 studies, 10 estimates) showed a high level of sensitivity: mydriatic 88% (95% CI 86-89), non-mydriatic 82% (95%CI 80-84%). However, a higher level of specificity was shown in non-mydriatic methods in detecting any level of DR: non-mydriatic 92% (95%CI 91-93%), mydriatic 89% (95% CI 88-90%). Forest plots of these estimates are available in Additional file 8 in Appendix 8. Four studies used non-ophthalmologist personnel as primary graders in the index test. The pooled sensitivity and specificity of detection any level of DR (either non-mydriatic or mydriatic) were 74% (95% CI 71-77%) and 85% (95% CI 83-87%) respectively [27,28,46,48].

Discussion

Overall, both mydriatic and nonmydriatic digital imaging methods generate a satisfactory level of sensitivity i.e., 86% (95% CI 85-87%) in usual clinical settings, once ungradable images are excluded from analysis. This sensitivity level is above the DRS recommendation of established national programmes (Sensitivity >80%) [50]. Neither strategies achieved the recommended level of 95% specificity for any level of DR: non-mydriatic 95% CI (92-93%), mydriatic 95% CI (89-90%). In addition, mydriatic >2 field strategy showed the highest level of sensitivity (92%, 95% CI 90-94) and specificity (94%, 95% CI 93-96%), a finding to be considered when setting-up a screening strategy.

The optimum level of referable DR will depend on the accuracy of the screening strategy chosen and the resources available in the specific screening setting in order to strike a balance between screening PwDM at non-ophthalmic settings safely, but without overloading the eye clinics for further assessments. Annual DRS, followed by timely treatment of those confirmed to have STDR is the recommended screening pathway [51]. The current method of DRS in most LMICs is an opportunistic screening using mydriatic bio-microscopic ophthalmoscopy by an ophthalmologist [18]. This is not an efficient way of screening for DR considering the limitations in human resources and access barriers. In contrast, DRS using digital imaging requires specific training and skills, but these can be obtained by non-medical personnel, and as such the pool of potential workforce is much larger than for trained ophthalmologists.

In this meta-analysis, we aimed to show the effect of pupil status on DTA for any DR. For those images sets with gradable images, the pooled sensitivity of non-mydriatic strategies were the same as the mydriatic strategies. However, only six studies (6/21) used the same participants before and after pupil dilatation [25,35,40,42,44,47]. The non-mydriatic methods results were primarily dominated by one larger study (sample size n=1549) conducted in a HIC [40] and another study used wide field (Optomap® 180-200^0 field view) imaging [26]. Therefore, outcome of this review should be applied to LMICs cautiously. A similar result was reported in a meta-analysis by Bragge, P. et al although heterogeneity among those studies was high due to pooling of different examination techniques in one estimation [17]. In the current meta-analysis heterogeneity was minimised by including studies which used digital retinal imaging only in the index test.

A DRS method which is suited to the health system is a key factor in the success of a program. Non-mydriatic imaging can be used in settings where there are fewer ophthalmic personnel and avoiding pupil dilatation reduces screening time and causes less perceived inconvenience to PwDM. A concern, however, is variability in image quality, particularly in populations with a high prevalence of cataract

and corneal opacities [14,52]. The Scottish National Health Services DRSP now uses non-mydriatic imaging systems, with minimal need for pupil dilatation in screened patients [53]. This is an evidence-based pragmatic approach with greater convenience for PwDM and lower cost to service providers [54,55] However, implementation of nonmydriatic test in DRS will depend on population characteristics such as the prevalence of cataract.

Selection of suitable personnel for DRS and grading depends on workforce capacity and availability. DRS by ophthalmologists is not an efficient way of screening for any setting [55]. DM related blindness is still on the rise everywhere in the world and is a public health concern in LMIC settings as well [18]. These countries will have to rapidly adopt clinically safe and cost effective strategies to address this issue, using the limited resources available and establish such a programme quickly [56]. In this analysis, retinal image graders could achieve the recommended level of 80% sensitivity and specificity closer to 95% in both mydriatic and non-mydriatic strategies. Therefore, it is justifiable to train non-ophthalmic personnel in DR grading, just as it was done in the UK national programme.

DR screening's success depends on the gradability of images, as such most of the studies included only gradable images. High population coverage with good quality gradable images is an important pragmatic consideration to achieve high DTA and high acceptability of a DRSP. Therefore, interpretation of the results shown in this study require judgement of the context and objectives of a specific DRSP. PwDM with ungradable images are a special category of people whose fundus is not visible due to some other ocular pathology like dense lenticular opacities. These people therefore need not only the management that test negatives receive in terms of management of diabetic retinopathy but will also need additional management of ocular pathology which is obliterating the fundus image. Therefore, this meta-analysis highlights the concerns as to how to manage data on ungradable images, as studies differ in their approach of dealing with such a concern. Most authors (13 studies) had excluded ungradable images from their analysis while others included them as having screened positives

(6 studies). In addition, reporting of ungradable by study authors was heterogeneous, which imply requirement of standardized reporting of ungradable images in DRS.

The mean proportions of ungradable images in nonmydriatic and mydriatic imaging were 17.8% (95%CI 10.8-24.8%) and 6.1% (95% CI 3.7-8.4%) respectively. The decisions made by each study authors may have introduced reporting bias in their measures of DTA. Considering ungradable images as test positives, may have led to inflated estimates of DTA in some studies [25,26,40,42–44]. The mean proportions of ungradable images included by study authors as test positives in nonmydriatic and mydriatic imaging were 12.5% (95% CI 9.0-16.1%) and 2.5% (95% CI 1.0-3.9%) respectively. Therefore, we adjusted DTA to take account of ungradable images by excluding those to reduce heterogeneity. This was possible for four of the six studies in which ungradable images were included as screening positive, [25,26,40,43] but two did not report adequate data to allow for this [42,44]. As an example, we made adjustment (calculated sensitivity 42/49 = 85.7%, specificity 227/262 = 86.6%) for the inflated DTA (reported sensitivity 98%, specificity 100%) in the study of Ahmed, J. et al using the 2x2 table data reported by study authors [29]. In another two studies it was not clear how ungradable images had been managed [28,38]. The proportions of ungradable images and DTA after adjustments in each strategy is available in Additional file 5.

Limitations

The definition of ungradable images was not uniform in the studies included in the current review We minimized the heterogeneity by excluding the ungradable images and by sub-group analysis.

The studies which used non-mydriatic imaging techniques were more recent, being conducted after rapid advancements in technology for such imaging technology leading to better quality images using non-mydriatic systems without pupil dilatation as well and a major confounder in the meta-analysis.

The results of the different strategies described in this review are to be considered fully if a comprehensive DRSP facilitating greater screening coverage with improved accessibility and good quality imaging is to be set up. However, due to lack of relevant good quality data, sub-analysis by countries' income setting was not possible to perform due to absence of studies from LMICs.

We excluded 3 articles which were not in English due to practical barriers in translations and assessment of methodological quality. The DTA of detection of maculopathy had not been considered. The maculopathy is also an important aspect in DRS and it may have to be considered in a separate review.

Conclusions

Diagnostic test accuracy for the detection of any level of DR showed that DRS using 2 fields delivered at non-primary care settings is a feasible approach. Dilatation of pupils did not improve the detection of any level of DR for those with gradable images, but such a wide range of ungradable were presented in these studies that this aspect must be taken into account when setting up DRSP. There wasn't adequate evidence in primary studies to comment on DTA of non-ophthalmological human resources on DRS, so this aspect requires further research. Good quality digital imaging has the potential for real time interpretation of retinal images, which together with counselling for risk factors may improve the acceptability of DRS and uptake of referral for ophthalmic assessment if conducted in a culturally acceptable way.

Recommendations

Diagnostic test accuracies of the newer non-mydriatic imaging systems should be further explored in different environments and using a different skill-mix of graders, especially in LMICs.

Studies should focus on the accuracy of non-ophthalmic graders and non-ophthalmic settings to explore the potential of initiating DRSP especially in low-income settings. This will reduce the number of referrals to eye departments, many of which are already over-burdened with cataract and other eye conditions, particularly in LMIC where resources are limited.

The reporting definitions of technical failures or ungradability of the images should be standardised using a reporting guideline.

A systematic review and meta-analysis of DTA of different levels of DR and maculopathy can be recommended in future research.

Appendix 8 - Summary of Additional files

8.1 - Additional file 1 - PRISMA check list

8.2 - Additional file 2 - Details of the excluded studies

8.3 - Additional file 3 - Participant characteristics of the included articles

8.4 - Additional file 4 - DTA of different strategies and ungradable image proportions as reported by study authors

8.5 - Additional file 5 - DTA following adjustments in relevant to exclusion of ungradable proportions in the current review

8.6 - Additional file 6 - Forest plots of DTA variation by type of reference standard and by the level of service delivery (by clinic settings)

8.7 - Additional file 7 - Forest plots of DTA by different index test human resources

8.8 - Additional file 8 - Forest plots of sub-analyses – DTA using same participant undergoing imaging before and after pupil dilatation

8.9 - Additional file 9 - DTA parameters by pupil status and field strategy using HSROC curves

References cited in the published paper (Chapter 10)

1. Whiting DR, Guariguata L, Weil C, Shaw J . Global estimates of the prevalence of diabetes for 2011 and 2030. Diabetes Res Clin Pract. 2011;94(3):311–21. doi:10.1016/j.diabres.2011.10.029

2. Diabetes - International Diabetes Federation. 2017 [Internet] http://www.idf.org/idf-diabetes-atlas-seventh-edition. Accessed 10 Jan 2018

3. Shaw JE, Sicree RA, Zimmet PZ . Global estimates of the prevalence of diabetes for 2010 and

2030. Diabetes Res Clin Pract. Diabetes Res Clin Pr. 2010;87(1):04–14. doi:10.1016/j.diabres.2009.10.007.

4. Guariguata L, Whiting DR, Hambleton I, Beagley J. Global estimates of diabetes prevalence for 2013 and projections for 2035. Diabetes Res Clin Pract. 2013;103(2):137–49. doi.org/10.1016/j.diabres.2013.11.002

5. Klein R, Klein BEK. The Epidemiology of Diabetic Retinopathy [Internet]. Fifth Edit. Vols. 2–3, Retina: Fourth Edition. Elsevier Inc.; 2005. 1503-1521.doi.org/10.1016/B978-1-4557-0737-9.00045-X

6. Yau JWY, Rogers SL, Kawasaki R, Lamoureux EL, Kowalski JW, Bek T, et al. Global prevalence and major risk factors of diabetic retinopathy. Diabetes Care. 2012;35:556–64. doi.org/10.2337/dc11-1909

7. Zhang X, Norris SL, Saadine J, Chowdhury FM, Horsley T, Kanjilal S, et al. Effectiveness of Interventions to Promote Screening for Diabetic Retinopathy. Am J Prev Med. 2007;33(4):318–35. doi: 10.1016/j.amepre.2007.05.002

8. Klein BE. Overview of Epidemiologic Studies of Diabetic Retinopathy. Ophthalmic Epidemiol. 2007;14(4):179–83.

9. The Diabetes Control and Complications Trial Research Group. The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med. 1993;329:977–86. doi: 10.1056/NEJM199309303291401

10. Klein R, Knudtson MD, Lee KE, Gangnon R, Klein BEK. The Wisconsin Epidemiologic Study of Diabetic Retinopathy xxii. The Twenty-Five-Year Progression of Retinopathy in Persons with Type 1 Diabetes. NIH Public Access. Diabetes. 2009;115(11):263–0279.

11. Kohner EM, Aldington SJ, Stratton IM, Manley SE, Holman RR, Mathews DR, Turner RC .

United Kingdom Prospective Diabetes Study, 30: diabetic retinopathy at diagnosis of non-insulin-dependent diabetes mellitus and associated risk factors. Arch Ophthalmol. 1998;116(3):297–303.

12. The Diabetic Retinopathy Study Research Group. Photocoagulation Treatment of Proliferative Diabetic Retinopathy. Ophthalmology.1976;88(7):583–600. doi.org/10.1016/S0161-6420(81)34978-1

13. Scanlon PH. The English National Screening Programme for diabetic retinopathy 2003–2016. Acta Diabetol. 2017;54(6):515–25. DOI:10.1007/s00592-017-0974-1

14. Banaee T, Ansari-Astaneh MR, Pourreza H, Faal Hosseini F, Vatanparast M, Shoeibi N, et al. Utility of 1% Tropicamide in Improving the Quality of Images for Tele-Screening of Diabetic Retinopathy in Patients with Dark Irides. Ophthalmic Epidemiol. 2017;24(4):217–21. doi.org/10.1080/09286586.2016.1274039

15. Hutchinson A, McIntosh A, Peters J, Keeffe JE, Khunti K, Baker R. Effectiveness of screening and monitoring tests for diabetic retinopathy - a systematic review. Diabet Med. 2000;17(17):495–506. PMID: 10972578

16. Shi L, Wu H, Dong J, Jiang K, Lu X, Shi J. Telemedicine for detecting diabetic retinopathy: a systematic review and meta-analysis. Br J Ophthalmol. 2015;99(6):823–31. doi: 10.1136/bjophthalmol-2014-305631

17. Bragge P, Gruen RL, Chau M, Forbes A, Taylor HR. Screening for Presence or Absence of Diabetic Retinopathy. Arch Ophthalmol. 2011;129(4):435–44. doi: 10.1001/archophthalmol.2010.319

18. Lin S, Ramulu P, Lamoureux EL, Sabanayagam C. Addressing risk factors, screening, and preventative treatment for diabetic retinopathy in developing countries: A review. Clin Exp Ophthalmol. 2016;44(4):300–20. PMID: 26991970 DOI: 10.1111/ceo.12745

19. Hipwell AE, Sturt J, Lindenmeyer A, Stratton I, Gadsby R, Hare PO. Attitudes , access and anguish : a qualitative interview study of staff and patients ' experiences of diabetic retinopathy screening.BMJ Open 2014;4:e005498. doi: 10.1136/bmjopen-2014-005498

20. vonElm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC VJSI. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. PLoS Med. 2007;4(10):e296. https://doi.org/10.1371/journal.pmed.

21. Macaskill P, Gatsonis C, Deeks J, Harbord R, Takwoingi Y. Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy Chapter 10 Analysing and Presenting Results. Cochrane DTA Handb. 2010;1–61. http://methods.cochrane.org/sites/methods.cochrane.org.sdt/files/public/uploads/Chapter%2010%20-%20Version%201.0.pdf. Accessed 30 Sept 2015

22. Whiting PF, Rutjes AWS, Westwood ME, Mallet S, Deeks JJ, Reitsma JB, et al. Research and Reporting Methods Accuracy Studies. Ann Intern Med. 2011;155(4):529–36. doi: 10.7326/0003-4819-155-8-201110180-00009.

23. Herbert HM, Jordan K, Flanagan DW. Is screening with digital imaging using one retinal view adequate? Eye (Lond). 2003;17(4):497–500. DOI: 10.1038/sj.eye.6700409

24. Olson JA, Strachan FM, Hipwell JH, Goatman KA, McHardy KC, Forrester J V., et al. A comparative evaluation of digital imaging, retinal photography and optometrist examination in screening for diabetic retinopathy. Diabet Med. 2003;20(7):528–34. PMID: 12823232

25. Hansen AB, Sander B, Larsen M, Kleener J, Borch-Johnsen K, Klein R, et al. Screening for diabetic retinopathy using a digital non-mydriatic camera compared with standard 35-mm stereo colour transparencies. Acta Ophthalmol Scand. 2004;82(6):656–65. PMID: 15606460 DOI: 10.1111/j.1600-0420.2004.00347.x

26. Neubauer AS, Kernt M, Haritoglou C, Priglinger SG, Kampik A, Ulbig MW. Nonmydriatic

screening for diabetic retinopathy by ultra-widefield scanning laser ophthalmoscopy (Optomap). Graefe's Arch Clin Exp Ophthalmol. 2008;246(2):229–35. PMID: 17622548 DOI: 10.1007/s00417-007-0631-4

27. Henricsson M, Karlsson C, Ekholm L, Kaikkonen P, Sellman A, Steffert E, et al. Colour slides or digital photography in diabetes screening-a comparison. Acta Ophthalmol Scand. 2000;78(2):164–8. PMID: 10794249. doi/10.1034/j.1600-0420.2000.078002164.x/

28. Sundling V, Gulbrandsen P, Straand J. Sensitivity and specificity of Norwegian optometrists' evaluation of diabetic retinopathy in single-field retinal images - a cross-sectional experimental study. BMC Health Serv Res. 2013;13:17. doi: 10.1186/1472-6963-13-17

29. Ahmed J, Ward TP, Bursell SE, Aiello LM, Cavallerano JD, Vigersky RA. The sensitivity and specificity of nonmydriatic digital stereoscopic retinal imaging in detecting diabetic retinopathy. Diabetes Care. 2006;29(10):2205–9. DOI: 10.2337/dc06-0295

30. Shiffman R, Jacobsen G, Nussbaun J, Desai U, Carey D, Glasser D, et al. Comparison of a Digital Retinal Imaging System and Seven-Field Stereo Colour Fundus Photography to Detect Diabetic Retinopathy in the Primary Care Environment. Ophthalmic Surg Lasers Imaging. 2005;36:46–57. PMID: 15688971

31. Boucher MC, Gresset JA, Angioi K, Olivier S. Effectiveness and safety of screening for diabetic retinopathy with two nonmydriatic digital images compared with the seven standard stereoscopic photographic fields. Can J Ophthalmol. 2003;38(7):557–68. PMID: 14740797

32. Maberley D, Cruess AF, Barile G, Slakter J. Digital photographic screening for diabetic retinopathy in the James Bay Cree. Ophthalmic Epidemiol. 2002;9(3):169–78. PMID: 12045884

33. Perrier M, Boucher MC, Angioi K, Gresset JA, Olivier S. Comparison of two, three and four 45 degrees image fields obtained with the Topcon CRW6 nonmydriatic camera for screening for diabetic retinopathy. Can J Ophthalmol. 2003;38(7):569–74. PMID: 14740798

34. Bhargava M, Cheung CYL, Sabanayagam C, Kawasaki R, Harper CA, Lamoureux EL, et al. Accuracy of diabetic retinopathy screening by trained non-physician graders using non-mydriatic fundus camera. Singapore Med J. 2012;53(11):715–9. PMID: 23192497

35. Murgatroyd H. Effect of mydriasis and different field strategies on digital image screening of diabetic eye disease. Br J Ophthalmol. 2004;88(7):920–4. PMID: 15205238 PMCID: PMC1772219 DOI: 10.1136/bjo.2003.026385

36. Mizrachi Y, Knyazer B, Guigui S. Evaluation of diabetic retinopathy screening using a non-mydriatic retinal digital camera in primary care settings in south Israel. Int Ophthalmol. 2014;831–7. PMID: 24292883 DOI: 10.1007/s10792-013-9887-3

37. Ku JY, Landers J, Henderson T, Craig JE. The reliability of single-field fundus photography in screening for diabetic retinopathy: The central australian ocular health study. Med J Aust. 2013;198(2):93–5. doi: 10.5694/mja12.10607

38. Phiri R, Keeffe JE, Harper CA, Taylor HR. Comparative study of the polaroid and digital non-mydriatic cameras in the detection of referrable diabetic retinopathy in Australia. Diabet Med. 2006;23(8):867–72. DOI: 10.1111/j.1464-5491.2006.01824.x

39. Scanlon PH, Malhotra R, Greenwood RH, Aldington SJ, Foy C, Flatman M, et al. Comparison of two reference standards in validating two field mydriatic digital photography as a method of screening for diabetic retinopathy. Br J Ophthalmol. 2003;87(10):1258–63. PMID: 14507762 PMCID: PMC1920793

40. Scanlon PH, Malhotra R, Thomas G, Foyt C, Kirkpatrick JN, Lewis-Barned N, et al. The effectiveness of screening for diabetic retinopathy by digital imaging photography and technician ophthalmoscopy. Diabet Med. 2003;20(6):467–74. PMID: 12786681

41. Tu K, Palmer P, Sen S, Matthew P, Khaleel A. Comparison of optometry vs digital photography screening for diabetic retinopathy in a single district. Eye. 2004;18(July 2002):3–8. DOI: 10.1038/sj.eye.6700497

42. Aptel F, Denis P, Rouberol F, Thivolet C. Screening of diabetic retinopathy: Effect of field number and mydriasis on sensitivity and specificity of digital fundus photography. Diabetes Metab. 2008;34(3):290–3. doi: 10.1016/j.diabet.2007.12.007

43. Massin P, Erginay A, Ben Mehidi A, Vicaut E, Quentel G, Victor Z, et al. Evaluation of a new non-mydriatic digital camera for detection of diabetic retinopathy. Diabet Med. 2003;20(8):635–41.

44. Baeza M, Orozco-Beltrán D, Gil-Guillen VF, Pedrera V, Ribera MC, Pertusa S, et al. Screening for sight threatening diabetic retinopathy using non-mydriatic retinal camera in a primary care setting: To dilate or not to dilate? Int J Clin Pract. 2009;63(3):433–8. doi: 10.1111/j.1742-1241.2008.01921.x

45. Lopez-Bastida J, Cabrera-Lopez F, Serrano-Aguilar P. Sensitivity and specificity of digital retinal imaging for screening diabetic retinopathy. Diabet Med. 2007;24(4):403–7. DOI: 10.1111/j.1464-5491.2007.02074.x

46. Suansilpong A, Rawdaree P. Accuracy of Single-Feild Nonmydriatic Digital Fundus Image in Screening for Diabetic Retinopathy. J Med Assoc Thai. 2008;91(9):1397–403. PMID: 18843870

47. Ding J, Zou Y, Liu N, Jiang L, Ren X, Jia W, et al. Strategies of Digital Fundus Photography for Screening Diabetic Retinopathy in a Diabetic Population in Urban China. Ophthalmic Epidemiol. 2016;19(6):414-9. doi: 10.3109/09286586.2012.716895.

48. Kuo HK, Hsieh HH, Liu RT. Screening for diabetic retinopathy by one-field, non-mydriatic, 45° digital photography is inadequate. Ophthalmologica. 2005;219(5):292–6. DOI: 10.1159/000086114

49. Massin P, Aubert JP, Eschwege E, Erginay A, Bourovitch JC, BenMehidi A, et al. Evaluation of a screening program for diabetic retinopathy in a primary care setting Dodia (Dépistage ophtalmologique du diabète) study. Diabetes Metab. 2005;31(2):153–62. PMID: 15959421

50. Mead A, Burnett S, Davey C. Diabetic retinal screening in the UK. J R Soc Med. 2001;94:127–9. DOI: 10.1177/014107680109400307

51. Taylor-Phillips S, Mistry H, Leslie R, Todkill D, Tsertsvadze A, Connock M, et al. Extending the diabetic retinopathy screening interval beyond 1 year: systematic review. Br J Ophthalmol. 2016;100(1):105–14. http://dx.doi.org/10/1136/bjophthalmol-2014-305938

52. Scanlon P, Foy C, Malhotra R, Aldington S. The Influence of Age , Duration of Diabetes , Cataract , and Pupil Size on. Diabetes Care. 2005;28(10). PMID: 16186278

53. The Diabetic Retinopathy Screening Implementation Group - Diabetic Retinopathy Screening Services in Scotland:Recommendations for Implementation [Internet]. 2003. Available from: http://www.ndrs-wp.scot.nhs.uk/wp-content/uploads/2013/04/Recommendations-for-Implementing-DRS.pdf Accessed on 15 Sep 2017

54. Guigui S, Lifshitz T, Levy J. Screening for diabetic retinopathy: review of current methods. Hosp Pract. 2012;40(2):64–72. PMID: 22615080 DOI: 10.3810/hp.2012.04.971

55. Swanson M. Retinopathy screening in individuals with type 2 diabetes: who, how, how often, and at what cost--an epidemiologic review. Optometry. 2005;76(11):636–46. PMID: 16298316 DOI: 10.1016/j.optm.2005.08.019

56. Khandekar R. Screening and public health strategies for diabetic retinopathy in the Eastern Mediterranean Region. Middle East Afr J Ophthalmol. 2012;19(2):178. doi: 10.4103/0974-9233.95245. PMCID: PMC3353664. PMID: 22623855

Chapter 11

Illustrations of outcome of training of physician graders on DR screening and grading using a non-mydriatic hand held retinal camera at a tertiary level medical clinic

[*Linking document only, not included in a publication]

11.1 Training of physician graders - Knowledge component

Nine general physicians at a tertiary level medical unit in the Western province of Sri Lanka underwent training starting from February 2017. They gained knowledge and skills required for pupil dilatation, capturing retinal fields (two field technique), assessment gradability and DR grading according to the recommended classification system.

In the first stage physician graders participated in teaching sessions (knowledge component) conducted by a specialist retinologist, facilitated by the research student.

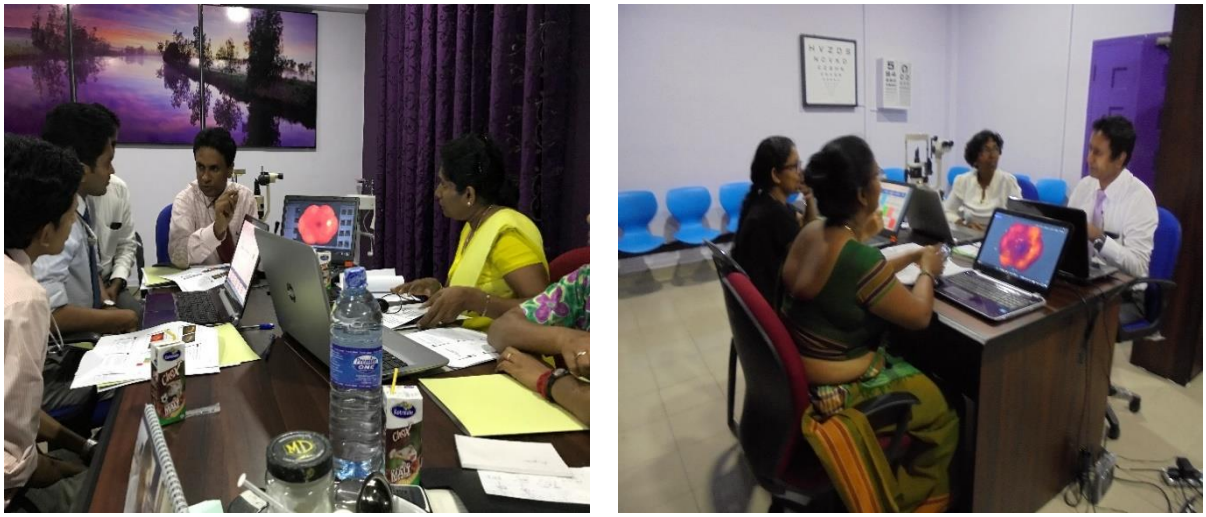


Image file 11.14 - Training of physician graders by the consultant retinologist and research student at National Eye Hospital - Colombo.

11.1.1 Training of physician graders - Introduction to the on-line learning material

Following the training on theory-based knowledge component, physicians were introduced to the on-line training resources, as described in the training curriculum in Chapter 6.

Image file 11.15 - Teaching and training of physicians at their medical unit on using on-line resources - conducted by the research student

11.2 Training of physician graders - Skills component - pupil dilatation

In the next stage, physicians were trained on the skills component at the retinal clinic followed by training at the medical clinic. Here, they acquired skills on pupil dilatation and capturing required fields using the hand-held retinal camera. For the retinal imaging one-to-one training was provided by me. Physicians underwent skills development until they were competent in capturing the required retinal fields of a person with diabetes.

Image file 11.16 - Practical demonstrations on pupil dilatation, assessment of pupils and slit lamp examination - conducted by the research student.

11.2.1 Training of physician graders - Skills component - Handling the retinal camera, capturing and storing retinal images

In the next stage of skills development, I organized lecture demonstrations on handling and capturing required retinal fields using the hand-held retinal camera. I trained physician graders on a one-on-one basis, until they acquired the required level of skills. Initially physicians practiced imaging on pupil dilated patients at the retinal clinic followed by nonmydriatic imaging at the medical clinic.




Image file 11.17 - Demonstration of handling the retinal camera and capturing retinal fields - conducted by the research student

11.2.2 Training of physician graders - Day to day practicing of retinal imaging at medical clinic by physician graders before the assessment

In the next stage, physician graders were allowed to screen the PwDM at the medical clinic under my supervision, once they were competent in capturing retinal fields correctly.

Image file 11.18 - Continuation of practicing of retinal imaging at the medical clinic before conducting the assessment - under supervision of the research student

11.2.3 Assessment of physician graders to choose two best agreed graders for the validation study

The physician graders underwent an assessment using a set of archived images in identifying DR signs, grading DR and identifying the level of gradability. Table 1 shows the assessment results. We selected the two best physicians (based on agreement levels) after the assessment to conduct the validation of the proposed screening modality.

Image file 11.19 - Continuation of practicing imaging by the selected two physician graders and conducting the validation study at the medical clinic.

Table 1 - Assessment results of the physician graders

Grader ID	Age	Gender	Year of internship	Years of experience - under the Ministry of Health	Previous Experience in DR screening	Current position	Overall score of identification of DR signs	Kappa value (agreement with the retinologist - for the level of DR and image quality)
Gr1	47	Female	1999	17	No	SHO-Medicine	95.20%	0.92
Gr2	32	Female	2012	5	No	SHO-Medicine	72%	0.80
Gr3	29	Male	2013	4	No	Registrar-Medicine	74.40%	0.64
Gr4	30	Male	2014	3	No	Registrar-Medicine	77.60%	0.60
Gr5	43	Female	2003	14	No	SHO-Medicine	74.00%	0.60
Gr6	30	Male	2014	3	No	Registrar-Medicine	80%	0.56
Gr7	40	Male	2005	12	No	SHO-Medicine	80.80%	0.52
Gr8	48	Female	1999	17	No	SHO-Medicine	65.00%	0.48
Gr9	49	Female	1999	17	No	SHO-Medicine	(Could not participate)	

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
E: registry@lshtm.ac.uk

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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Mapa Mudiyanselage Prabhath Nishantha Piyasena
Principal Supervisor	Prof.G.V.S.Murthy
Thesis Title	A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	N/A		
When was the work published?	N/A		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	**Yes**

**If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.*

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Bio Med Central (BMC) - Ophthalmology - Open Source
Please list the paper's authors in the intended authorship order:	Piyasena MMPN, Yip JLY, Kim M, MacLeod D, Gudlavalleti VSM.
Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceived the concept of this validation study after identifying gaps in evidence from the local context, through situational analysis and formative research work. I prepared the study design, training curriculum of physician graders and validation study protocol and presented those at the PhD upgrading.

	Afterwards, I revised the protocol under guidance of upgrading panel, supervisors and advisers, leading to this study. The validation study protocol has been published in the Journal of Medical Internet Research - Protocols (JMIR). I trained and assessed the physician graders under suprvision of a local retinologist. I monitored the screening and grading and assessed the quality of imaging and grading through double grading. The data were entered by trained research assistants. An independent statistician conducted data cleaning. I analysed and interpreted the data under supervision of statisticians. I prepared this manuscript and it was revised by the suprvisors before submitting to BMC - Ophthalmology. The 1st revision comments were recived in Janunary 2019 and the corrections submitted in February 2019. This manuscript has been accepted for publication in March/2019.

Student Signature: [redacted] **Date:** 27/03/2019

Supervisor Signature: [redacted] **Date:** 27/03/2019

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RESEARCH ARTICLE Open Access

Diagnostic test accuracy of diabetic retinopathy screening by physician graders using a hand-held non-mydriatic retinal camera at a tertiary level medical clinic

Mapa Mudiyanselage Prabhath Nishantha Piyasena[1*], Jennifer L. Y. Yip[2], David MacLeod[3], Min Kim[3] and Venkata S. Murthy Gudlavalleti[4]

Abstract

Background: The evidence on diagnostic test accuracy (DTA) of diabetic retinopathy (DR) screening utilising photographic studies by non-ophthalmologist personnel in low and middle-income country (LMIC) settings is scarce. We aimed to assess DTA of DR screening using a nonmydriatic hand-held digital camera by trained general physicians in a non-ophthalmic setting.

Methods: This study is a validation of a screening intervention. We selected 700 people with diabetes (PwDM) > 18 years of age, not previously screened or treated for DR, presenting at a tertiary medical clinic in Sri Lanka. Two-field retinal imaging was used to capture fundus images before and after pupil dilatation, using a hand-held non-mydriatic (Visuscout 100®-Germany) digital retinal camera. The images were captured and graded by two trained, masked independent physician graders. The DTA of different levels of DR was assessed comparing physician's grading with a retinologist's clinical examination by mydriatic bio-microscopy, according to a locally adopted guideline.

Results: Seven hundred eligible PwDM were screened by physician graders. The mean age of participants was 60.8 years (SD ±10.08) and mean duration of DM was 9.9 years (SD ±8.09). Ungradable image proportion in non-mydriatic imaging was 43.4% (either eye-31.3%, both eyes 12.1%). This decreased to 12.8% (either eye-11.6%, both eyes-1.2%) following pupil dilatation. In comparison to detection of any level of DR, a referable level DR (moderate non-proliferative DR and levels above) showed a higher level of DTA. The sensitivity of the defined referable DR was 88.7% (95% CI 81.7–93.8%) for grader 1 (positive predictive value [PPV] 59.1%) and 92.5% (95% CI 86.4–96.5%) for grader 2 (PPV 68%), using mydriatic imaging, after including ungradable images as screen positives. The specificity was 94.9% (95% CI 93.6–96.0%) for grader 1 (negative predictive value [NPV] 99%) and 96.4% (95% CI 95.3–97.3%) for grader 2 (NPV 99.4%).

Conclusions: The Physicians grading of images from a digital hand-held non-mydriatic camera at a medical clinic, with dilatation of pupil of those who have ungradable images, provides a valid modality to identify referable level of DR. This could be a feasible alternative modality to the existing opportunistic screening to improve the access and coverage.

Trial registration: Current Controlled Trials ISRCTN47559703. Date of Registration 18th March 2019, Retrospectively registered.

Keywords: Diabetes, Diabetic retinopathy, Diagnostic accuracy, Digital imaging, Screening

* Correspondence: Prabhath.piyasena@lshtm.ac.uk
[1]Clinical Research Department, International Centre for Eye Health, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT, UK
Full list of author information is available at the end of the article

Chapter 12

Diagnostic Test Accuracy of Diabetic Retinopathy Screening by Physician Graders Using a Hand Held Non-Mydriatic Retinal Camera at a Tertiary Level Medical Clinic

Piyasena MMPN, Yip JYL, MacLeod D, Kim M, Murthy GVS. Diagnostic Test Accuracy of Diabetic Retinopathy Screening by Physician Graders Using a Hand Held Non-Mydriatic Retinal Camera at a Tertiary Level Medical Clinic in a Lower-Middle Income Country Setting. BMC-Ophthalmology. 2019;19(1):89 PMID: 30961576 PMCID: PMC6454614 DOI: 10.1186/s12886-019-1092-3

Abstract

Background

The evidence on diagnostic test accuracy (DTA) of diabetic retinopathy (DR) screening utilising photographic studies by non-ophthalmologist personnel in low and middle-income country (LMIC) settings is scarce. We aimed to assess DTA of DR screening using a nonmydriatic hand-held digital camera by trained general physicians in a non-ophthalmic setting.

Methods

This study is a validation of a screening intervention. We selected 700 people with diabetes (PwDM) > 18 years of age, not previously screened or treated for DR, presenting at a tertiary medical clinic in Sri Lanka. Two-field retinal imaging was used to capture fundus images before and after pupil dilatation, using a hand-held non-mydriatic (Visuscout 100®-Germany) digital retinal camera. The images were captured and graded by two trained, masked independent physician graders. The DTA of different levels of DR was assessed comparing physician's grading with a retinologist's clinical examination by mydriatic bio-microscopy, according to a locally adopted guideline.

Results

Seven hundred eligible PwDM were screened by physician graders. The mean age of participants was 60.8 years (SD ±10.08) and mean duration of DM was 9.9 years (SD ±8.09). Ungradable image proportion in non-mydriatic imaging was 43.4% (either eye-31.3%, both eyes 12.1%). This decreased to 12.8% (either eye-11.6%, both eyes-1.2%) following pupil dilatation. In comparison to detection of any level of DR, a referable level DR (moderate non-proliferative DR and levels above) showed a higher level of DTA. The sensitivity of the defined referable DR was 88.7% (95% CI 81.7-93.8%) for grader 1 (positive predictive value [PPV] 59.1%) and 92.5% (95% CI 86.4-96.5%) for grader 2 (PPV 68%), using mydriatic imaging, after including ungradable images as screen positives. The specificity was 94.9% (95% CI 93.6-96.0%) for grader 1 (negative predictive value [NPV] 99%) and 96.4% (95% CI 95.3-97.3%) for grader 2 (NPV 99.4%).

Conclusions

The Physicians grading of images from a digital hand-held non-mydriatic camera at a medical clinic, with dilatation of pupil of those who have ungradable images, provides a valid modality to identify referable level of DR. This could be a feasible alternative modality to the existing opportunistic screening to improve the access and coverage.

Key words - Diabetes, Diabetic retinopathy, Diagnostic accuracy, Digital imaging, Screening.

Study Protocol Number - Registered report identifier number – (JMIR-doi:10.2196/10900)

Trial Registration Number - ISRCTN47559703

Background

Diabetic retinopathy (DR) is a common complication of diabetes mellitus (DM), leading to sight loss if not detected and treated in time [1]. The International Diabetes Federation (IDF) estimated that cases of DM will increase to 629 million by 2045, with a significant burden (80%) in low and middle income countries (LMIC) [2]. Systematic DR screening (DRS) is a challenge in many of the LMICs due to limited resources [3]. The St Vincent declaration stated that all nations should make efforts to reduce DM related complications, including DR blindness [4]. These recommendations were followed by most of the high-income countries (HICs). The LMICs would also be able to achieve this aim with the adaptation and use of existing technologies according to the local contextual requirements.

The most common method of detecting DR in LMICs is direct ophthalmoscopy and slit-lamp bio-microscopy. The direct ophthalmoscopy has a low sensitivity and specificity even at the hands of experienced eye care specialists [5]. The mydriatic bio-microscopic examination by an ophthalmo-logist is not practical in these countries due to the low number of ophthalmologists and eye clinics which are already over-subscribed with more common blinding conditions such as cataract [6]. In these circumstances, DR is detected through opportunistic case detection only. Insufficient capacity and lack of screening infrastructure hampers efforts to implement DRS programs (DRSP) in these settings, and there is a lack of evidence of what works in LMICs [7]–[9].

Different models of DRS have been implemented in many parts of the world. In resource poor LMICs development of a DRS model is complex [10]. The lack of trained human resources and infrastructure has outstripped the capacity to deliver systematic DRS in low income settings [11]. There are also poor recording systems to identify the people with DM (PwDM). Therefore, a comprehensive population-based DRSP may not be feasible in LMICs in the near future [8],[10]. DRS also requires appropriate integration into routine care for sustainability [10]. It was shown that public health integration of DRS is a feasible strategy to control avoidable blindness [12]. As such, one feasible

model of systematic DRS in LMICs could be screening of PwDM when they attend for routine medical care. This can provide a participant list of PwDM, who can be offered screening at regular intervals. Integrated DRS at medical care clinics can also facilitate risk stratification and prioritisation of referrals to busy eye clinics. In these circumstances, a key consideration would be the availability of skilled human resources facilitating task shifting and sharing and efficient, cost effective and valid technology for DRS.

Retinal fundus photography is the most common DRS method used globally [13] and digital systems are mostly preferred [14]. Conventional desk-top digital cameras require significant physical space, skilled photographers and large image storage devices which incur high capital investment but are cost effective [15]. Hand-held digital cameras are portable, require less space, minimum power consumption and less skills and training [16]. Non-mydriatic retinal imaging is more popular considering the convenience for both service user and provider due to absence of procedures such as pupil dilatation [17]. However, this may have an impact on image gradability and screening coverage [18].

Hand held retinal cameras use for DRS in various settings and outcomes mainly depend on the image quality. Yogesan et al., (2000) reported that images captured by a hand-held camera were not suitable for tele-screening due to poor quality (only 24% in good quality). However in this study sample size was very low (n=25 participants, 49 eyes) [19]. A study conducted in France, concluded that hand-held retinal imaging system was less efficient with poor image quality. However, in this study the photographer had undergone training only on 10 patients before the study, which is a highly inadequate for a hand-held camera [20]. In contrast, A study conducted in China reported that 63% of the images were in excellent quality, however the age of the participants was started as low as 9 years (age range 9-84 years) [21]. A review by Cuadros et al., (2017) concluded that hand-held cameras are

practically convenient but do not provide sufficient image quality [22]. Therefore, quality of the images is a major concern in hand-held devices, though they are easy to use.

To the authors' knowledge there is no evidence on DRS using digital retinal imaging from Sri Lanka. A situational analysis conducted in the Western province showed a large gap in DRS services delivery compared to the estimated need [23]. This study aims to demonstrate the functional and technical feasibility of using a hand-held non-mydriatic digital camera in a LMIC non-ophthalmic setting. We assessed the DTA of DR detection by general physicians using this method compared to the local clinical reference standard of mydriatic indirect ophthalmoscopy and bio-microscopic examination by a retinologist.

Methods

Ethics approval was obtained from both ethics review committees of the London School of Hygiene & Tropical Medicine-United Kingdom and the National Eye Hospital-Sri Lanka. This study adhered to the tenets of the 'Declaration of Helsinki'. A prospective screening intervention validation study was conducted between May 2017 and May 2018 at a tertiary level, public sector out-patient medical clinic in the Western province of Sri Lanka. The main outcome measure was detection of signs of DR (any DR or a referable level) by physician graders using captured digital images, according to a locally adopted guideline. The protocol of this validation study has been published in Journal of Medical Internet Research (JMIR-doi:10.2196/10900) and a summary is outlined below [24].

Summary of the methods

Nine general physicians from a tertiary level institution underwent a competency-based training programme following written informed consent, delivered by two retinologists. The training included the following: capturing retinal fields using a hand-held non-mydriatic fundus camera (Zeiss-Visuscout100®-Germany), identification of signs of DR using images and DR grading according to an

adopted classification system based on the United Kingdom - National Screening System [25] (Additional File 1-Table 1 in Appendix 9). The hand-held imaging system has the ability to capture colour and red free retinal images in a range of +20 diopters (D) to -20 D, at 40 ^{0} field of view angle. The camera comprised of 9 fixation targets and resolution of the camera is 800 x 480 (5 megapixels). Guidelines were used to standardize reporting of image quality, and ungradable images were classified based on the proportion of the retina visible for grading (Additional File 1-figure 1 in Appendix 9). Physicians were tested using a set of standard images of DR and the two who reached the required level of agreement with the retinologist (k=0.8-0.9) were selected as graders in the validation study.

A sample size of n=506 participants was chosen, in order to estimate the sensitivity within a margin of error 10% (based on 95% confidence intervals), with an expected sensitivity of 70% and prevalence of moderate NPDR among PwDM of 20%. This included an additional 25% to take account of ungradable images (i.e., <50% of the retina visible). Interim analysis was undertaken to ascertain the level of ungradable images and, to take account of a higher than expected proportion of ungradable images, the sample size was increased to 700 PwDM. A consecutive sample (n=700) of diagnosed PwDM (>18years) without previous DRS at an eye clinic who were included in the study following written informed consent. Participants were identified at a tertiary level medical clinic, in the Western province of Sri Lanka.

In the index test imaging, two-field (1st field-macula cantered, 2nd field-disc centred) (Additional File 1-figure 2 in Appendix 9), 45-degree retinal images were captured in each eye before and after pupillary dilatation, using 2% phenylephrine, following adequate mydriasis (5-6 mm) by each physician grader. During grading, the non-mydriatic images were graded first. We calculated DTA at 3 levels for the non-ophthalmic settings: i.e., 1) any DR (detection of R1, R2, R3 and R4), 2) referable DR (R2 and above) and 3) detection of referable level and maculopathy combined with a visual acuity

cut off (worse eye >6/18 Snellen visual acuity) (see Additional File 1-Table 1 in Appendix 9). The graders were masked to the history and clinical examination findings and pupil status of the images. The clinical reference test entailed a detailed, dilated fundus examination by an experienced trainer retinologist using slit-lamp bio-microscopy with a 90D lens and indirect ophthalmoscopy using a 20D lens. The reference test was conducted by one retinologist with more than 15 years of clinical experience in vitreo-retina field. The 7-field 'Early Treatment diabetic Retinopathy Study' references test was logistically not feasible in this resource poor setting. This reference examination took place as soon after imaging as possible in all 700 PwDM that were included in the index test. The retinologist was masked to the clinical status and physician graders' findings.

For quality assurance, 15% of each non-mydriatic and mydriatic image sets were evaluated by the retinologist for technique, ability to image the required field and gradability. Fifteen percent of each hundred image sets were given back to the physician graders for double grading to assess the repeatability and intra-grader agreement in the 1st and 2nd attempts of grading images. A sample of the same image sets (n=212) were graded by the retinologist to calculate inter-grader agreement.

Analysis

Data were entered into an MS Excel-16.0 worksheet and transferred to SPSS-Version-20.0 (Armonk-NY-IBM Corp-2011) and STATA/IC-Version-14.2 (Texas-77845-USA) for analysis. DTA variables of sensitivity, specificity and predictive values and agreement analyses (kappa statistics) were calculated with 95% confidence intervals, for each grader and each pupil status compared to the reference standard using individual eyes as the unit of analysis, considering each gradable eye as a separate case. Two approaches were used in the calculations to examine the impact of ungradable images on the outcomes. i.e., by excluding the ungradable images and by including ungradable as test positive in the analysis. As ungradable images indicate a requirement for referral to an eye clinic, we analysed ungradable images as screen positives to examine the sensitivity and specificity of detecting

a need for referral. This also allows comparisons with previous studies, which have used both methods.

Subgroup analysis conducted for identification of presence/absence of DR (any DR), moderate NPDR and above with / without macular signs, to make recommendations for a referable criterion for the local context. We used different referable criteria i.e., by pupil status, level of DR, level of visual acuity and presence of macular signs in the analysis to understand the variation in DTA to assess the most suitable and accurate cut off level of DR without overloading the eye clinic and also facilitating safe practice at a non-ophthalmic setting.

Results

Participants' characteristics

Of the 826 eligible PwDM identified from medical clinical records, response rate was 84.7% (700/826). Mean age of the participants was 60.8 years (SD ±10.08) and majority were women (66%, 462/700). Only 27.9% (195/700) of the participants were employed and 79.1% (554/700) lived in the capital city of Colombo and hailed from low income families (88%, 616/700, monthly income <£150). Of these, 98.4% (689/700) had type 2 DM and 1.6% (11/689) were diagnosed with DM at age < 30 years and were on insulin. The mean age at diagnosis of DM was 50.9 years (SD ±11.03) and mean duration of diabetes was 9.9 years (SD ±8.09). Mean fasting plasma glucose with in the last 3 months was 140.4 mg/dl (SD ±55.43). Additional co-morbidities included; hypertension (70%), hyperlipidaemia (57.3%), ischaemic heart disease (31.9%), nephropathy (9%) and neuropathy (35%). The Table 1 shows the characteristics of the PwDM in this study. The maximum time interval between index and reference test was 4 weeks.

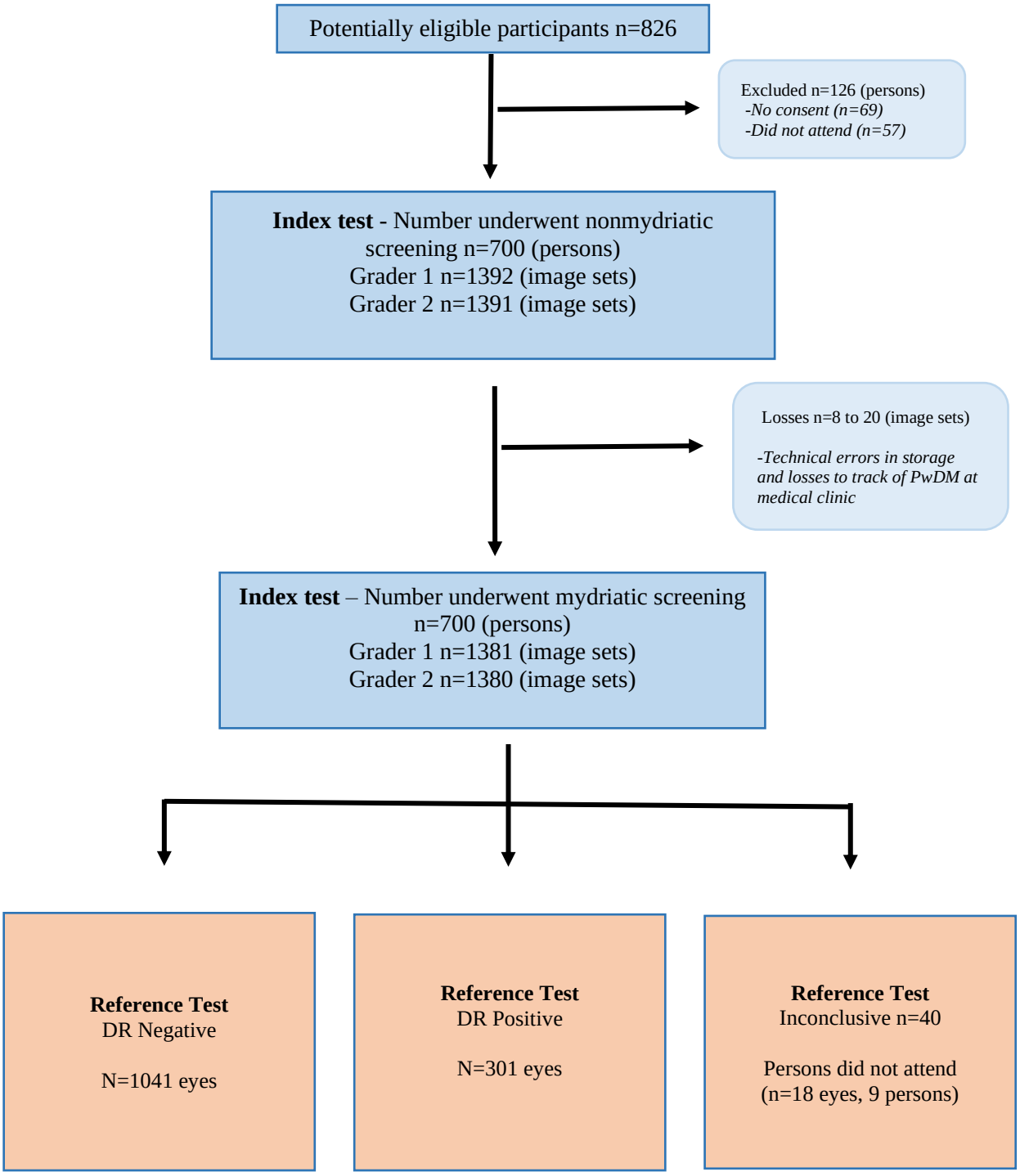

Figure 1. Flow chart of the number of participants and image sets used in the DTA analysis

Table 1. Participants' characteristics

Variable	Categories	Results
Mean age	Mean	60.8 years (SD 10.1)
Sex	Male	34% (n=238)
	Female	66% (n=462)
Employment status	Employed	27.9%(n=195)
	Unemployed	41.0% (n=287)
	Retired	31.1%(n=218)
Monthly household income	Low (<£150)	88.0% (n=616)
	Middle (>£150 - <£300)	9.6% (n=67)
	High (>£300)	2.4% (n=17)
Ethnic group	Sinhalese	66.9% (n=468)
	Tamil	16.4% (n=115)
	Moor	14.1%(n=99)
	Other	2.6% (n=18)
Age at diagnosis of diabetes	Mean	50.9 years (SD 11.0)
Duration of diabetes	Mean	9.9 years (SD 8.1)
Current treatment of DM	Diet only	5.6% (n=39)
	Oral medication only	79.7% (n=558)
	Insulin only	5.6% (n=39)
	Oral medication and insulin	9.1% (n=64)
Fasting glucose level (within 3 months)	Mean	140.44 mg/dl (SD 55.4) 95% CI (136.2-144.0)
HbA1c level (only n=42 available)	Mean	7.9 % (SD 2.2) 95% CI (7.3-8.7)
Other comorbidities	Hypertension	70%
	Hypercholesterolaemia	57.3%
	Ischaemic heart disease	31.9%
	Nephropathy	9%
	Neuropathy	35%

	Leg / peripheral ulcers	5%
Age at diagnosis of hypertension	Mean	52.8 years (SD 9.6)
Family history	Diabetes	63.3%
	Hypertension	50.4%
	Hypercholesterolaemia	30%
	Ischaemic heart diseases	28.7%

Image gradability and number of images sets available for DTA analysis

Seven hundred PwDM were included in the study and 126 (15.2%, 126/826) were excluded (n=69-no consent and n=57-did not attend for imaging) (See Figure 1). Since both physician graders captured image sets of each participant, ideally there should be 1400 image sets (by eyes) for each grader for each pupil status. However, we ended up as shown in Additional File 2 in Appendix 9 - flow chart, due to technical errors in storage and failure to track PwDM (8-20 eyes, 0.6-1.4%) at the medical clinic. Overall ungradable proportion in non-mydriatic imaging was 31.0% (217/700) for at least one eye ungradable for either grader. In 12.0% (84/700) both eyes were ungradable for both graders. This decreased to 11.4% (80/700) and 1.1% (8/700) respectively, following pupil dilatation. We noted that 9 PwDM (18 eyes) did not attend for the reference test. In addition, reference test was not possible in 40 eyes (40/1400, 2.8%, in 21 participants: 37 advanced lens opacity, 1 posterior capsular opacity, 1 phthisical eye 1 and 1 eviscerated). After excluding eyes of those who did not attend and ungradable even at the reference test (total n=58) we left with 1342 image sets (by eyes) in DTA analysis. Overall there were 1041 DR positive eyes and 301 DR negative eyes as identified at the reference test. The technical failure rates by the area of visibility of the retinal fields for each image set in the index test by pupil status and grader level (by eyes) are described in the Table 2 and Additional Files 2 and 3 in Appendix 9. In addition, a very good gradability agreement (range k=0.72-0.96) was observed for physician graders in comparison to retinologist's findings using a sample of images.

Table 2. Gradability of the images as marked by each grader and agreement with the reference grader

Gradability percentage of the retinal fields		Non-mydriatic imaging		Mydriatic imaging	
		Grader 1 N[c]=1392	**Grader 2** N=1391	**Grader 1** N=1381	**Grader 2** N=1380
Gradable					
	100% [a]	286 (20.5%)	352 (25.3%)	537 (38.9%)	605 (43.8%)
	75%	308 (22.1%)	431 (31.0%)	395 (28.6%)	519 (37.6%)
	50%	386 (27.7%)	276 (19.8%)	351 (25.4%)	186 (13.5%)
Ungradable					
	<50%	412 (29.6%)	332 (23.9%)	98 (7.1%)	70 (5.1%)
Inter-grader Agreement [b], kappa (95% CI)		0.90 (0.85,0.95)	0.90 (0.86,0.95)	0.72 (0.56,0.89)	0.96 (0.89,1.00)

a. Percentage of visibility in a given field, by eyes
b. Physician grader vs retinologist – grading a random sample of image sets (n=212, total n=424).
c. Number of image sets by eyes.

DTA after including ungradable images (primary analysis)

We aimed to demonstrate the DTA for referrals to eye clinic rather than the DTA of detecting DR in the primary analysis. When considering the ungradable images as screen positives, sensitivity of detection of any level of DR using non-mydriatic imaging was 82.7% (95% CI 78.4-86.5%) in grader 1 and 78.3% (95% CI 73.7-82.5%) in grader 2. However, since they were referring a higher proportion of ungradable, probably those who did not have the disease, specificity values dropped to 70.4% (95% CI 67.6-73.1%) in grader 1 and 76.2% (95% CI 73.6-78.7%) in grader 2 in non-mydriatic imaging. In mydriatic imaging when we included the ungradable images in the analysis sensitivity was 79.3% (74.7-84.8%) in grader 1 and 78.0% (95% CI 73.4-82.2%) in grader 2. The specificity value of grader 1 was 89.2% (95% CI 87.2-90.9%) and grader 2 was 91.5% (95% CI 89.7-93.1%). The sensitivity, specificity, NPV, PPV and kappa agreement at different levels of DR after including the ungradable images are described in Table 3.

Table 3. Diagnostic test accuracy of each grader by each pupil status (unit of analysis, by eyes, after including ungradable images)

Index Test			Sensitivity (95% CI) (%)	Specificity (95% CI) (%)	PPV (95% CI) (%)	NPV (95% CI) (%)	Kappa (95% CI) (%)
Any DR grading							
	Non-mydiatric image						
		Grader 1	82.7 (78.5, 86.5)	70.4 (67.6, 73.1)	47.4 (43.4, 51.5)	92.7 (90.7, 94.4)	0.42 (0.38, 0.47)
		Grader 2	78.3 (73.7, 82.5)	76.2 (73.6, 78.8)	51.6 (47.3, 55.9)	91.6 (89.6, 93.3)	0.46 (0.42, 0.51)
	Mydiatric image						
		Grader 1	79.3 (74.7, 83.4)	89.2 (87.2, 90.9)	70.3 (65.6, 74.8)	93.0 (91.3, 94.5)	0.66 (0.61, 0.70)
		Grader 2	78.0 (73.4, 82.2)	91.5 (89.7, 93.1)	74.7 (70.0, 79.1)	92.8 (91.1, 94.3)	0.68 (0.64, 0.73)
Referable DR grading [a]							
	Non-mydiatric image						
		Grader 1	86.8 (79.5, 92.3)	71.7 (69.2, 74.2)	20.4 (16.9, 24.3)	98.5 (97.6, 99.1)	0.23 (0.19, 0.28)
		Grader 2	84.9 (77.3, 90.9)	77.3 (75.0, 79.6)	23.8 (19.7, 28.3)	98.4 (97.5, 99.0)	0.29 (0.23, 0.34)
	Mydiatric image						
		Grader 1	88.7 (81.7, 93.8)	94.9 (93.6, 96.0)	59.1 (51.4, 66.6)	99.0 (98.4, 99.5)	0.68 (0.61, 0.75)
		Grader 2	92.5 (86.4, 96.5)	96.4 (95.3, 97.3)	68.0 (60.2, 75.3)	99.4 (98.8, 99.7)	0.76 (0.70, 0.82)
Maculopathy grading [b]							
	Non-mydiatric image						
		Grader 1	89.2 (83.5, 93.5)	70.1 (67.5, 72.6)	26.5 (22.7, 30.4)	98.2 (97.2, 98.9)	0.29 (0.25, 0.34)
		Grader 2	80.4 (73.5, 86.6)	77.0 (74.6, 79.3)	29.7 (25.3, 34.3)	97.0 (95.8, 98.0)	0.33 (0.28,0.38)
	Mydiatric image						
		Grader 1	86.5 (80.4, 91.4)	91.5 (89.8, 92.9)	54.9 (48.5, 61.2)	98.3 (97.4, 98.9)	0.62 (0.56,0.68)
		Grader 2	82.4 (75.8, 87.9)	95.4 (94.1, 96.5)	68.2 (61.1, 74.7)	97.0 (96.9, 98.6)	0.71 (0.65,0.77)

a-Referable level DR – moderate non-proliferative DR and above

b-Maculopathy – presence of haemorrhage/s or exudates within 2-disc diameters of the centre of fovea

DTA after excluding ungradable images

The DTA estimates were calculated after excluding ungradable images (<50% of the field visible) in the next step as an accuracy measure of the modality. In the comparison physician's grading using 2-field imaging against the clinical reference standard, in detection of any level of DR, there was no significant difference in DTA by pupil status, in each grader. Similar results were observed in detection of macular signs. Table 4 shows the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for each grader and for each pupil status for this analysis. A higher range of PPV values were observed in detecting a referable level DR (79.7%-92.8%) (moderate non-proliferative DR and above) compared to identification of macular signs (63.2%-73.5%) (presence of haemorrhage/s or exudate/s within 2-disc diameters of centre of fovea). However, such differences were not observed in NPV.

Table 4. Diagnostic test accuracy of each grader by each pupil status (unit of analysis, by eyes, after excluding ungradable images)

Index Test			Sensitivity (95% CI) (%)	Specificity (95% CI) (%)	PPV (95% CI) (%)	NPV (95% CI) (%)	Kappa (95% CI) (%)
Any DR grading							
	Non-mydiatric image						
		Grader 1	71.1 (64.9, 77.4)	95.6 (94.1, 97.0)	80.8 (75.0, 86.6)	92.7 (90.8, 94.5)	0.70 (0.64, 0.76)
		Grader 2	66.4 (60.0, 72.7)	95.4 (94.0, 96.8)	78.9 (72.9, 84.9)	91.7 (89.8,93.5)	0.66 (0.60,0.72)
	Mydiatric image						
		Grader 1	76.2 (71.3, 81.0)	94.0 (92.6, 95.5)	79.1 (74.4, 83.9)	93.0 (91.4, 94.6)	0.71 (0.66, 0.76)
		Grader 2	75.2 (70.2, 80.1)	93.9 (92.5, 95.4)	78.3 (73.6, 83.1)	92.9 (91.3, 94.5)	0.70 (0.65, 0.75)
Referable DR grading[a]							
	Non-mydiatric image						

		Grader 1	73.6 (61.7, 85.5)	99.7 (99.3, 100.0)	92.9 (85.1, 100.7)	98.5 (97.7, 99.3)	0.81 (0.72, 0.90)
		Grader 2	71.7 (59.6, 83.8)	99.0 (98.4, 99.6)	79.2 (67.7, 90.7)	98.5 (97.8, 99.3)	0.74 (0.64, 0.84)
	Mydiatric image						
		Grader 1	81.8 (72.5, 91.1)	99.4 (99.0, 99.9)	88.5 (80.5, 96.5)	99.0 (98.5, 99.6)	0.84 (0.77, 0.91)
		Grader 2	89.4 (82.0, 96.8)	98.8 (98.2, 99.4)	79.7 (70.6, 88.9)	99.4 (99.0, 99.9)	0.83 (0.77, 0.90)
Maculopathy grading[b]							
	Non-mydiatric image						
		Grader 1	78.1 (68.6, 87.6)	96.6 (95.5,97.8)	65.5 (55.5, 75.5)	98.1 (97.29, 99.1)	0.69 (0.60, 0.77)
		Grader 2	64.1 (53.5, 74.8)	98.1 (97.3, 99.0)	73.5 (63.0, 84.0)	97.1 (96.1, 98.2)	0.66 (0.57, 0.75)
	Mydiatric image						
		Grader 1	81.0 (73.3, 88.7)	96.0 (94.9, 97.1)	63.3 (54.9, 71.6)	98.3 (97.6, 99.1)	0.68 (0.61, 0.75)
		Grader 2	75.3 (66.8,83.7)	97.8 (96.91, 98.6)	73.8 (65.3,82.3)	97.9 (97.1, 98.7)	0.72 (0.65, 0.79)

a-Referable level DR – moderate non-proliferative DR and above
b-Maculopathy – presence of haemorrhage/s or exudates within 2-disc diameters of the centre of fovea.

Sub-analyses of DTA

As a pragmatic approach for a resource poor non-ophthalmic setting, we reported the DTA of DRS using non-mydriatic imaging and dilatation of the pupils of only those who have ungradable images (two-step process). In this sub-analysis, the eye which was ungradable even following mydriasis were considered as screen positives. We derived a sensitivity of referable level of DR 81.1% (95% CI 72.9-87.9%) for grader 1 and 82.1% (95% CI 74.0-88.6%) for grader 2. The specificity values were 95.4% (95% CI 94.2-96.5%) for grader 1 and 97.1% (95% CI 96.1-97.9%) for grader 2 in this approach. We observed an improved level of PPV (59.7-70.2%) and NPV (98.4-98.5%) in this strategy. The details are described in Additional File 4 in Appendix 9.

We combined the DTA of the detection of referable level DR (moderate NPDR and above) with positive macular signs, using non-mydriatic imaging, where the sensitivity was 79.0% for grader 1

and 70.8% for the grader 2. These estimates improved to 84.5% and 85.8% respectively for grader 1 and 2 after dilatation. For the same referable level specificity values were 96.6% and 98.0% for grader 1 and 2 respectively and there was no significant change with the pupil dilatation (non-mydriatic grader 1-97.3%, grader 2-98.4%).

We also incorporated visual acuity threshold for referrals (considering worse eye visual acuity 6/18 and above, retinopathy moderate and above and positive macular signs) and found a sensitivity of grader 1 was 98.3% (95% CI 94.9-99.7%) and grader 2, 97.4% (95% CI 93.5-99.3%). However, in the same referable level specificity values showed an overall reduction (grader-1 49.4%, 95% CI 45.3-53.5% and grader-2 51.6%, 95% CI 47.5-55.7%), probably due to high number of PwDM referred to the next level without ≥ moderate NPDR. These approaches will be useful in making recommendations for a referable level for a non-ophthalmic setting.

Agreement analysis

The percentage of image gradability agreement, between index graders and retinologist (inter-grader agreement), in non-mydriatic imaging; grader 1 was 85.2% ([kappa] k=0.9, 95% CI 0.85-0.95) and grader 2, 78.5% (k=0.9, 95% CI 0.86-0.95). In mydriatic imaging, inter-grader gradability agreement of grader 1 was 76.2% (k=0.72, 95% CI 0.56-0.89) and grader 2, 72.7% (k=0.96, 95% CI 0.89-1.03).

We proposed grading the same images by the retinologist would provide a fair comparison for the physician graders in agreement analysis. However, here the concerns were limitations in the degree of view of a hand-held retinal camera and skills of capturing images by the physicians. In this analysis, in the grading of DR and macular signs, we found that inter-grader agreement was mostly >0.8 except for the grader 2 non-mydriatic images (any DR k=0.80-0.89, referable DR k=0.77-0.85, macular signs k=0.77-0.85). We observed a satisfactory level of agreement of the physician graders findings using a 2-field modality. The overall concordance of the results is described in Table 5.

Table 5. Agreement by comparing findings of sample of same images (captured by physicians) graded by retinologist (inter-grader agreement: physician grader 1 or 2 vs retinologist) (n=212, 424 image sets)

Index Test	Sensitivity (95% CI) (%)	Specificity (95% CI) (%)	Kappa value (95% CI) (k)
Any DR grading			
Non-mydriatic image			
Grader 1	92.3 (86.4, 98.2)	96.8 (94.5, 99.1)	0.89 (0.83, 0.95)
Grader 2	84.9 (77.3, 92.5)	94.9 (92.1, 97.7)	0.80 (0.73, 0.88)
Mydriatic image			
Grader 1	90.2 (85.0, 95.5)	96.7 (94.6, 98.8)	0.88 (0.82, 0.93)
Grader 2	90.5 (85.5, 95.6)	95.0 (92.5, 97.6)	0.85 (0.80, 0.91)
Referable DR grading [a]			
Non-mydriatic image			
Grader 1	80.0 (64.3, 95.7)	99.3 (98.3, 100.3)	0.84 (0.72, 0.96)
Grader 2	79.2 (62.3, 95.4)	98.3 (96.9, 99.8)	0.77 (0.64, 0.91)
Mydriatic image			
Grader 1	77.1 (63.2, 91.1)	98.9 (97.8, 100.0)	0.80 (0.69, 0.91)
Grader 2	97.0 (91.1, 102.9)	97.6 (96.4, 99.2)	0.85 (0.76, 0.94)
Maculopathy grading [b]			
Non-mydriatic image			
Grader 1	94.3 (86.6, 102.0)	97.0 (94.9, 99.0)	0.85 (0.76, 0.94)
Grader 2	75.0 (61.6, 88.5)	98.2 (96.7, 99.8)	0.77 (0.66, 0.88)
Mydriatic image			
Grader 1	88.1 (79.9, 96.4)	96.5 (94.5, 98.4)	0.82 (0.74, 0.90)
Grader 2	76.6 (66.2, 86.9)	98.5 (97.3, 99.8)	0.80 (0.72, 0.89)

a-Referable level DR – moderate non-proliferative DR and above

b-Maculopathy – presence of haemorrhage/s or exudates within 2-disc diameters of the centre of fovea

Quality assurance

The index graders re-graded the coded image sets in a masked fashion independently without having access to the first attempt data. In this, first attempt vs second attempt weighted kappa agreement was calculated to assess the repeatability of DR grading at level of retinopathy. The kappa value of grader 1 was 0.69 (95% CI 0.60-0.78) and grader 2, 0.66 (95% CI 0.58-0.73). In comparison of grader 1 vs grader 2, first attempt kappa was 0.82 (95% CI 0.76-0.89) and in second attempt it was 0.74 (95% CI 0.66-0.83%) (see Additional File 5 in Appendix 9).

Reasons for ungradability of images, prevalence of DR and time and flow of the participants

We described the possible reasons for ungradability, using the highest recorded ungradability values, which was observed by grader 1. Of the 29.4% of ungradable images for grader 1, non-mydriatic imaging, 69.2% (285/412) had lens opacity. Among these 29.8% (85/285) eyes had significant level of lens opacity which required cataract assessment. Following reference test 37 eyes were identified as having lens opacities that required urgent cataract surgery. Overall, 75.6% of the participants had no DR, 16.7% mild DR (R1), 3.6% moderate NPDR (R2), 0.4% severe NPDR (R3) and only 1% had PDR (R4). Among the ungradable images in non-mydriatic imaging, 66.5% (274/412) had no retinopathy (R0), 19.9%-mild NPDR (R1), 1.7%-moderate NPDR (R2), 0.7%-severe NPDR (R3) and 1.5%-proliferative DR (PDR-R4) (see Additional File 3 in Appendix 9).

The mean time gap between index imaging and reference test was 3.6 days (SD ± 0.2) (95% CI 3.2-4.0, range 0-48 days). Six hundred and ninety-two PwDM completed the reference test examination and 98% (684/692) of them underwent retinologists examination < 4 weeks period.

Discussion

We demonstrated that DRS by general physicians using a mydriatic two field technique was a feasible modality to detect a defined level of referable DR (moderate NPDR and above, after including ungradable images: sensitivity 88.7-92.5% and specificity 94.9-96.4%) in a non-ophthalmic setting,

considering the level of DTA achieved. This may be suitable for LMIC settings where it would be difficult to implement full population based DRSP due to resource and information constraints. Compared to a locally accepted clinical reference standard, DRS using mydriatic 2-field strategy by general physicians showed an accepted level of DTA which most of the HIC screening programs follow (sensitivity of >80% and specificity of >95%) [25]. We assumed that inclusion of ungradable images in the DTA analysis is a pragmatic approach for a non-ophthalmic setting, considering the requirement of referring those PwDM to the eye clinic for further assessment and treatment. The proposed imaging strategy could act as a filter minimizing the number of referrals at eye clinic, thereby reducing the strain on the system. The United Kingdom prospective diabetes study group (UKPDS) reported that 15.3% of those with signs of DR at baseline, required laser at 3 years [26]. Therefore, identification of even minor levels of DR will be beneficial to stratify the risk groups early.

Digital retinal imaging showed promising results in DRS [25]. The digital imaging systems have the advantage of instant availability of images for quality assessment and convenient storage and retrieval. Several studies have compared digital fundus photography with 7-fields used in early treatment diabetic retinopathy study (ETDRS) [27]–[29] or mydriatic ophthalmoscopy [30], [31] in DRS and shown an acceptable level of DTA. The DTA studies from high income countries (HIC) used trained graders or ophthalmologists/retinologists in index test and table top static cameras with advanced technology such as wider angle and high resolution, which may be prohibitively expensive for LMICs. Though DTA is lower in this study, this strategy would be useful in a context where there is no systematic DRS. On the other hand, it may be arbitrary to compare the findings of this study with HICs. LMICs such as Sri Lanka require pragmatic solutions for control of visual loss due to DR with rising prevalence of DM.

The optimum number of retinal fields in a DRS strategy is a key factor that affects accuracy. The ETDRS 7-field strategy is considered to be the gold standard for DR detection but is not practical in a

screening program [32]. Previous studies showed that single retinal field is inadequate to achieve required standards [33]–[37]. Studies have also demonstrated that 3-fields would not improve DTA of detection of any referable DR [38]. A non-mydriatic two field strategy in detection of sight threatening DR (STDR) in a HIC showed a sensitivity of 92% (95% CI 90-94%) and specificity of 96% (95% CI 95-98%) (proportion of ungradability - non-mydriatic 15.3-17.6%, mydriatic 1.4-2.1%) [27]. In our study, sensitivity was 71.7-73.5% and specificity 98.9-99.6% for detection of referable DR using non-mydriatic imaging. We could not achieve a higher level of sensitivity comparable with the studies done in HICs, due to poor image quality. The main causes of poor image quality are dark iris colour, poor pupil dilation status and lens opacity [17], [39]. In HICs prevalence of cataract is less compared to LMICs like Sri Lanka [40]–[42]. We observed that sensitivity increased to 81.8%-89.3% when pupils were dilated. In addition, specificity was high irrespective of the pupil status, because physician graders were confident in grading in the absence of any signs. The study by Henricsson, M. et al. (2000) showed that dilatation and increasing number of fields to 5, the DTA improved to sensitivity of 93% and specificity of 91% [43]. It is apparent that one or more fields to the two central fields in DRS, has increased DTA minimally [28]. Therefore, a 2-field DRS strategy is justifiable for this context. In addition, slit-lamp examination by the retinologist is a justifiable reference test for this context. Scanlon, PH. et al., (2003) showed that there was no significant difference in the assessment of DTA between using 7-field ETDRS and slit lamp examination by ophthalmologists [31].

In some settings, several non-ophthalmological personnel had been employed in DRS. In our study we proposed DRS by trained general physician at medical clinic following assessment of barriers. The estimates from previous studies are comparable with the finding of our study [39]. In a study from the United Kingdom, DRS by general practitioners using 35mm colour images shown that detecting any level of DR was increased from 62.6% (95% CI 55.9-69.4%) with direct ophthalmoscopy to 79.2% (95% CI 73.6-84.9%) using retinal photographs (and specificity remained unchanged (direct ophthalmoscopy 75.0% (95% CI 69.5-80.5%) vs 73.5% (95% CI 68.0-79.1%)) [44]. They concluded that retinal photography by trained general practitioners in primary care setting could achieve an

acceptable level of detection of STDR (87%) [44]. In our validation study physician graders showed a sensitivity range of 88.6-92.4% and specificity range of 94.8-96.3% in detection of referable level of DR using mydriatic imaging which is better than the reported studies. However, this may depend on the proportion of ungradable images. In our sub-analysis we included the technical failures as test positives, since physician graders refer these to the eye clinic. A review of 22 cross sectional photographic studies showed non-mydriatic retinal photography sensitivity range of 25-66% for general practitioners, 43-79% for optometrists and 27-73% for other non-ophthalmic health professionals and an overall specificity of >91% [45]. The sensitivity of detection of any level of DR increased to 87-100% for general practitioners and >91% for optometrists with pupil dilatation [45]. As a first line, this study has shown that physician graders are capable of DRS in a non-ophthalmic setting in Sri Lanka. However, we will have to study the effectiveness of this modality in a larger number to make specific recommendations to implement a population-based program.

In our study 75.6% of the participants had no DR, 16.7% mild DR (R1), 3.6% moderate NPDR (R2), 0.4% severe NPDR (R3) and only 1% had PDR (R4). A study conducted among the slum populations (age > 40 years, known PwDM) in India, using a hand-held nonmydriatic camera reported 8.1% severe NPDR and 6.8% PDR which are higher prevalence than our study [46]. One reason for higher prevalence could be poor diabetes management among the slum populations. However, in this study, relatively a higher gradability of images (89.4% gradable) was observed even in non-mydriatic mode, probably due to images were graded at the site after directly visualising on the display of the hand-held camera. We have noticed that image quality is apparently higher on a small screen compared to displaying on a traditional viewing monitor. In another study conducted in India, among 500 PwDM at an endocrinology clinic, proportion ungradable was 30.6% and 31% among two observers which is comparable to our results [39]. In comparison we observed that studies conducted in HICs reported high proportions of gradability compared to our study. A study conducted in USA 86-94% images were gradable before pupil dilatation in hand-held retinal imaging [47]. Similarly a study conducted in a upper middle income setting (China) reported a low ungradable proportion of 4.75% (19/400) using

a hand-held camera [21]. The low prevalence of DR in our study could be attributed to many factors. One reason for this would be excluding those who had undergone previous DRS and treatment. In Sri Lanka about 50% of the PwDM in clinics had DRS [48]. Forty percent (572/1398) of the PwDM had previous DRS or DR treatment in our study. The high proportion poor image quality in our study could be due to smaller pupil size and presence of lens opacities.

Non-mydriatic imaging has lower resolution and lower image quality leading to poorer detection of DR [17], [49]. However, digital imaging has lower technical failure rates than imaging using colour slides [50]. The hand-held non-mydriatic camera used in this study required a minimum of 3.5 mm pupil diameter and average pupil diameter in this study population was 2.01 mm at presentation. When pupils were dilated, proportion of ungradable images was reduced from 43.4% to 12.8%. Even at the reference test 37 eyes were ungradable due to lens opacity. The improvement of image quality in people with dark irises by pupil dilatation has been demonstrated in a previous study [17]. The referral of ungradable images to an ophthalmologist's clinic is in the best interest of patient safety. Scanlon, P. et al. showed that in the > 80 years age group the technical failure rates reduced from 41.6% to 16.9% following mydriasis [18]. This study concluded that the odds of having one eye ungradable, increased by 2.6% (95% CI 1.6-3.7%) for each extra year of life since diagnosis of DM and major cause of ungradable images was having a central cataract (57%) [18]. Therefore, a non-mydriatic strategy with dilatation of pupil for ungradable images only would be more appropriate for this context. Another reason for low DTA in non-mydriatic imaging could be low resolution, which may have led to poor visibility of delicate signs such as microaneurysms, as suggested in the study by Henriccson et al. (2000) [43].

Limitations

We excluded PwDM with previous eye screening or treatment, which reduced the proportion of people with DR, which may have introduced spectrum bias. However, the resulting sample included a wide range of pathologies, albeit with fewer people with more advanced disease. When considering

any DR as referable level, there were 301 DR positive and 1041 DR negative eyes in the analysis. There were only 69 DR positive eyes when considering moderate NPDR and above as the referable level. However, PwDM who already visited the eye clinic would not usually participate in a screening programme, therefore the sample examined in this study reflects the PwDM who would be eligible for DRS. Another limitation was high proportion of ungradable images from non-mydriatic imaging compared to other studies. However, the populations in LMICs have a higher prevalence of untreated cataracts, which would prevent adequate retinal view and would require referral. In a potential DRSP, these participants will be referred to the next level of eye care and the patient would benefit from the imaging even if the DR status remains unknown.

The most common gold standard for a reference test would be the ETDRS 7-field image grading by an expert grader. However, it was not possible in this setting for a large sample due to resource and time limitations. In addition, any misclassifications in the clinical reference test could have been mitigated, with a second reference grader. In order to have a higher precision of the DTA, the sample size should be adjusted according to the reported low prevalence of higher grades of DR such as severe NPDR and PDR.

Our proposed DRS modality of using a hand-held non-mydriatic retinal camera at a medical clinic may be more appropriate for a resource poor LMIC setting, with the rising prevalence of DM. However, the caution is quality of the images. Our findings may not applicable to a HIC setting where there are more resources and avenues for development of a population-based DRS program using table-top digital imaging systems. On the other hand, this modality can be piggy back in a population-based program in any setting, to improve the access.

Conclusion

In this study we demonstrated that the diagnostic test accuracy of the physician graders was closer to the standard practice of national level screening programs in other settings. We conclude that 2-field retinal imaging using a hand-held digital camera at a medical clinic, by physician graders, with dilatation of pupil of those who have ungradable images, provides a valid modality to identify

referable level of diabetic retinopathy. This strategy is an accurate screening method of detection of a referable level in a health care facility-based people with diabetes who are at risk of developing sight threatening diabetic retinopathy.

Appendix 9 - Summary of Additional files

9.1 - Additional file 1 - Figures of evaluation of image quality and DR classification system

9.2 - Additional file 2 - Detailed flow chart of the number of participants and image sets used in the analysis

9.3 - Additional file 3 - Prevalence of lens opacity and other condition that would affect image gradability and reference test examination

9.4 - Additional file 4 - DTA for two step grading process - (DTA for gradable nonmydriatic images and nonmydriatic ungradable eyes classified based on mydriatic grading)

9.5 - Additional file 5 - Intra-grader agreement analysis of double grading

References cited in submitted manuscript (Chapter 12)

1. Klein BE. Overview of Epidemiologic Studies of Diabetic Retinopathy. Ophthalmic Epidemiol. 2007;14(04):179–83. PMID: 17896294. DOI:10.1080/09286580701396720

2. IDF. International Diabetes Federation Diabetes Atlas - Eighth Edition - 2017 [Internet]. Available at http://www.diabetesatlas.org/resources/2017-atlas.html. Accessed 10 June 2018.

3. Lin S, Ramulu P, Lamoureux EL, Sabanayagam C. Addressing risk factors, screening, and preventative treatment for diabetic retinopathy in developing countries: A review. Clin Exp Ophthalmol. 2016;44(4):300–20. PMID: 26991970. DOI: 10.1111/ceo.12745

4. The Saint Vincent Declaration. Acta Ophthalmol Scand. 1997;75(S223):63. http://onlinelibrary.wiley.com/doi/10.1111/j.1600-0420.1997.tb00440.x/pdf. Accessed 15

June 2018.

5. Harding SP, Broadbent DM, Neoh C, White MC, Vora J. Sensitivity and specificity of photography and direct ophthalmoscopy in screening for sight threatening eye disease: The Liverpool Diabetic Eye Study. BMJ. 1995;311(7013):1131-5. PMCID: PMC2551056 PMID: 7580708

6. Bamashmus MA, Ophth FRC, Gunaid AA. Regular Visits to a Diabetes Clinic Were Associated with Lower Magnitude of Visual Disability and Diabetic Retinopathy- A Hospital-Based Historical Cohort Study in Yemen. Diabetes Technol Ther. 2009 Jan;11(1):45-50. PMID: 19132855. DOI: 10.1089/dia.2007.0299

7. Adriono G, Wang D, Octavianus C, Congdon N. Use of eye care services among diabetic patients in urban Indonesia. Arch Ophthalmol. 2011 Jul;129(7):930-5. PMID: 21746983. DOI: 10.1001/archophthalmol.2011.147

8. Burgess PI, Msukwa G, Beare NA V. Diabetic retinopathy in sub-Saharan Africa: meeting the challenges of an emerging epidemic. BMC Medicine. 2013;11(1):157. http://www.scopus.com/inward/record.url?eid=2-s2.0-84879800827&partnerID=tZOtx3y1. Accessed on 20 June 2018.

9. Muecke JS, Newland HS, Ryan P, Ramsay E, Aung M, Myint S, et al. Awareness of diabetic eye disease among general practitioners and diabetic patients in Yangon, Myanmar. Clin Exp Ophthalmol. 2008;36(3):265–73. PMID: 18412597 DOI: 10.1111/j.1442-9071.2008.01724.x

10. Khandekar R. Screening and Public Health Strategies for Diabetic Retinopathy in the Eastern Mediterranean Region. Middle East Afr J Ophthalmol. 2012;19(2):178–84. PMID: 22623855 PMCID: PMC3353664 DOI: 10.4103/0974-9233.95245

11. Zheng Y, He M, Congdon N. The worldwide epidemic of diabetic retinopathy. Indian J Ophthalmol. 2012;60(5):428-31. PMID: 22944754 PMCID: PMC3491270 DOI: 10.4103/0301-4738.100542

12. Gudlavalleti VSM, Shukla R, Batchu T, Malladi BVS, Gilbert C. Public health system integration of avoidable blindness screening and management, India. Bull World Health Organ. 2018;96(10):705-715. PMCID: PMC6238995 PMID: 30455518 doi:10.2471/BLT.18.212167

13. Goh JK, Cheung CY, Sim SS, Tan PC, Tan GS, Wong TY. Retinal Imaging Techniques for Diabetic Retinopathy Screening. J Diabetes Sci Technol. 2016;10(2):282-94. PMID: 26830491 PMCID: PMC4773981 DOI: 10.1177/1932296816629491

14. Squirrel DM, Talbot JF. Screening for diabetic retinopathy. J R Soc Med. 2003;96(6):273-276. PMCID: PMC539506 PMID: 12782690 https://doi.org/10.1177/014107680309600604

15. James M, Turner D, Broadbent D, Vora J, Harding S. Cost effectiveness analysis of screening for sight threatening diabetic eye disease. BMJ. 2000;320(7250):1627–31. doi: https://doi.org/10.1136/bmj.320.7250.1627

16. Tran KT, Mendel TA, Holbrook KL, Yates PA. Construction of an inexpensive, hand-held fundus camera through modification of a consumer “point-and-shoot” camera. Investig Ophthalmol Vis Sci. 2012;53(12):7600–7607. DOI:10.1167/iovs.12-10449

17. Banaee T, Ansari-Astaneh MR, Pourreza H, Faal-Hosseini F, Vatanparast M, Shoeibi N, et al. Utility of 1% Tropicamide in Improving the Quality of Images for Tele-Screening of Diabetic Retinopathy in Patients with Dark Irides. Ophthalmic Epidemiol. 2017;24(4):217–21. PMID: 28658588 DOI: 10.1080/09286586.2016.1274039

18. Scanlon P, Foy C, Malhotra R, Aldington S. The Influence of Age, Duration of Diabetes, Cataract, and Pupil Size on. Diabetes Care. 2005 Oct;28(10):2448-53. PMID: 16186278

19. Yogesan K, Constable IJ, Barry CJ, Eikelboom RH, McAllister IL, Tay-Kearney ML. Telemedicine screening of diabetic retinopathy using a hand-held fundus camera. Telemed J. 2000;6(2):219-23. PMID: 10957734 DOI: 10.1089/107830200415153

20. Quellec G, Bazin L, Cazuguel G, Delafoy I, Cochener B, et al. Suitability of a Low-Cost,

Handheld Nonmydriatic Retinograpgh for Diabetic Retinopathy Diagnosis. Transl Vis Sci Technol. 2016;5(2):16. PMCID: PMC4849542 PMID: 27134775 doi:10.1167/tvst.5.2.16

21. Jin K, Lu H, Su Z, Cheng C, Ye J, Qian D. Telemedicine screening of retinal diseases with a handheld portable non-mydriatic fundus camera. BMC Ophthalmol. 2017 Jun 13;17(1):89. PMID: 28610611 PMCID: PMC5470179 doi: 10.1186/s12886-017-0484-5

22. Cuadros J, Bresnick G. Can Commercially Available Handheld Retinal Cameras Effectively Screen Diabetic Retinopathy? J Diabetes Sci Technol. 2017 Jan;11(1):135-137. PMID: 28264174 PMCID: PMC5375086 doi: 10.1177/1932296816682033

23. Piyasena PN, Murthy GV. A situation analysis of diabetic eye care service delivery in health care institutions of the Western Province of Sri Lanka. Ceylon Med J. 2017 Sep 30;62(3):205-206. DOI: http://doi.org/10.4038/cmj.v62i3.8527

24. Piyasena MMPN, Gudlavalleti VSM, Gilbert C, Yip JL, Peto T, MacLeod D, et al. Development and Validation of a Diabetic Retinopathy Screening Modality Using a Hand-Held Nonmydriatic Digital Retinal Camera by Physician Graders at a Tertiary-Level Medical Clinic: Protocol for a Validation Study. JMIR Res Protoc 2018;7(12):e10900. DOI: 10.2196/resprot.10900 PMID:30530458. PMCID: 6305894

25. Scanlon PH. The English National Screening Programme for diabetic retinopathy 2003–2016. Acta Diabetol. 2017;54(6):515–25. PMID: 28224275 PMCID: PMC5429356 DOI: 10.1007/s00592-017-0974-1

26. Kohner E, Stratton I, Aldington S, Holman R, Matthews D. Relationship between the severity of retinopathy and progression to photocoagulation in patients with Type 2 diabetes mellitus in the UKPDS (UKPDS 52). UK Prospect Diabetes Study Group. Diabet Med. 2001;18(3):178–84. PMID: 11318837

27. Baeza M, Orozco-Beltrán D, Gil-Guillen VF, Pedrera V, Ribera MC, Pertusa S, et al. Screening for sight threatening diabetic retinopathy using non-mydriatic retinal camera in a

primary care setting: To dilate or not to dilate? Int J Clin Pract. 2009;63(3):433–8. PMID: 19222628 DOI: 10.1111/j.1742-1241.2008.01921.x

28. Perrier M, Boucher MC, Angioi K, Gresset JA, Olivier S. Comparison of two, three and four 45 degrees image fields obtained with the Topcon CRW6 nonmydriatic camera for screening for diabetic retinopathy. Can J Ophthalmol. 2003;38(7):569–74. PMID: 14740798

29. Hansen AB, Hartvig N V., Jensen MS, Borch-Johnsen K, Lund-Andersen H, Larsen M. Diabetic retinopathy screening using digital non-mydriatic fundus photography and automated image analysis. Acta Ophthalmol Scand. 2004;82(6):666–72. PMID: 15606461 DOI: 10.1111/j.1600-0420.2004.00350.x

30. Aptel F, Denis P, Rouberol F, Thivolet C. Screening of diabetic retinopathy: Effect of field number and mydriasis on sensitivity and specificity of digital fundus photography. Diabetes Metab. 2008;34(3):290–3. PMID: 18406188 DOI: 10.1016/j.diabet.2007.12.007

31. Scanlon PH, Malhotra R, Greenwood RH, Aldington SJ, Foy C, Flatman M, et al. Comparison of two reference standards in validating two field mydriatic digital photography as a method of screening for diabetic retinopathy. Br J Ophthalmol. 2003;87(10):1258–63. PMID: 14507762 PMCID: PMC1920793

32. Grading diabetic retinopathy from stereoscopic colour fundus photographs - An extension of the modified Airlie House classification: ETDRS report number 10. Early Treatment Diabetic Retinopathy Study Group. Ophthalmology. 1991 May;98(5 Suppl):786-806. PMID: 2062513

33. Herbert HM, Jordan K, Flanagan DW. Is screening with digital imaging using one retinal view adequate? Eye (Lond). 2003;17(4):497–500. PMID: 12802350 DOI: 10.1038/sj.eye.6700409

34. Ku JY, Landers J, Henderson T, Craig JE. The reliability of single-field fundus photography in screening for diabetic retinopathy: The central Australian ocular health study. Med J Aust. 2013;198(2):93–5. DOI: 10.5694/mja12.10607

35. Farley TF. Accuracy of Primary Care Clinicians in Screening for Diabetic Retinopathy Using

Single-Image Retinal Photography. Ann Fam Med. 2008 Sep-Oct;6(5):428-34. PMID: 18779547 PMCID: PMC2532778 DOI: 10.1370/afm.857

36. Suansilpong A, Rawdaree P. Accuracy of Single-Field Nonmydriatic Digital Fundus Image in Screening for Diabetic Retinopathy. J Med Assoc Thai. 2008;91(9):1397–403. PMID: 18843870

37. Kuo HK, Hsieh HH, Liu RT. Screening for diabetic retinopathy by one-field, non-mydriatic, 45° digital photography is inadequate. Ophthalmologica. 2005;219(5):292–6. PMID: 16123556 DOI: 10.1159/000086114

38. Murgatroyd H, Ellingford A, Cox A, Binnie M, Ellis JD, et al. Effect of mydriasis and different field strategies on digital image screening of diabetic eye disease. Br J Ophthalmol. 2004;88(7):920–4. PMID: 15205238 PMCID: PMC1772219 DOI: 10.1136/bjo.2003.026385

39. Gupta V, Bansal R, Gupta A, Bhansali A. Sensitivity and specificity of nonmydriatic digital imaging in screening diabetic retinopathy in Indian eyes. Indian J Ophthalmol. 2014 Aug;62(8):851-6. DOI: 10.4103/0301-4738.141039

40. Bourne RRA, Jonas JB, Bron AM, Cicinelli MV, Das A, Flaxman SR, et al. Vision Loss Expert Group of the Global Burden of Disease Study. Prevalence and causes of vision loss in high-income countries and in Eastern and Central Europe in 2015: magnitude, temporal trends and projections. Br J Ophthalmol. 2018 May;102(5):575-585. PMID: 29545417 PMCID: PMC5909755 DOI: 10.1136/bjophthalmol-2017-311258

41. Pascolini D, Mariotti SP. Global estimates of visual impairment: 2010. Br J Ophthalmol. 2012;96(5):614–8. PMID: 22133988 DOI: 10.1136/bjophthalmol-2011-300539

42. Murthy GVS, Gupta SK, John N, Vashist P. Current status of cataract blindness and Vision 2020: The right to sight initiative in India. Indian J Ophthalmol. 2008 Nov-Dec; 56(6): 489–494.

43. Henricsson M, Karlsson C, Ekholm L, Kaikkonen P, Sellman A, Steffert E, et al. Colour slides

or digital photography in diabetes screening-a comparison. Acta Ophthalmol Scand. 2000;78(2):164–8.

44. Owens D, Gibbins R, Lewis P, Wall S, Allen J, Morton R. Screening for diabetic retinopathy by general practitioners: Ophthalmoscopy or retinal photography as 35 mm colour transparencies? Diabet Med.1998;15(2):170–5. PMID: 9507921 DOI: 10.1002/(SICI)1096-9136(199802)15:2<170::AID-DIA518>3.0.CO;2-H

45. Hutchinson A, McIntosh A, Peters J, et al. Review: Mydriatic retinal photography is the most effective test for detecting diabetic retinopathy. Evid Based Med. 2001;6(2):56. http://ebm.bmj.com/content/ebmed/6/2/56.full.pdf. Accessed 20 May 2018.

46. Wadhwani M, Vashist P, Singh SS, Gupta N, Malhotra S, et al. Diabetic retinopathy screening programme utilising non-mydriatic fundus imaging in slum populations of New Delhi, India. Trop Med Int Health. 2018 Apr;23(4):405-414. doi: 10.1111/tmi.13039 PMID: 29430785

47. Zhang W, Nicholas P, Schuman SG, Allingham MJ, Faridi A, et al. Screening for Diabetic Retinopathy Using a Portable, Noncontact, Nonmydriatic Handheld Retinal Camera. J Diabetes Sci Technol. 2017 Jan;11(1):128-134. PMID: 27402242 PMCID: PMC5375071 doi: 10.1177/1932296816658902

48. Katulanda P, Waniganayake YC, Ranasinghe P, Udai WM, Wijetunga A, Jayaweera M, et al. Retinopathy among young adults with Diabetes Mellitus from a tertiary care setting in Sri Lanka. BMC Endocr Disord. 2014;14(1):1–8. https://doi.org/10.1186/1472-6823-14-20

49. Taylor DJ, Goatman KA, Gregory A, Histed M, Martin CN, Warburton TJ, et al. Image-quality standardization for diabetic retinopathy screening. Expert Rev Ophthalmol. 2009;4(5):469–76.

50. Olson JA, Strachan FM, Hipwell JH, Goatman KA, McHardy KC, Forrester J V, et al. A comparative evaluation of digital imaging, retinal photography and optometrist examination in screening for diabetic retinopathy. Diabet Med. 2003;20(7):528–34. PMID: 12823232

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
www.lshtm.ac.uk

Registry
T: +44(0)20 7299 4646
F: +44(0)20 7299 4656
E: registry@lshtm.ac.uk

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

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SECTION A – Student Details

Student	Mapa Mudiyanselage Prabhath Nishantha Piyasena
Principal Supervisor	Prof.G.V.S.Murthy
Thesis Title	A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	N/A		
When was the work published?	N/A		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	**Yes**

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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Bio Med Central (BMC) - Public Health - Open Source
Please list the paper's authors in the intended authorship order:	Piyasena MMPN, Zuurmond M, Yip JLY, Gudlavalleti VSM.
Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceived the concept of development of a health educational intervention in local languages after identifying the need in community through the formative research work. I prepared the study design and presented it at the PhD upgrading. Afterwards, I revised the study design and

	protocol under guidance of the upgrading panel, supervisors and qualitative research adviser. I conducted an electronic search of available health educational material in other contexts and assessed those for suitability of adapatation. In addition I trained a local team of sociologist to conduct this study. In the next stage, I conducted stakeholder interviews and participatory workshops in the Western province of Sri Lanka. Afterwards I developed and assessed the acceptability of a video and a leaflet based health educational intervention in two main local languages. The outcomes of this study were analysed under supervision of the qualitative research adviser. I prepared the manuscript and edited it according to the main supervisor and qualitative research adviser comments. I sumitted the manucript to the BMC - Public Health in Nov/2018 and reviewers comments were received in January 2019. Revised version resubmitted in Feb/2019.

Student Signature: [redacted] **Date:** 27/03/2019

Supervisor Signature: [redacted] **Date:** 27/03/2019

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BMC Public Health

RESEARCH ARTICLE Open Access

Process of adaptation, development and assessment of acceptability of a health educational intervention to improve referral uptake by people with diabetes in Sri Lanka

M. M. P. N. Piyasena[1,2*], Maria Zuurmond[3], Jennifer L. Y. Yip[2] and G. V. S. Murthy[2]

Abstract

Background: One major barrier to uptake of diabetic retinopathy (DR) services is lack of knowledge and awareness of DR among the people with diabetes (PwDM). Targeted health education (HE) can be a key element in improving the uptake of eye care services. Such interventions are lacking in Sri Lanka.

Methods: A local context specific HE intervention (HEI) was developed by adopting available resources and incorporating views from PwDM and key stakeholders. Four sessions of participatory workshops with PwDM (20 Sinhala and 13 Tamil speaking) and two stage 12 stakeholder interviews were conducted to both develop and pre-test the material. The products were a video and a leaflet, delivered at a medical clinic to a sample of 45 PwDM identified as having DR. Semi-structured interviews were conducted after 4 weeks, to evaluate the acceptability and comprehension of the HEI. Additionally, nine interviews were conducted with clinical providers to explore process issues related to delivery of the HEI. Data analysis was conducted using thematic analysis.

Results: The lack of knowledge and awareness on DR, and of the importance of regular DR screening and follow up, combined with poor information on referral pathways were key elements identified from the workshops with PwDM. The stakeholders prioritised the importance of using simple language, and the need for emphasis on improving understanding about the asymptomatic phase of DR. The overall acceptability of the HEI material was satisfactory, although there was some difficulty with interpretation of medical images. Overall, although PwDM liked the ideas of the video, the leaflet was seen as a more practical option, given the busy clinic environment. The key issue was both formats required interaction with the provider, in order to support understanding of the messages.

Conclusions: The process of adapting HE material is not simply translation into the appropriate language. Instead, a tailored approach in a country, context and particular health services setting is needed. This study illustrates the value of using a participatory approach and involving PwDM and stakeholders in the adaptation and pilot testing of a HEI to improve uptake of screening for DR in the context of Sri Lanka.

Keywords: Acceptability, Diabetic retinopathy, Health education, Referral, Screening, Sri Lanka

* Correspondence: Prabhath.piyasena@lshtm.ac.uk
[1]Vitreo-retina unit, National Eye Hospital, Colombo 10, Sri Lanka
[2]Clinical Research Department, International Centre for Eye Health, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT, UK
Full list of author information is available at the end of the article

Chapter 13

Process of adaptation, development and assessment of acceptability of a health educational intervention to improve referral uptake by people with diabetes in Sri Lanka

Piyasena MMPN, Zuurmond M, Yip JYL, Murthy GVS. Process of adaptation, development and assessment of acceptability of a health educational intervention to improve referral uptake by people with diabetes in Sri Lanka. BMC Public Health (2019) 19:614. doi: 10.1186/s12889-019-6880-4. PMID: 31113393

Abstract

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Methods

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Keywords

Acceptability, Diabetic retinopathy, Health education, Referral, Screening, Sri Lanka.

Background

Diabetes mellitus (DM) is a global epidemic. Evidence suggests that there will be an increase in the number of people with DM (PwDM) globally with a higher increase in low and middle income countries (LMIC) [1]. One major complication of DM is diabetic retinopathy (DR) and this leads to visual impairment and blindness if not detected and treated on time. The "St Vincent Declaration" stated that all nations should plan efforts to control the complications of DM in their populations [2]. Despite current efforts, DR screening (DRS) coverage is low in many settings. As an example, in USA only 33-68% of PwDM underwent an annual fundus examination [3] and in UK approximately 80% attended for DRS, following an invitation [4]. Therefore, screening uptake is not even optimal even in high income countries (HICs), despite availability of free services. Inequity had been observed in DRS services delivery, even in HICs [5].

A review conducted on interventions to promote DRS, highlighted the need for strategies to improve PwDM's awareness on DR [6]. Studies show that low functional health literacy [7], language barriers such as the lack of provision of health education (HE) in local languages and dialects and suitability of the content of provider-patient communication should be considered in effective management of chronic diseases like DM [8,9]. Uptake of DRS depends on the knowledge, attitude and practice of PwDM [10,11]. Most studies have shown that lack of knowledge and awareness about DR and poor understanding of the need for regular follow-up are major barriers to access [12,13]. Further, the asymptomatic early stage of DR is a hindrance to access [14]. Therefore, HE about DR must be a key element of any screening strategy for DR [15].

In Sri Lanka, despite free eye care being provided through the public sector, the uptake of DR services is low. The current method of detecting DR is opportunistic screening by ophthalmologists following referral from general physicians or when PwDM present for other eye problems. The highest recorded prevalence of DM of 18.6% (95% CI 15.8-21.5%) in Sri Lanka is in the Western province [16],

where a situational analysis showed a significant level of unmet need [17]. A qualitative research study on barriers to accessing services in the Western region also found that knowledge and awareness of DR and DRS among the PwDM was low (under review; service user perspectives - BMC Tropical Medicine and Health and service provider perspectives - BMC Health Services Research). Health education forms an essential component of the health promotional activities for chronic diseases such as DM [18]. A review on eye health promotion in low income settings stated that behaviour change HE, improvement of access to services and effective advocacy are the major components to address control of blindness [19]. In this approach, reviewers described HE as the "*back bone*" of the health promotion efforts [19]. One major challenge is the translation of behaviour change principles into practical environments attaining the expected outcome [20]. There are many influences at community level such as culture, economy, traditions and social norms that would affect the behaviour of a person [19]. A systematic review of studies which have assessed effectiveness of interventions to improve DRS stated that increasing PwDM awareness on DR can improve the uptake of DRS [21]. Therefore, provision of information through HE material would be an important component in any health promotional strategy to improve uptake of DRS services.

Frameworks and guidelines

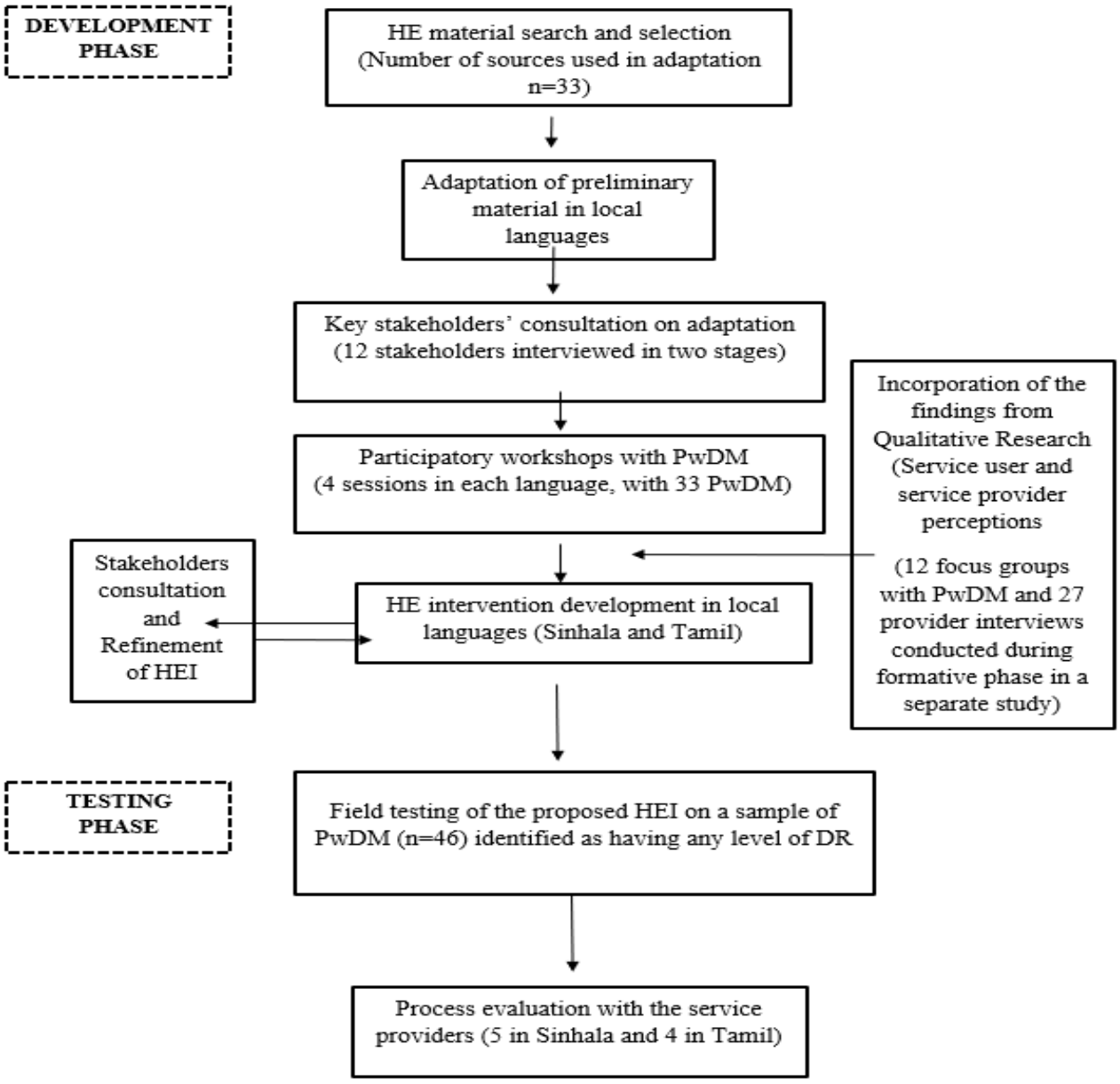
In the development of any HE intervention (HEI), there are a variety of behaviour change models which can be applied. Social Cognitive Theory (SCT) underpins many approaches to behaviour change [22], and was the underpinning framework for this study. It describes how knowledge of risks and benefits of a health condition is a necessary pre-condition needed for a change. This knowledge is related to observing others, social interactions and experiences. A person's behaviour is understood to both influence and in turn, is influenced by a range of personal and environmental factors.

The overall purpose of this study was to develop a relevant, acceptable and comprehensible HEI for the Sri Lanka context to improve referral uptake at the ophthalmologist's clinic. This was part of a larger feasibility study to develop an integrated DRS program in the Western province of Sri Lanka.

Methods

It is a descriptive qualitative study which details the process of the development and field testing of a relevant and acceptable HEI. The different phases are described in Figure 1. For the stages of consultation and revision of the HEI, we adopted a participatory approach, to promote greater acceptance and relevance of the material, in line with general guidance on community based participatory research [23].

Figure 1. Flowchart of steps in development of HE intervention



Data collection and analysis

Ethics

Ethics approval was obtained from the Ethics Review Committees of the London School of Hygiene and Tropical Medicine-United Kingdom and from the National Eye Hospital-Colombo-Sri Lanka. Written informed consent was obtained from all participants for participation, audio recording and usage of anonymous quotes in publications.

Development phase

Initially a search was conducted for existing HE resources over the last 10 years that promoted uptake of DRS or DR services. Details of the electronic data search are provided in Additional file 1 in Appendix 10. The resources were assessed for comprehensibility and actionability using 'Patient Education Material Assessment Tool' (PEMAT) guidelines [24]. A selection of relevant materials was then translated into the two main local languages (Sinhala and Tamil) for reviewing with stakeholders and PwDM.

The second step was one of the two-stage consultation process with 12 key stakeholders who worked in clinical management and health promotion of DM and DR in the public sector (see Table 1). The stakeholders were selected considering their experience and engagement in clinical management of PwDM and involvement of DR related eye care programs. Initially, materials were reviewed to agree on content, culture relevance and suitable mode of delivery for the local context.

Table 1. Key stakeholders

Public health sector	Service delivery personnel
1) Health Education and Promotion Unit - Ministry of Health - Sri Lanka 2) College of Community Physicians of Sri Lanka 3) Diabetes Education Unit – National Hospital of Sri Lanka 4) Vision 2020 Program (DR blindness prevention program) - Ministry of Health – Sri Lanka 5) Department of Sociology (Medical anthropology) 6) Media personnel (a newspaper reporter) [7) A person with diabetes and a person with DR from the Western province (patient representatives]	8) Association of Vitreo Retina Specialists of Sri Lanka 9) College of Ophthalmologists of Sri Lanka 10) Sri Lanka Optometric Association - Sri Lanka 11) Ceylon College of Physicians - Sri Lanka 12) College of Endocrinologists - Sri Lanka

The next step was running a total of eight participatory workshops with a purposive sample of PwDM in Sinhala (n=10, 4 sessions) and Tamil (n=10, 4 sessions). The diagnosed PwDM identified at the medical clinic were selected considering gender, main language and to represent various levels of education and income levels. The overall aim was to explore the participants' views on the selected materials in terms of (1) cultural acceptability of key messages, (2) comprehension, (3) content, (4) layout and design and (5) medium of delivery of the HEI. Details of the participatory workshops are available in Table 2. Final refinement of the material, in terms of the clinical, educational, technical and affective properties of the HEI [25] was then approved at a second meeting with stakeholders. A secondary aim of the meetings was to foster ownership of the developing process of the HEI by key professionals, given they would then be responsible for the implementation of the HEI.

Table 2. Schedule of the participatory workshop

Day	Participants	Activity
Day 1	All	Introduced to the research question by main investigator
	Sub group 1 - Sinhala Sub group 2 - Tamil	Group work on identifying needs, problems and solutions on accessing services at ophthalmologist's / retinologist's clinic following referral (those who identified with referable level DR) from medical clinic - facilitated by moderators
	Sub groups 1 and 2	Exposure to adapted and developed provisional HE interventions - facilitated by moderators
Day 2	Sub groups 1 and 2	Development / modification of HE interventions appropriate to the local context by incorporating participants' ideas - facilitated by moderators
Day 3	Sub group 1	Presentation and discussion of findings of assessment of developed HE interventions by participants - facilitated by main investigator with co-moderators.
Day 4	Sub group 2	

Finally, qualitative research findings, conducted as part of the wider study and published separately (under review), were incorporated into the adaption and development of the HEI. The end result was the production of a video and leaflet, available in two local languages (see Additional File 2 in Appendix 10 for the leaflets and the videos multi-media files).

Data Analysis

The participatory workshops and semi-structured interviews (SSIs) were audio recorded and for stakeholders' meetings detailed notes were taken. A simple thematic analysis was undertaken which included covering themes of comprehension, readability and cultural acceptability. The analysis was conducted in local languages by experienced sociologists. Recordings were transcribed, and together with field notes, were coded in Sinhala and Tamil by local sociologists and then cross checked by the lead sociologist and by the lead investigator. Final themes were translated into English.

Field testing Phase

The video and leaflet were then field tested at a tertiary level medical clinic setting by administering to a purposive sample of 45 PwDM who had diagnosed any level of DR (see Table 3 for participants' characteristics). We recruited PwDM in order to equally distribute by gender, main language and ethnic group and those who have already treated for DR were not included. The material was delivered by physician graders in Sinhala, and a trained sociologist in Tamil during the consultation when they presented for out-patient care at the medical clinic. On average video run time was 5 minutes. It required about 3-5 minutes to read all pages of the leaflet. First, we shared the leaflet while PwDM were waiting and then the video during the clinical consultation. SSI were then conducted with the PwDM up to 4 weeks later. A purposive sample of service providers (n=9, 5 in Sinhala and 4 in Tamil language) were also interviewed from medical and eye clinics to explore their perspectives on the process of delivery of the HEI. The field-testing interview topic guides details described in Additional File 3 in Appendix 10.

Table 3. Participants characteristics of those who underwent delivering and assessment of HEI

Variable	Results
Mean age (SD)	62.3 years (±9.7)
Mean age at diagnosis of diabetes mellitus (SD)	50.8 years (±8.9)
Mean duration of diabetes mellitus (SD)	11.5 years (±9.0)
Gender	Female 57.8% (26/45) Male 42.2% (19/45)
Ethnic group	Sinhalese 53.35% (24/45) Tamil 24.4% (11/45) Moor 22.2% (10/45)
Main language	Sinhala 53.3% (24/45) Tamil 46.7 (21/45)
Residing district	Colombo 93.3% (42/45)

	Gampaha 4.4% (2/45) Kalutara 2.2% (1/45)
Level of education	No Schooling 15.6% (7/45) Primary (Grade 1 to 5) 31. 1% (14/45) Secondary (Grade 6 to 10) 17.85 (8/45) Up to GCE O/L (Grade 11) 15.6% (7/45) Up to GCE A/L (Grade 12) 17.8% (8/45) Degree and above 2.2% (1/45)
Level of monthly income	Low (< £150) 80.0% (36/45) Middle (<£300 >£ 150) 8.9% (4/45) High (> £300) 11.1% (5/45)
Wearing spectacles at presentation (near or distant)	Had spectacles at presentation 46.7% (21/45) Did not have 53.3% (24/45)
Level of diabetic retinopathy	Right eye - No DR 8.9%, any DR 91.1% Left eye - No DR 11.1%, any DR 88.9%

Results

In the developmental phase, a total of 96 HE resources were initially identified for improving DRS uptake (74 printable and 22 non-printable). 63 sources were reviewed for adaptation after exclusion of material based on the relevance (Additional File 1 in Appendix 10, Table 2), and a final selection of 33 resources were then reviewed for adaptation to the local context. A total of 16 key themes were identified, which needed to be addressed in the adaptation and development of HEI (see Table 4).

Table 4. Main themes and source of information for development of the HE material development.

Theme/ Subtheme and Source of Information	Illustrative Quotations	Implication for Development of HE Material
1. Main domain- Individual level-personal factors		
Knowledge, expectations and attitude		
1.1 Lack of knowledge on DR &DRS *SIs* [a] -Lack of biological knowledge of the eye, DR affects the back of the inside of the eye and changes are not visible from outside. -Lack of understanding of early asymptomatic stage. *PWs* [b] -Necessity of providing distinct information to make PwDM aware of DR.	*"We don't know about eye issues that can occur with diabetes, hospital staff need to make us aware about that" [PwDM_PW]* *"We don't know about DR blindness or that effects of diabetes on the eye leading to blindness" [PwDM_PW]*	-Inclusion of information on DM caused by high sugar levels in blood, this will lead to changes of blood vessels at the back of the inside of the eye which are not visible from outside. -Incorporation of graphics and animations to explain the changes in the eye.
1.2 Lack of knowledge on referral system *FGDs and SSIs-* [c, d] -Lack of clear information on referral processes (where to go, when to go, how to access, etc.). -Inadequate information in the referral letter. *PWs-* -Need of clear stepwise guide on directions of reaching to eye clinic from the medical clinic, with a suggestion to include a map and how to get an appointment. -Information on procedures that will take place at the eye clinic, days and time of eye clinics. -Forgetfulness of the information relevant to the eye screening appointment. *SIs-* -Suggest including a flow chart about the process of referral pathways – step wise actions to go from the medical clinic to eye clinic.	*"We forget what doctor said when come out form the doctor's room. Sometime people don't like to ask again from doctor, thinking that doctor will blame" [PwDM_PW]* *"At the very first time we do not aware, don't we? One will say this way, other will say that way only wasting of time" [PwDM_PW]* *"List out the availability of eye clinics that diabetic patients can attend" [Ophthalmologist_SI]*	-Inclusion of information on availability of free services at the nearest eye clinic. -Map with directions (in the leaflet), how to get an appointment of out-patient eye clinic, the details of eye examination / consultation processes happen at each stage. -Provide a space in the leaflet to mention details of next appointment (to be documented by the eye doctor). -Inclusion of a flowchart guidance on processes at eye clinic/eye hospital.
1.3 Attitude on uptake of DR services *SIs* -Need to emphasise the necessity of DRS even without having visual symptoms.	*"Emphasise that diabetic retinopathy changes are not visible to outside therefore you won't be aware about this problem until you*	-Emphasise on early asymptomatic phase and need of regular screening

PW- Reluctant to uptake services due to long waiting time at the eye clinic.	*become blind" [Media personnel_SI]* *"some time whole day we wait in the queue, but no treatment given" [PwDM_PW]*	even without any symptoms.
1.4 Attitude of lack of perceived threat on DR blindness *SIs* -Benefits of action (screening) and threats of inaction (sight loss). *PWs* -Benefits of annual screening, DR assessment and treatment at the eye clinic.	*"People don't know about DR, we think it as a just eye check-up, we don't know that it is important to check eyes" [PwDM_PW]*	-Highlight the danger of losing sight due to DM / DR and it is irreversible. -Information on early screening, detection and treatment can prevent sight loss.
1.5 Attitude of fear of uptake of services *FGDs -* -Fear of dilated fundoscopy, -Need of accompaniment following dilatation, -Lack of knowledge on process and requirement of pupil dilatation in retinal examination. *SSIs* -PwDM reluctant to undergo pupil dilatation *PWs* -Ensure details of eye examination do not promote fear. *SIs* -Recognise the discomfort side effects but place emphasis in the benefits of the eye examination -Fear to uptake laser and surgery.	*"There is a drop before eye examination, and putting it to the eye is very painful" [PwDM_PW]* *"It was like burning, and covered the vision like fog" [PwDM_PW]* *"My eyes became blue, it was such an electric shock." [PwDM_PW]* *"bringing a guardian is compulsory for putting eye drop, otherwise you can't move due to blurred vision" [PwDM_PW]* *"Mention that they have to undergo dilated fundal examination to examine the inside of eye" [Optometrist_SI]*	-Inclusion of information on why there is a need for pupil dilatation (to have a better view of the back of the inside of the eye). Provisions of reassurance by an expert patient -Include information on blurring as a temporary side effect but include reassurance that this is normal. -To include guidance that accompaniment needed. -Guidance that no driving recommended following examination for up to 4-6 hr time period.
1.6 Current level of expectation *SIs* -Need to describe DR as a separate entity, and it is different from cataract, glaucoma and vision problems that would require spectacles *PWs* -Confusions on DR screening over other forms of eye examination (refraction and cataract assessment)	*"We don't know about the diabetic retinopathy and how it could be treated, we though cataract surgery and spectacles is the solution" [PwDM_PW]*	-Inclusion of information DR as a separate eye problem and undergoing cataract surgery and using spectacles will not correct all visual problems. - Need of salient information on DR and DRS.
1.7 Expectation of Information on outcome of eye examination		

SIs -Describe the outcomes of screening	*"Patients tend not to come once they have undergone a few treatment sessions, therefore need to tell the importance of attending for treatment regularly" [Consultant Ophthalmologist_PW]*	-Include information on outcome of the DRS and necessity of undergoing treatment as required. -Inclusion of information on availability of free DR treatment facilities at the eye clinic/public sector hospital.
2.Main domain - Environment		
Social norms and access to information		
2.1 Social norms in the local context (lay referral systems) *FGD* -Practice of indigenous medicine, engage in religious activities and use of home remedies, -Belief of blindness occur due to ageing, karma or faith. *PW* -Decision making for women happen at the home environment decided by a male member of family.	*"Doing 'Bodhi puja' activities and some other 'bali-thowil' (rituals and religious activities)" [PwDM_FGD]* *"Keep tea powder on the eye, washing eye using pomegranate leaves and jasmine" [PwDM_DM]* *"With aging diabetic is a normal disease. Also, most of these diseases occur due to our own sins" [PwDM_DM]*	-Provision of information to refrain from those activities.
2.2 Access to information and influences from the environment *SSI and SIs* -Lack of availability of health educational interventions on DR in local languages. *PW* -Difficulties in communication with the providers (language barriers and usage of technical terms).	*"We don't know about eye issues that can occur with diabetes, hospital staff need to make us aware about that" [PwDM_DM]* *"We do not have proper methods on health education especially for diabetic retinopathy" [Medical officer_SSI]*	The need of HEI in local languages.
3. Main domain -Mode of Delivery		
Medium, personnel and place of delivery		
3.1 Views on medium of delivery *SIs* -Video, leaflet and poster as the suitable media for this context. *PWs* -Majority preferred a leaflet, -Majority of the participants who speak Tamil preferred a video-based health educational intervention (assessed using a ranking system at PW).	*"Video, leaflet and booklet are the preferable medium. We can have a video for about 15 minutes. Or quick advert <1min." [Optometrist_SI]*	-Investigators consensus - Development of a leaflet and a video intervention in local languages (original version in English)

3.2 Views on place of delivery *SIs* -Medical clinic as the best place to deliver. *PWs* -Majority wanted HE to be conducted at the medical clinics.	*"Medical clinic is the best place to deliver this education intervention" [Expert PwDM_SI]*	-Field testing of the HEI at medical clinic.
3.3 Views on personnel of delivery *SIs* -Delivery by doctor or a nurse. *PWs* -Health education should be done by a doctor or a nurse, best delivered by a doctor.	*"Health education can be delivered verbally to a small group by a doctor, or need an educator to deliver information in especially in Tamil" [Medical officer_SI]*	-Field testing delivery of the HEI by the physicians at the medical clinic
4.Main domain – Comprehensibility and Readability		
Comprehension, readability and terminology		
4.1 Difficulties in finding the terminology in local languages *PWs* -Difficulties in understanding the terms of; retina, diabetic retinopathy, laser, pupil, pupil dilation, blood glucose.	*"For dilating drops, dilatation of pupils, retina, retinopathy, use simple terms. Comprehensive eye examination word is hard to understand, mention that it is an examination of the back of the eye. To describe the word retina: use - inside of the eyes or wall of the eye at the back or describe retina is like the roll of a film camera". [Optometrist_SI]*	-Use of phrases in local languages when there were no appropriate terms in local language.
4.2 Views on layout and format (printed material and video). *SIs* -Inclusion of information on question and answer format. -Incorporation of graphics and animations to explain that DR affects back of the inside of the eye. -Reduce the number of sentences per page. *PWs* -Usage of high-resolution images. -Usage of large fronts and large page sizes.	*"Use more images to get the attention" [Consultant Ophthalmologist_SI]* *"In the leaflet, each page can be divided using sub-topics, page 1- Title with a theme, 2nd – some background details of diabetes in Sri Lanka, 3rd – changes in the retina due to DM, 4th – screening and treatment options of DR, 5th – How to control DM, 6th – main messages, where to go for eye checking etc" [Community Physician_SI]*	-Follow the suggestions given
4.3 Usage of appropriate language matching the literacy level of the PwDM in the context *PWs*	*"doctors explain fast and sometime can't understand, they use English words in between which we*	-Followed the suggestions given in development of HEI.

-Minimise the usage of technical terms and direct use of words in English. -Availability of the alternatives for illiterate PwDM. - Need of locally acceptable terminology to deliver information. *SIs* -Minimal usage of technical terms and usage of phrases when it is difficult to find the terms in local languages.	*cannot understand. We do not ask those back again due to fear that doctor get angry" [PwDM_PW]*	
5. Main domain - Behaviour		
Skills of acquiring information and cues for action		
5.1 Component of potential behaviour change *SIs* -Sharing the experiences of PwDM, those who had STDR / acute loss of vision. PW - Skills and practice of acquiring knowledge and uptake of services	*"We can include a video clip of a patient who lost vision due to diabetic retinopathy telling her/his experience, by this ask diabetic people to go for annual DR screening"* *[Lecturer in Media Communications_SI]*	-Inclusion of a video segment of a patient sharing the experiences of acute vision loss (e.g. vitreous haemorrhage)

a-stakeholder interviews, b-participatory workshops with PwDM, c-focus group discussions with PwDM, d-semi-structured interviews with providers.

Thirty-three PwDM (20 Sinhala speaking, 13 Tamil speaking) attended participatory workshops. Overall there were low levels of knowledge of DR and DRS, a lack of perceived threat of DR blindness, combined with DR not being seen as a life-threatening condition, in particular during the asymptomatic phase. Commonly, for example, cataract surgery or the provisions of spectacles were understood to be the solution for all eye health problems. The use of medical terms, often in English, was also identified as a barrier to their understanding, including terms such as 'retina' and 'pupil dilation', although these terms could not be easily translated into the local languages. Knowledge about treatment options in government hospitals was also limited, combined with poor understanding of the referral pathways, and of the need for regular screening. The confusion about referrals and forgetfulness about appointments was often exacerbated by the lack of a printed referral form, and/or lack of information available in the local languages. Another barrier to uptake of services was negative attitudes

about very long waiting times at clinics which deterred patients from regular screening. Fear about the procedures, such as pupil dilation, was another barrier.

In terms of environmental factors, social norms emerged as a key theme, which influence management of DM. Some PwDM practiced indigenous medication, whilst a common belief was also that blindness was an inevitable part of ageing, karma or faith which was not avoidable and therefore difficult to treat. The decision making on accessing services and requirements of an escort, especially for women, mostly happened at the family level, in what is a patriarchal society system. Therefore, development of HEI needed to be family-centred and any materials to be developed in a way that it would be easy to share.

In terms of readability of the HEI a common request was for clear and colourful images and to use large page size and font size for printable material. Stakeholders identified that an animated video could enrich understanding of biological changes to the eye. In terms of the mode of delivery there was an overall preference from the Tamil speaking groups for the video, whilst in contrast the Sinhala groups in general expressed a preference for printed reading material. All groups agreed that the medical clinic provided a useful space to deliver this HEI, whilst waiting for appointments.

Field testing of acceptability, relevance and understanding

Overall as a result of the field testing of the video and leaflet, there were a number of lessons learnt about the relevance and acceptability of the HEI, reflected in 3 major themes; 1) levels of comprehension and readability, 2) actionability of uptake of services and 3) views on mode of delivery. The details of themes and sub-themes are available in Table 5.

Table 5. Main and sub-themes of field testing of the developed HEI

Main Domain	Theme	Sub-theme	Example Quotation
1)Comprehension and readability	1.1) Intelligibility of the leaflet and video	Understanding of diabetes lead to blindness and eye check-up prevent sight loss	*"Diabetes can cause a huge damage to the eyes. It can lead to blindness. We can spend little time and get our eyes checked and prevent this damage." [HE_S22_64yrs_F]*
		Difficulties in reading the leaflet by some PwDM	*"I like the video because I can see it clearly. To read the leaflet I have to put some effort. It was bit of a hard work for me." [HE_S03_65yrs_F]*
	1.2) Difficulty in interpreting figures and medical images	Difficulty in understanding of the fundus images (in page number 03-leaflet).	*"I could understand most of the things; However, I could not get the message from the pictures in the 2nd or the 3rd page. I cannot understand what is explained here." [HE_M14_51yrs_M]*
	1.3) Level of simplicity and cultural appropriateness of the language style	Not preferring different colloquial languages in Tamil	*"This is Jaffna Tamil. It is difficult to follow the video." [HE_M17 _65yrs_F]*
2)Actionability	2.1) Ability to extract key messages of referral uptake	Understanding importance of follow-up as a key message	*"I think the more serious message I captured from the video is that the 'right follow up' is very important to protect the sight'. Old lady's story was interesting for me." [HE_S21_58yrs_M]*
		Understanding of Facilities are available at XX hospital.	*"XX hospital is more capable of providing the latest treatments. We should get the maximum benefits out of it as diabetic patients." [HE_S11_62yrs_M]*
3)Mode of Delivery	3.1) Preference over delivery at the medical clinic	Preference of delivering and effective use of waiting time at the medical clinic.	*"It is good to get the details like this at the Room 26 (medical clinic). After giving the leaflet I had enough time to read it, till I get my turn. I was sitting more than one hour." [HE_T06_51yrs_M]*
	3.2) Usability and willingness to share the HE material	Level of sharing resources	*"My husband comes home late after work. He is tired after working and I am reluctant to discuss about my diseases when he is back home." [HE_S27_50yrs_F]*
	3.3) Overall high social acceptability and attractiveness of the HEI	High acceptance of the delivered leaflet and video.	*"I prefer both leaflet and video, but for more common use, leaflet would be better. It is easy to carry inside my bag." [HE_S06_71yrs_F]*

Comprehension and readability

Overall the majority of the participants in both language groups stated that key messages were clear in both media of delivery. However, a common difficulty was interpreting some of the biological images, such as fundus images depicting the progression of DR and how vision varies. There were also difficulties in interpreting and understanding the relevance of numbers and percentages that described the disease burden of DR. PwDM also requested more information on the dangers of DR in the leaflet.

In terms of the cultural appropriateness of the language, the majority of the Sinhala patients were satisfied with the use of language in the video and leaflet. Whilst in contrast, some phrases and terms were in a different regional language for the Tamil group, and therefore more difficult to follow, as one 65year old female explained, *"This is Jaffna Tamil, so it is difficult to follow the video".* The Moor PwDM highlighted the limited representation of Moors in the video and were critical of the unintentional background footage of images of Tamil religious symbolism. A major theme across most patients and providers was the need to interact with someone about the video or leaflet to aid clarification. This was illustrated by a 65-year woman who explained that *"I didn't understand the animations straight away. But after several explanations I could understand some of it".*

The providers as well as the PwDM, suggested that lay-out and design of the leaflet and showing the directions to the eye clinic could be improved further; suggestions included incorporation of segments of the eye care hospital into the video.

Actionability- Understanding of referral processes

Overall there was good understanding of the key steps to undertake for referrals, including the need for regular screening and follow up, and of facilities available in the public sector eye hospitals: *"I think the more serious message I captured from the video is that the 'right follow up' is very important to protect the sight. The old lady's story was interesting for me".* Participants also showed an indicative positive attitude about intention to seek care. However, improved maps of the location of services were a common request.

Mode of delivery

In terms of mode of delivery, the majority of the participants reflected on the usefulness of receiving the leaflet whilst waiting for the consultation. PwDM said they liked delivery of leaflet and video to be facilitated by their physician, so that it could support an interactive session. Yet at the same time a common complaint was that the environment was too noisy for the video: "*Sounds and voices were not clear in some parts, because of the noisy environment inside the clinic".* Providers also highlighted the practical difficulties in delivering the video at the clinic setting when there were no facilities for a larger number of PwDM.

A central component of the HEI was that it would prompt a willingness to share the resource with other family members. However, the field testing showed that in practise, there was limited showing of the video, and it was unclear the extent to which the leaflet was shared. The main reasons given were lack of any facility to watch and/or lack of time for a family member to watch a video. Overall there was a small preference for the leaflet in the field testing, because of the practical ease of carrying it and being able to refer to it.

Both PwDM and providers suggested that lay-out and design of the leaflet and showing the directions to the eye clinic could be improved further; suggestions included incorporation of segments of the eye care hospital into the video.

Providers' views on the delivery of HEI

The physicians who delivered the HEI stated that major practical issue was lack of time to deliver and talk through the material. One physician expressed her view as follows. *"A clinical setting at a hospital is very congested and busy. A Few doctors are there to provide for the needs of hundreds of patients. A single patient has a very limited time to spend with the doctor, not enough time for an efficient health educational intervention"*. Providers emphasised that unavailability of proper technical facilities and limited space to display the video was the main challenge they faced in delivering the HEI at the medical clinic. *"The video has a more likelihood of capturing people's attention, but there*

must be proper tools to deliver it. There must be enough space and facilities for all this. In my opinion, the leaflet is far more practical when it comes to congested hospital setting.".

We observed the value of bringing the providers and other stakeholders along the journey from early consultation through to the final field testing. This was helpful to build their ownership to the developed material with a greater likelihood of utilising it as a HEI in future.

Discussion

This study showed that the process of adapting HE material is not simply translation into the appropriate language. Instead adopting a participatory process, and working with PwDM and with providers, we identified important content and process issues, necessary to make the material relevant and acceptable, with some lessons learnt for scaling up. The key findings were, PwDM had low levels of knowledge and awareness on DRS, referral pathways and follow ups. Stakeholders prioritised the importance of using of simple language and need of highlighting the importance of DRS in asymptomatic phase. In the field testing we found that most of the PwDM could comprehend the content with overall good understanding of the key steps, except on a few occasions among Tamil and Moor ethnic groups. Additionally, we observed that there were technical and human resources constraints to deliver the HEI at a medical clinic setting. Our HE video and leaflet had satisfactory level of acceptability to the PwDM based on their verbal responses. This HEI would have a greater potential of using as an HEI to improve the referral uptake following further refinement according to the contextual requirements.

The World Health Organization (WHO) Shanghai Declaration stated that health promotion should be an essential component in all health systems to have an equitable access [26] and eye health promotion consists of a mix of HE, services improvement and advocacy [19]. In terms of DRS services uptake of screening and treatment is low, therefore an effective HE strategy is one essential component to ensure equitable access [19]. This is one of the first studies to describe the process of adaptation, development and assessment of an acceptable HEI on DR in Sri Lanka.

The use of participatory methods targeted at the intended community has been shown in a study to be an effective way to develop material which has a high level of acceptability [27]. This method enabled us to tailor the material to be more culturally sensitive, for example in terms of understanding any particular needs of different ethnic groups. The importance of culture sensitive adaptation of the material compared to the conventional translated material has been described in a controlled study conducted in a high income country migrant populations and showed that adapted material were significantly more useful than translated versions [28]. A study on development of HE material in hypertension for an Indo-Asian community stated that active participation of the targeted community was helpful in developing acceptable material [27]. We identified that the existing resources on DR were developed according to the various contextual requirements in different contexts.

Our study showed that overall knowledge on DM and DRS was low, and this needed to be addressed with the HEI. A study conducted in South India, in a population similar to Sri Lanka showed that only about 40.7% of PwDM had good knowledge on DM and DR and 9.6% has undergone DRS [29]. In addition, we identified various attitudinal and behaviour patterns such as fear, lack of understanding between DRS and routine eye check-up affects uptake. Similar findings were reported in other studies on barriers to uptake DRS [30,31]. In addition, we observed that PwDM were reluctant follow up with screening and treatment when there was no threat to sight or during asymptomatic stage. A similar challenge was described in a systematic review of HE interventions to improve the adherence to glaucoma medication [32].

The field-testing phase showed that despite high level of literacy in Sri Lanka [33], the functional health literacy was low among some participants, and in particular there was difficulty in interpreting and understanding medical jargon and biological pictures. The WHO highlights that HE is necessary to improve functional health literacy, which in turn would reduce inequalities to access [18]. A systematic review on assessment of readability of ophthalmology HE material showed that most of the

eye care HE material required high level of literacy for understanding [34]. Therefore, any HEI needs to be further developed in a way that is understandable to wide range of PwDM with various levels of functional health literacy. Another key element identified in our study was necessity of using locally derived, simple, and understandable terms (i.e., retina, diabetic retinopathy, pupil dilatation, vitrectomy etc.) in different dialects, as described in a study on glaucoma HE in Nigeria [35]. This shows that working on multiple languages requires a lot of competency in translation and back-translation, to maintain the integrity of the HEI.

Our study showed that socio-cultural adaptation of the material is a crucial factor to improve uptake, in a patriarchal society like in Sri Lanka. A study from Sri Lanka showed that PwDM behave with regard to DM based on various socio-cultural beliefs [36]. Therefore, gender and culture sensitive HE strategies should be developed, where females are mostly not involved in decision making [37]. A similar finding of the importance of family in making decisions and gender role of women on service uptake has been described in a cataract surgery uptake study done in Tanzania [38]. We therefore developed the HEI in a way that it could be shared with family members, although in practise there was little evidence of sharing.

Our study showed an overall satisfactory level of acceptability for the leaflet and video material. We showed and expressed preference among the participants about the use of a video during the participatory development phase. A systematic review of assessing the efficacy of video-based HE to modify behaviour in handling health related issues showed that videos showing actual people can be more effective than graphical presentation [39]. However, the field-testing phase indicated that video used in the clinic was problematic for several reasons. It might be that finding an alternative way to present the video, for example using a smart phone / social media might be a more pragmatic approach which also offers wider coverage, as piloted in a study conducted in a similar community in South India for

stroke survivor education [40]. We identified that either of the material may be insufficient as a stand-alone HEI and the video and the leaflet should both be more complementary to each other.

One of the key findings in our study was that HE benefits from a more interactive approach where there is an opportunity to discuss the material with a provider and seek clarification. The clinic work load [41], lack of prioritising the HE at clinic setting [42] and lack of training of human resources [43] have been described as barriers to HE in other studies. In our study the lack of physician time was identified as major barrier and highlighting the need to consider task sharing or shifting and finding other staff or expert patients who might play an important educator role. The need of a health educator for a busy clinic has been suggested in health promotion study done in USA on Glaucoma [44].

Limitations

One limitation of the study was that, we assessed the acceptability of the HEI using subjective responses of the PwDM and providers. We did not assess knowledge and awareness of the PwDM at the baseline. Our study sample consisted mostly of elderly PwDM. Further, the small sample size may not represent the diversity of the community in this region. Therefore, conclusions drawn from this study may not generalisable. We did not assess the variations in acceptability by age, gender or socio-economic status.

Conclusions

The development of HE material in DR is a complex process, requires adaptation and development suitable to the local context. The process of adapting the health educational material is not simply translation into the appropriate language but rather an individualised tailored approach in different health services to meet the needs of variuos patient communities. Socio-cultural norms should be considered when defining the actionable steps. We can conclude that there is a satisfactory level of acceptability for this HEI and to deliver at a medical clinic setting would require further development of human resources and infrastructure appropriate to the intervention.

Recommendations

- Improve functional health literacy by further simplification of the resource, including minimal use of medical jargon.
- Strengthen the interactive use of HEI, with a skilled educator to discuss, clarify and counsel.
- Explore options for task sharing or task shifting the educator role from the physician to another staff member and or expert person with DM.
- Use the waiting time at the medical clinic as a dedicated and targeted time for HE. This should include ensuring there is adequate space, including a quiet space for delivery of the video material.
- Develop the video into shorter film clips for use at the waiting areas of the medical clinics before consultation, prompting to clarify the queries during consultation to improve access.
- Consider options for developing a cadre of expert patients who could work in local dialects and may be in better position to work with minor ethnic groups, and to engage with other family members.
- This HEI should be one component of a wider health promotional strategy to improve the uptake of DRS in Sri Lanka. A next step is then to test the effectiveness of this strategy in a controlled trial.

Appendix 10 - Summary of Additional files

10.1 - Additional file 1 - HEI material search terms, search outcomes

10.2 - Additional file 2 - 2.1 - Video script in three langauages with video clips picture frames, 2.2 - Leaflet tiles in three languages [*Video files are enclosed with the thesis in a compact disc]

10.3 - Additional file 3 - Semi-strcutured interview topic guides for field testing of the HEI - service user and service provider.

References cited in submitted manuscript (Chapter 13)

1. Shaw JE, Sicree RA, Zimmet PZ . Global estimates of the prevalence of diabetes for 2010 and 2030. Diabetes Res Clin Pract. Diabetes Res Clin Pr. 2010;87(1):04-14. DOI: 10.1016/j.diabres.2009.10.007. PMID: 19896746

2. The Saint Vincent Declaration. Acta Ophthalmol Scand [Internet]. [cited 2018 March 08] 1997;75(S223):63. Available from: http://onlinelibrary.wiley.com/doi/10.1111/j.1600-0420.1997.tb00440.x/pdf

3. Nsiah-Kumi P, Ortmeier SR, Brown AE. Disparities in diabetic retinopathy screening and disease for racial and ethnic minority populations-a literature review. J Natl Med Assoc. 2009;101(5):430–7. PMID: 19476196

4. Scanlon PH. The English National Screening Programme for diabetic retinopathy 2003-2016. Acta Diabetol. 2017;54(6):515–25. DOI: 10.1007/s00592-017-0974-1. PMID: 28224275

5. Millet C, Dodhia H . Diabetic retinopathy screening: audit of equity in participation and selected outcomes in South East London. J Med Screen. 2006;13(3):152–5. DOI: 10.1258/096914106778440608. PMID: 17007657

6. Zhang X, Norris SL, Saadine J, Chowdhury FM, Horsley T, Kanjilal S, et al. Effectiveness of Interventions to Promote Screening for Diabetic Retinopathy. Am J Prev Med. 2007;33(4):318–35. DOI: 10.1016/j.amepre.2007.05.002. PMID: 17888859

7. Schillinger D, Piette J, Grumback K, Wang F, Wilson C, Daher C, et al. Closing the loop: Physician communication with diabetic patients who have low health literacy. Arch Intern Med. 2003;163(1):83–90. PMID: 12523921

8. Aikens J, Bingham R, JD P. Patient-provider communication and self-care behavior among type 2 diabetes patients. Diabetes Educ. 2005;31(5):681–90. DOI:10.1177/0145721705280829. PMID: 16203852.

9. Piette J, Schillinger D, Potter M, Heisler M. Dimensions of patient-provider communication and diabetes self-care in an ethnically diverse population. J Gen Intern Med. 2003;18(8):624–33. PMID: 12911644.

10. Mumba M, Hall A, Lewellen S. Compliance with Eye Screening Examinations among Diabetic Patients at a Tanzanian Referral Hospital. Ophthalmic Epidemiol. 2007;14:306–10. DOI: 10.1080/09286580701272079. PMID: 17994440

11. Thapa R, Paudyal G, Maharjan N, Bernstein P. Demographics and awareness of diabetic retinopathy among diabetic patients attending the vitreo-retinal service at a tertiary eye care center in Nepal. Nepal J Ophthalmol. 2012;4(1):10–6. DOI: 10.3126/nepjoph.v4i1.5844. PMID: 22343990.

12. Adriono G, Wang D, Octavianus C, Congdon N. Use of eye care services among diabetic patients in urban Indonesia. Arch Ophthalmol. 2011;129(7):930–5. DOI: 10.1001/archophthalmol.2011.147. PMID: 21746983.

13. Bamashmus MA, Khandekar R, Gunaid AA. Regular Visits to a Diabetes Clinic Were Associated with Lower Magnitude of Visual Disability and Diabetic Retinopathy - A Hospital-Based Historical Cohort Study in Yemen. Diabetes Technol Ther. 2009;11(1):45-50. DOI: 10.1089/dia.2007.0299. PMID: 19132855.

14. Onakpoya OH, Adeoye AO, Kolawole BA. Determinants of previous dilated eye examination among type II diabetics in Southwestern Nigeria. Eur J Intern Med. 2010;21(3):176–9. DOI: 10.1016/j.ejim.2010.01.009. PMID: 20493418

15. Shamoon H, Zybert P, Basch C, Walker E, Howard C. The Effect of Health Education on the rate of ophthalmic examinations among African Americans with diabetes mellitus. Am J Public Health. 1999;89(12):1878-1882. PMID: 10589324

16. Katulanda P, Rathnapala D, Sheriff R, Matthews D. Province and ethnic specific prevalence of diabetes among Sri Lankan adults. Sri Lanka J Diabetes Endocrinol Metab [Internet].

2012;1(1):2–7. DOI: http://doi.org/10.4038/sjdem.v1i1.4180

17. Piyasena PN, Murthy GVS. A situation analysis of diabetic eye care service delivery in health care institutions of the Western Province of Sri Lanka. Ceylon Med J [Internet]. 2017;62(3):205–6. DOI: http://doi.org/10.4038/cmj.v62i3.8527

18. WHO. World Health Organization (Foundation Document). Health Education: Theoritical concepts, effective strategies and core competencies [Internet]. Genewa, Switzerland; [Cited on 2018 April 10] 2012. Available from: http://applications.emro.who.int/dsaf/EMRPUB_2012_EN_1362.pdf.

19. Hubley J, Gilbert C. Eye health promotion and the prevention of blindness in developing countries: critical issues. Br J Ophthalmol. 2006;279–84. DOI:10.1136/bjo.2005.078451. PMID:16488944

20. Michie S, West R, Sheals K, Godinho C. Evaluating the effetiveness of behaviuor change techniques in health-related behavoir: a scoping review methods used. Transl Behav Med. 2018;8:212–214 doi: 10.1093/tbm/ibx019 PMID:29381786

21. Lawrenson JG, Graham-Rowe E, Lorencatto F, Burr JM, Bunce C, et al. Intervention to increase attendance for diabetic retinopathy screening. Cochrane Database Syst Rev. 2018;1:CD012054. PMID: 29333660 DOI: 10.1002/14651858.CD012054.pub2

22. Bandura A. Health promotion from the perspective of social cognitive theory. Psychol Heal. 1998;13(4):623–49. https://doi.org/10.1080/08870449808407422

23. O'Fallon LR, Tyson FL, Dearry A. Successful Models of Community-Based Participatory Reseach. [Internet] 2000;85. [cited 2017 Dec 10] Available from: https://www.orau.gov/cdcynergy/soc2web/Content/activeinformation/resources/SOC_comm_participatory_res.pdf

24. Shoemaker SJ, Wolf MS, Brach C. Development of the Patient Education Materials

Assessment Tool (PEMAT): A new measure of understandability and actionability for print and audiovisual patient information. Patient Educ Couns. 2014;96(3):395-403. doi: 10.1016/j.pec.2014.05.027. PMID: 24973195

25. Guidelines for the Development of Patient Education Materials. Report by Scotia Nova Cancer Care Programs [Internet]. 2004;(March): [cited on 2018 Jan 05] Available from: http://www.cdha.nshealth.ca/nova-scotia-cancer-care-program-3

26. World Health Organisation. Shanghai Declaration on Health Promotion in the 2030 Agenda for Sustainable Development. [Internet]. 2016 [cited 2018 Dec 10] Available from: https://www.who.int/healthpromotion/conferences/9gchp/shanghai-declaration-zero-draft.pdf?ua=1

27. Jones CA, Mawani S, King KM, Allu SO, Smith M, Mohan S, et al. Tackling health literacy : adaptation of public hypertension educational materials for an Indo-Asian population in Canada. BMC Public Health. 2011;11:24 doi: 10.1186/1471-2458-11-24 PMID: 21223580

28. Hölzel LP, Ries Z, Kriston L, Dirmaier J, Zill JM, Rummel-kluge C, et al. Effects of culture-sensitive adaptation of patient information material on usefulness in migrants : a multicentre , blinded randomised controlled trial. BMJ Open. 2016;23(11): e012008. doi: 10.1136/bmjopen-2016-012008. PMID: 27881523

29. Hussain R, Rajesh B, Giridhar A, Gopalakrishnan M, Sadasivan S, James J, et al. Knowledge and awareness about diabetes mellitus and diabetic retinopathy in suburban population of a South Indian state and its practice among the patients with diabetes mellitus : A population - based study. Indian J Ophthalmol. 2016;64(4):272–6. doi: 10.4103/0301-4738.182937. PMID: 27221678

30. Lewis K, Patel D, Yorston D, Charteris D. A qualitative study in the United Kingdom of factors influencing attendance by patients with diabetes at ophthalmic outpatient clinics. Ophthalmic Epidemiol [Internet]. 2007;14(6):375–80. DOI: 10.1080/09286580701375195.

PMID: 18161611.

31. Hipwell AE, Sturt J, Lindenmeyer A, Stratton I, Gadsby R, O'Hare P, et al. Attitudes, access and anguish: a qualitative interview study of staff and patients' experiences of diabetic retinopathy screening. BMJ Open [Internet]. 2014;4(12):e005498. doi: 10.1136/bmjopen-2014-005498

32. Newman-Casey P, Weizer J, Heisler M, Lee P, Stein J. Systematic Review of Educational Interventions to Improve Glaucoma Medication Adherence. Semin Ophthalmol. 2013;28(3):191–201 doi:10.3109/08820538.2013.771198. PMID: 23697623.

33. Census of Population and Housing 2012. Department of Census and Statistics of Sri Lanka [Internet]. 2012 [cited 2016 Aug 19]. Available from: http://www.statistics.gov.lk/PopHouSat/CPH2011/Pages/Activities/Reports/CPH_2012_5Per_Rpt.pdf

34. Williams AM, Muir KW, Rosdahl JA. Readability of patient education materials in ophthalmology : a single-institution study and systematic review. BMC Ophthalmol [Internet] 2016;16:133 PMID: 27487960 DOI: 10.1186/s12886-016-0315-0

35. Abdull MM, Chandler C, Gilbert C. Glaucoma , " the silent thief of sight " : patients ' perspectives and health seeking behaviour in Bauchi , northern Nigeria. BMC Ophthalmology; 2016;16(44):1-9 DOI 10.1186/s12886-016-0220-6

36. Amarasekara AATD, Fongkaew W, Turale S, Wimalasekara SW, Chanprasit C. An ethnographic study of diabetes health beliefs and practices in Sri Lankan adults. Int Nurs Rev [Internet]. 2014;61(4):507–514 8p. doi: 10.1111/inr.12136. PMID: 25363651.

37. Fikree FF. Role of gender in health disparity: the South Asian context. Bmj [Internet]. 2004;328(7443):823–6. PMID: 15070642 DOI: 10.1136/bmj.328.7443.823

38. Geneau R, Lewallen S, Bronsard A, Paul I, Courtright P. The social and family dynamics

behind the uptake of cataract surgery: Findings from Kilimanjaro region, Tanzania. Br J Ophthalmol. 2005;89(11):1399–402. DOI: 10.1136/bjo.2005.075572. PMID: 16234438

39. Abu M, Himmel W, Vormfelde S, Koschack J. Video-assisted patient education to modify behavior : A systematic review. Patient Educ Couns. 2014;97(1):16–22. DOI: 10.1016/j.pec.2014.06.015. PMID: 25043785

40. Sureshkumar K, Murthy GVS, Munuswamy S, Goenka S, Kuper H. "Care for Stroke", a web-based, smartphone-enabled educational intervention for management of physical disabilities following stroke: feasibility in the Indian context. BMJ Innov [Internet]. 2015;1(3):127–36. doi: 10.1136/bmjinnov-2015-000056. PMID: 26246902

41. Livne Y, Peterfreund I, Sheps J. Barriers to patient education and their relationship to nurses' perceptions of patient education climate. Clin Nurs Stud. 2017;5(4):65–72 DOI: 10.5430/cns.v5n4p65.

42. Wilhelmsson S, Lindberg M. Health promotion: Facilitators and barriers perceived by district nurses. Int J Nurs Pract. 2009;15:156–163 doi:10.1111/j.1440–172X.2009.01740.x. PMID: 19531073

43. Dunn SM. Barriers and challenges in training health care providers for patient education. Patinet Educ Couns. 1995;26(1-3):131–8. PMID: 7494712

44. Deer L, Owsley C, Campbell L, Gao L, Wood A, Girkin C. Feasibility, Patient Accepatability, and Preliminary Efficacy of a Culturally Informed, Health Promotion Program to Improve Glaucoma Medication Adherence Among African Americans-"Glaucoma Management Optimsm for African Americans Living with Glaucoma" GOAL. Curr Eye Res. 2016;41(1):50–58 doi:10.3109/02713683.2014.1002045. PMID: 25625187.

Chapter 14

General Discussion

14.1-Possible reasons explaining the current provision of diabetic retinopathy services in Sri Lanka based on the formative research findings

I observed that visual impairment and blindness due to diabetic retinopathy (DR) is not yet a priority in Sri Lanka, as in most of the low and middle-income countries (LMICs), despite the increasing prevalence of diabetes mellitus (DM), which is described in detail in the introductory chapters. The evidence generated in this feasibility study should be useful for advocacy to develop a DR screening program in Sri Lanka. Based on the formative research findings, I discuss the possible explanations for the current provision of DR services in Sri Lanka below.

14.1.1-Lack of advocacy for DR services in Sri Lanka

Sri Lanka has achieved remarkable social development in education, health and nutrition [14.1]. However, DR screening and treatment services have not comparably developed, probably due to a lack of advocacy. Though Sri Lanka has an exemplary primary care network, the country's efforts to integrate DR screening have been minimal. I observed that the Sri Lankan public sector eyecare system is mainly based on curative service provision. This leads to an increased workload as described by the providers and had not developed based on the evidence on emerging diseases and transitions. Perhaps this would be the most cost-saving strategy for the government, rather than exploring and allocating funds for emerging eye diseases. Therefore, attention towards issues such as DR blindness was very low at policy and planning level as I described in Chapter 9.

A study conducted in India reported that providing solutions to manage sight threatening DR (STDR) required substantial reforms in eye care health systems and engagement with stakeholders i.e. service providers and users [14.2]. The study authors also elaborated that even if a minor proportion such as

0.5% of the people with DM (PwDM) became blind each year, this would surpass the number blinded due to cataracts [14.2]. Though DR blindness is not currently at an epidemic level, unless preventive programs are initiated at this stage, it may lead to socio-economic issues in the near future [14.3]. It is mentioned that context specific strategies should be developed to control blindness due to DR in LMICs, where models developed in high-income countries (HIC) may not be practical [14.4]. Considering these facts, we can say that there is a dire need for development and implementing more innovative strategies to prevent sight loss due to DR in Sri Lanka.

14.1.2-Lack of evidence on DR and DR screening from Sri Lanka

There is a paucity of Evidence on DR and DR screening from Sri Lanka despite the evidence indicating a high prevalence of DM [14.5]. Following the systematic literature search, I didn't find a single article on barriers assessment or DR screening in an indexed journal from Sri Lanka. This may have been a major drawback when lobbying and advocating for DR blindness prevention in Sri Lanka. Additionally, since the entity had not been explored in this context, even identification of a target group for advocacy was a problem, as observed during the provider interviews [14.6]. Due to lack of evidence generated from a local context, DR blindness prevention is low on the list of priorities for the policy makers.

14.1.3-Lack of awareness on DR among the providers

I observed in the formative research that health promotion regarding systemic DR screening is almost non-existent in the prevailing socio-political system of eye care service delivery in Sri Lanka. This led to poor knowledge and awareness of DR blindness among the service users as well as the providers as described in Chapters 8 and 9. Moreover, some institutional administrators were unaware of the current DR burden in the region. Additionally, I noted that expertise for digital retinal imaging in the country was lacking. Under these circumstances, Sri Lanka may struggle to develop a DR screening program without international collaboration and expertise currently. Even with the complexities of the problem and difficulty in providing solutions, most of the decision-makers in the public sector were reluctant to seek advice in such instances.

14.1.4-Lack of leadership and communication between clinicians and program planners

I found that there the lack of effective communication between the clinicians and program planners a major deficiency. It was also clear from the formative research that there was little leadership to initiate and oversee a screening program. As the Sri Lankan public health system had not been restructured according to disease transitions and emerging trends, there were no cadre allocations such as a 'DR screening program head'. On the other hand, creating new positions would require many administrative authorisation procedures. Additionally, creating and filling such positions under the Ministry of Health would be difficult to initiate until already vacant peripheral district positions are filled. However, appointing a DR screening program manager or a coordinator is deemed important for planning and implementing a program.

14.2-General discussion on the main finding of the study

The access to health care has multi-level perspectives including health systems, providers and the individual service users [14.7]. The first objective in my study was to identify the barriers to accessing DR screening. Of the dimensions suggested in access models, availability, acceptability and appropriateness seemed most relevant for Sri Lanka. As I targeted the free public sector, I did not specifically look at affordability. According to the second and third objectives of the study, in the next phase, I assessed the validity of the proposed DR screening modality and the acceptability of the health educational intervention (HEI) to improve the referral uptake.

14.2.1-What this study has added to the pool of evidence

The two systematic reviews I carried out by me were designed and aimed at studying the possible solutions for developing and improving access for screening modalities in Sri Lanka and in LMIC settings. To our knowledge, no other such reviews have targeted implementation of interventions in LMICs. In the barriers assessment, my main consideration was studying what hindered access to DR screening according to the specific contexts by country income. Though there were common barriers to access DR screening from the perspective of PwDM, such as a lack of knowledge and awareness,

most barriers were different from one context to the other. This is described in detail in chapter 7. I assumed that evidence generated from the proposed integrated DR screening model would improve the quality of services delivery and user satisfaction as reported in systematic reviews of integrated care [14.8,14.9]. Furthermore, evidence generated on diagnostic test accuracy (DTA) aids decision making by the program planners in terms of sensible use of the proposed modality in the local context [14.10].

14.2.2-Service users' barriers assessment

I studied the use of DR screening services as an operational proxy to understand how accessible they were. This was a stated method in a study of developing frameworks that addressed barriers to access of health services in low-income settings [14.11]. What I assessed could also be described as the potential access to services based on contextual factors [14.12]. The focus group discussions showed that one of the major barriers to uptake of DR screening services is a lack of knowledge and awareness among PwDM in the region. Barriers to service users have led to poor uptake of services. Furthermore, those who had already developed STDR were vulnerable to social and emotional impact as reported in a review article [14.13]. A systematic review showed that repeated non-attendance for screening was associated with developing STDR. Some of these factors were modifiable [14.14].

As the Western Province has a well-developed infrastructure, I did not regard issues such as transport barrier. In addition, though I identified each barrier separately and tried to identify the relevant interventions, their effectiveness is best measured when they are combined [14.11]. A Cochrane review has concluded that meaningful improvements in attendance can be achieved using interventions targeted at service users, providers and health systems in DR screening [14.15]. I considered this in formative research.

14.2.3-Providers' views on challenges in provision of DR screening

Another objective of the barriers assessment was to study the barriers as well as enablers at the service provider levels. Based on their perspectives, I could identify the realised access, i.e. the actual usage

of available opportunistic services by PwDM [14.12]. A study conducted in the UK showed that knowing the user barriers would allow providers to deliver more accessible services [14.16].

In my formative research, one of the major barriers identified was the lack of skilled workers (HR) to carry out DR screening. Lack of innovative technologies for screening aggravates the situation. In contrast, I observed that skilled HR and equipment were available for formal assessment and treatment of DR. The vitreo-retina is currently a well-established clinical sub-specialty in Sri Lanka that is capable of providing the necessary treatment for DR. For decades, clinicians have been practicing slit-lamp bio microscopy and direct ophthalmoscopy for opportunistic DR screening. As a screening method, it is not an efficient way to allocate specialist ophthalmologists for DR screening. From the perspective of ophthalmologist, opportunistic screening was a burden. Up to now, no attempts have been made to use innovative technologies such as widescale retinal imaging for DR screening.

14.2.4-Identification of a suitable setting for DR screening service delivery

A study conducted in Sri Lanka claimed that chronically ill patients mostly present to the public sector for day-to-day outpatient care [14.17]. Hence, we can expect a large proportion of PwDM at island wide public sector health care institutions. This allows the initial enumeration of population of PwDM to screen. Based on my hypothesis, using the theory of change and based on the service providers' views, I suggested that providing DR screening services by task-shifting at the medical clinic level by physicians was the best approach for an integrated DR screening program.

14.2.5-Proposing a DR screening model for the Western Province

Digital retinal imaging is the most advanced retinal imaging method currently in use. Different field strategies, pupillary status and HR for image grading are used in various national level DR screening programs around the world [14.18]. No systematic review of research is available that could define the best imaging and grading strategy for a DR screening program in LMICs. The available reviews used different imaging systems without separating those that were digital from non-digital. This led to high heterogeneity in the outcomes. Therefore, I wanted to separate the summary estimates of DTA in

different digital imaging techniques to see the effectiveness of each method for DR screening. This is described in detail in the Chapter 10 meta-analysis.

Though there is limited evidence from LMICs on effectiveness of prevention of sight loss by screening, most evidence from HICs show promise [14.18]. Most of the international guidelines recommend annual or biennial DR screening depending on the risk of the PwDM to develop STDR at the baseline [14.19]. However, in LMIC settings, the available finances are not even adequate to provide anti-diabetic medications. Therefore, a full population-based DR screening program: such as what we see in an HIC may not be feasible in a country like Sri Lanka. On the other hand, we cannot wait till we reach the point of sophistication to initiate a national level program. Therefore, to overcome this public health issue, we need locally adaptable innovative modalities such as the proposed DR screening model in this study.

Images from a hand-held nonmydriatic digital retinal camera that were graded by trained physicians was selected as the modality that should undergo testing for diagnostic accuracy. This was based on the evidence generated from my systematic review and meta-analysis, and the study on barriers to accessing DR screening. The implementation of the proposed modality of DR screening was a complex in the local setup, even in a single centre study. Systematic review of the literature and formative research work were helpful in identifying the potential impeders in advance. From the beginning, the incorporation of service providers' views was helpful in strengthening the proposed strategy and giving the stakeholders a sense of ownership of the process.

14.2.6-Validity of the proposed DR screening modality

My study showed that DR screening using a hand-held camera by physician graders at a medical clinic was a feasible strategy to primarily screen and identify a referable level of DR in a non-ophthalmic setting. This was described in detail in Chapter 12. The sensitivity values for the defined referable level were 88.7% and 92.5% for the two graders in the study, when using mydriatic imaging, and 86.8% and 84.9% for non-mydriatic imaging. This was above the recommended minimum sensitivity level of 80% followed in most of the HIC national programs [14.18]. The specificity values

of 94.9% and 96.4% for the two graders were close to the recommended minimum of 95% in mydriatic imaging. However, specificity was comparatively low, i.e., 71.7% and 77.3% for two graders in non-mydriatic imaging. We observed a high response rate (85%) for screening using this modality. One reason for the high response rate was that the PwDM were presenting for their regular out-patient medical care. This did not require an additional visit to the eye clinic.

14.2.7-Importance of HEI on improving referral uptake

Eye health promotion plays a major role in controlling avoidable blindness in LMICs [14.20]. This involves three major components, i.e. HE, service improvement, and advocacy. In this approach, HE is very important to improve the uptake of services. Empowering PwDM is an important aspect of controlling sight loss due to DR [14.21]. In this approach, I conducted assessments of the needs of the priority population through the formative and participatory work [14.22]. The results of my formative study strongly suggested the need for an HEI to improve the referral uptake at ophthalmology clinics. In my study, I focused on improving the uptake at eye clinics, as I identified this as specifically important in controlling the sight loss due to DR among the PwDM at medical clinic level.

14.2.8-Importance of a participatory approach in the development of HEI

A study concluded that engagement of the community is required to find the elements of an HE program [14.23]. It has been shown that involvement of stakeholders including intended end-users at the design stage of an intervention would reduce time for development and testing and lead to better results [14.24]. I followed this in my detailed research in Chapter 12. In addition, literacy levels and target audience are important factors to consider in the development of the HEI as reported in previous studies [14.25,14.26]. The information, education and communication (IEC) strategies had been developed and effectively used in LMIC settings such as India [14.27]. A systematic review showed that counselling, interviewing, education and provision of advice were effective for affecting behaviour change. These can be performed by physicians and nurses. Simple advice is generally more effective than intensive advice [14.28]. The evidence on HEI development, guidelines and a participatory

approach enabled me to engage the PwDM and other stakeholders at the HEI development stage. This ensured greater acceptability during pilot testing.

14.2.9-Human resources and technology to deliver the HEI at a medical clinic

In field testing I found that the personnel delivering the HEI and the availability of appropriate technology are important considerations when scaling up. This is described in detail in Chapter 13. A survey conducted in Sri Lanka showed that allied health personnel including a 'diabetes educator nursing officer' (DENO) could deliver multiple HE components to control and prevent DM and cardio-vascular risks [14.29]. In this study, 71% of the trained nurses were observed to integrate in DM-related work in health care institutions after training [14.29]. We can employ a similar approach in delivering the HEI developed in my study. In contrast, a systematic review on quality improvement strategies on DR screening stated that there was no significant difference between DR Screening specific HE strategies (Risk difference 0.04, 95% CI -0.11-0.19, number of studies n=3, I^2 68%) compared to the general diabetic care strategies (Risk difference 0.06, 95% CI 0.02-0.11, number of studies n=7, I^2 46%) in improving the uptake of DR screening [14.30]. However, in this meta-analysis, one arm contained only three studies and indicated a high heterogeneity, so the generalisability of the evidence is debatable.

14.2.10-Assessment of acceptability of the HEI

The inconsistencies of the definition of acceptability make it a debatable topic. In theory, some authors define acceptability as a multi-faceted construct consisting of cognitive and emotional responses to an intervention [14.31]. A review article described acceptability in two tiers, i.e. prospective and retrospective acceptability [14.31]. In my approach, I have assessed prospective acceptability through participatory workshops and stakeholder interviews. In addition, retrospective acceptability was assessed during field testing.

14.2.10.1-Acceptability of the HEI leaflet

In this component of the study, the potential acceptability of the HEI was assessed using the SSIs [14.32]. I identified that the leaflet should be further simplified to make it understandable for PwDM with lower literacy levels. A systematic review on ophthalmic patient education material highlighted a common tendency for eye care related educational material to be written at a level that was too difficult for many patients to understand [14.33]. Therefore, this aspect should be a major consideration when implementing an HE program. A systematic review concluded that leaflets were useful when users need information [34]. In addition, most of the guidelines stated that written educational material are the 'back-bone' of the comprehensive patient educational program [14.20,14.35]. Therefore, I can assume that the leaflet developed in this study will be very useful for improving knowledge and awareness among the PwDM in a future program. I observed a slightly higher preference for printed material in field testing, which has to be re-assessed in a larger study.

14.2.10.2-Acceptability of the video HEI

A study showed that video-based HEI is suitable for providing culturally sensitive information [14.36]. Similarly, video educational interventions have showed the potential for improving knowledge in other conditions such as with patients suffering from strokes [14.37]. With advancement in mobile information technologies, video interventions would have a highly penetrative impact in reaching a wider audience, compared to the printed material. I observed that a narrative representation of case studies using actual PwDM from the Western Province was a more effective way of providing education on behaviour change, that has also been concluded in a systematic review on video-assisted education [14.38]. The participatory workshops highlighted that video HEI was generally preferred by the Tamil ethnic community.

14.2.11-Lessons learnt from assessment of HEI

One significant learning in the adaptation process was that HEI should be developed according to the socio-cultural and health services requirements of Sri Lanka, rather than by directly translating material into local languages. I learnt that assessing the acceptability of leaflet and video interventions was very subjective. This may have been affected by the participants' previous knowledge of DR and

general level of literacy in health matters. In addition, this assessment would not reflect the effectiveness of the HEI. Moreover, no specific validated tools in local languages existed on the subject of assessing HE material. My assessment focussed on the social acceptability of the intervention and understanding cultural suitability and the adequacy of the information provided to improve the referral uptake. In addition, I did not intend to provide or assess wider knowledge on DR, DR screening and treatment. This was beyond the remit of the project.

14.3-How to strengthen the diabetic retinopathy screening services in Sri Lanka

When evaluating technical feasibility, assessing the complexity of the proposed integrated DR screening modality was important. The feasibility of implementing the proposed DR screening modality depends on its technical complexity and capacity to deliver at each public-sector healthcare institution. In the formative phase, I have assessed the demand and supply side barriers, which helps minimise the capacity gap [14.39]. A study has identified four main domains for defining a conceptual framework when evaluating the technical feasibility of an intervention. Based on this framework, I identified the following domains to better understand the constraints for scaling up the proposed DR screening modality.

1) Capacity of the government (national level) / institution (regional level).

2) Service user (PwDM) characteristics

3) Characteristics of the proposed DR screening modality

4) Characteristics of delivery of DR screening services

In accordance with the above domains, under the intervention characteristics DR screening equipment, DTA and medical supplies for those requiring treatment needs to be addressed. In the service delivery, one main consideration is the ability to deliver the DR screening services under the free public sector health care institutions. Here, task-shifting, training and developing the skills of the physician graders are the main concerns. In assessing the capacity of the government, regulation

changes are needed that lead to an allocation of a separate cadre for DR screening starting from program managers to physician graders. In the formative phase, I have assessed and discussed most of the service user characteristics.

There are various public health implications of this research project in different time frames. In the short term, dissemination of evidence and capacity building among general physicians should be considered. In the long run, evidence generated in this project can be used for advocacy and policy development that leads to the implementation of a DR screening program. However, a health system in an LMIC like Sri Lanka, generally develops slowly in line with changing population needs. A disparity exists between the capacity to adopt strategies for these epidemiological transitions. Therefore, facing challenges will be inevitable in the implementation of a local DR screening program. This chapter described the public health implications of the current feasibility study, how to overcome the barriers identified in formative research, and the challenges foreseen in its implementation.

14.3.1-How to do effective advocacy on DR

14.3.1.1-Challenges in the health and local political system

In any context, health-care systems are highly dynamic and almost always driven by limited resources. Furthermore, this environment is constantly affected by local political and economic conditions [14.40]. Governance and decision-making in an LMIC setting are also affected by many social, cultural and political factors that are unique to a particular context [14.41]. It is stated that effective advocacy can result in better compliance in the uptake of DR screening services, leading to a reduction of those with STDR [14.6]. I observed during the formative research that decision-making related to implementation of blindness prevention programs are mostly driven by local political systems in Sri Lanka most probably with the expectation of quick results from interventions delivered at a community level. I note that the actions of decision-makers will depend on whether the issue is economically and politically viable with the availability of good scientific evidence and demand from the users [14.42]. Other reasons for a failure in implementation are constraints in the socio-political

system, lack of coordination with the funders, and obstacles due to national regulations [14.43]. Furthermore, in an LMIC like Sri Lanka, bureaucracy and international influences are significant [14.42].

14.3.1.2-Stages of implementation of the DR screening model

Implementation encompasses what a program consists of when it is delivered in a certain context [14.44]. This will allow an understanding of how a proposed intervention works in the real world. A previous review identified three main domains i.e. community, provider and innovations characteristics that could affect implementation [14.44]. A study describing the ways of strengthening DR services in India stated that cooperation among all stakeholders was important to prevent sight loss due to DR [14.45]. Evidence-based strategies are required to fully utilise available resources [14.40]. Here the main stages are research and development, decision-making and implementation [14.46]. At present, my project targeted the research and development stage. Identifying the mile stones to achieve along with their time lines are important for effective future implementation. A wide delay from the time of research and development to actual implementation is also noted at a population level for new interventions in LMICs [14.46]. This will be critical when implementing a DR screening program.

14.3.1.3-Factors affecting implementation of the DR screening model

Implementation of a new intervention or modality will depend on many contextual factors [14.47]. It is mentioned that people's behaviour is linked with various cultural dimensions [14.48]. How it might work, and its actual effectiveness may vary according to the context. The success of implementation of my validated DR screening modality in a clinical environment would depend on its acceptance by the provider and user. Another aspect is its potential to be financed by the government in a free public sector setup and its affordability by the user in a paid system. One systematic review mentioned that in general the coverage of interventions is low in LMICs. Also, most of these interventions are targeted at user or provider levels, and not at organizational level [14.49]. One enabler for implementation of proposed DR screening model is the availability of free health care in Sri Lanka.

14.3.1.4 - Gaps in evidence in the system

It is shown that the disease burden can be reduced significantly when we reduce the difference between the level of knowledge on what to do and what has been already implemented in a setting based on available evidence [14.43]. In the formative research, I observed this as one important aspect in implementing DR screening using 'new' technologies for Sri Lanka. It is noted that a reason for unsuccessful upscaling is a reduction in the fidelity of the intervention, i.e. the repeatability of the intervention as prescribed in the evidence following implementation at population level [14.43]. A study using smart-phone technology in DR screening concluded that multi-site trialling and assessment of the impact of new technology on the clinical workflow is required to develop successful national strategies. This applies when implementing the proposed DR screening modality in Sri Lanka [14.50].

14.3.1.5-Ability to implement the DR screening modality in a public sector clinical setting

It is noted that implementation would be challenging if an intervention makes changes in clinical practice [14.49]. This feasibility study will provide insights into the possibility of scaling up the proposed modality in a clinical environment, which could not be attained purely by reviewing the existing literature [14.51]. A review mentioned that to achieve universal coverage and equitable services an effort should be made to shift public sector resources towards the poorer communities [14.52]. Therefore, assessing the feasibility of this DR screening modality through the public sector is justifiable for the Western Province of Sri Lanka.

14.3.1.6-Lack of resources and fidelity of the DR screening modality

A qualitative study on assessing the barriers to implement health interventions in LMICs reported that system factors, such as the workforce affect successful implementation and scale-up of interventions [14.43]. Another major obstacle is the setting's resource constraints. Such barriers to implementation in LMICs have been described in previous studies [14.43]. Most probably, a sector wide approach (SWAP) will be useful to overcome them [14.53,14.54,14.55]. This allows improvements in infrastructure and capacity building for the HR training needed for screening. Another aspect is

fidelity i.e. the degree to which an intervention of the proposed DR screening modality is delivered as intended when scaled-up up at population level [14.44]. Measures to maintain the same level of effectiveness observed in the validation study should be applied at the population level.

14.3.2-An approach for the implementation of the integrated DR screening model and scaling up - WHO health systems building blocks approach

A survey on planning and developing services for DR in sub-Saharan Africa concluded that a WHO health systems approach would provide a useful framework in planning a DR screening program [14.56]. It may be worth assessing the eye care system in Sri Lanka at national, or at least provincial level, before implementing a DR screening program. This would help in translating any suggested reforms into effective practices by harmonising with the existing system [14.57]. In a study on assessment of barriers to implement DR screening, it was noted that the leadership and system factors mainly affect the scaling up of an intervention [14.43].

It is reported that 'health systems thinking 'approach is required to tackle chronic eye diseases [14.58]. One major challenge for the current health system in Sri Lanka is the government's capacity to continue with free eye care services in the face of changing demographic and epidemiological needs [14.59]. This is further hampered by poor economic policies and inadequate revenue generation in the country. In addition, there is widening inequity in resource distribution between districts in Sri Lanka [14.59]. My study mainly focused on the processes involved in DR screening using digital imaging rather than the outcomes of an implemented systematic DR screening [14.60]. I am keen to assess the outcomes of DR screening in a separate study in future.

14.3.2.1-Major barriers to implement the DR screening model in the Sri Lankan health system

A successful implementation of an intervention will depend on understanding the theory, evidence and practical issues involved. One of the major concerns that would draw program planners' attention would be the availability of evidence on the higher burden of cataract blindness compared to DR. It is

true that nearly 50% of the blindness is due to cataracts as also reported in a WHO report [14.61]. A study conducted in India stated that the target of eliminating cataract blindness by 2020 as proposed by the WHO resolution on Vision 2020 is not achievable [14.62]. Noting this, we can expect a similar scenario in Sri Lanka. On the other hand, this evidence shows that, implementation of DR screening programs cannot be delayed until a country works through the cataract back log.

The evidence generated in my feasibility study may not be adequate to convince policy makers. Though I assessed the validity of the DR screening modality, I did not conduct evaluation studies to assess the acceptability of the modality by users or providers. Therefore, I recommend the undertaking of a larger study to evaluate the modality at different levels of services delivery and in multiple centres. In addition, I can validate different HR at these levels to select the most suitable category for screening. The acceptability of the proposed modality should also be assessed amongst these different cadres. Moreover, consideration should be made of how we can incorporate those with type 1 PwDM into the proposed model.

14.3.3-Feasibility of implementing a DR screening program using integrated model

There are no specific sources to assess and describe the criteria for implementation of a DR screening intervention in an LMIC let alone an HIC. The only available sources are the guidelines published for national level programs within the respective countries. Therefore, I followed the WHO health systems building block approach to describe the criteria for implementation of a DR screening program in Sri Lanka. In addition, I have described the criteria to improve the quality of the screening intervention based on the above domains.

14.3.3.1-Leadership and governance of a DR screening program

As I observed in the formative research, no separate cadres exist for commissioning and conducting blindness prevention programs under the Ministry of Health of Sri Lanka. Those currently working in this capacity are clinical ophthalmologists already involved in service delivery. On the other hand, services designed and delivered in an LMIC like Sri Lanka are based on demand from users. Sometimes, it is purely based on the provision of a solution to reduce the daily clinical workload.

Program coordination

Another important aspect to consider when launching a DR screening program in this region is the need for a dedicated overall leader for directing, training and conducting the program. In the highly bureaucratic health system of Sri Lanka, it would be difficult to achieve much without a strong dedicated leader. The lack of leadership to initiate and conduct a program may be one of the major obstacles for DR screening in Sri Lanka. Without strong leadership, proper lobbying and advocacy in a resources poor setting like Sri Lanka will be problematic.

Commissioning of a screening program

According to service providers, commissioning would be more effective if planned and carried out through a steering committee made up of experts. The committee would comprise of clinical ophthalmologists, general physicians, endocrinologists, institutional administrators, program planners and policy makers. Formulation of a steering committee on DR screening would be more sustainable under the VISION 2020 country program. There should also be local and international advisory committees for successful implementation of a DR screening program using digital imaging.

14.3.3.2-Financing a DR screening program

Current status of health expenditure in Sri Lanka

A systematic review on health care financing in LMICs concluded that policy makers should try to mobilise government resources to achieve the objectives of universal health care [14.52]. It was revealed during the provider interviews described in Chapter 9 that proper directing and channelling of the funds should be made to initiate a DR screening program. Generally, program planners pay attention to diseases with a high mortality. To compete for the funds, there should at least be evidence on what works in the local context. A systematic review of the cost-effectiveness of DR screening reported that the economic viability of a DR screening program would be high, with a lower frequency of screening for low-risk PwDM. A cost-effectiveness study has shown that annual screening of all PwDM is not cost-effective [14.63]. This would be a useful guideline to consider in a resource poor setting like Sri Lanka [14.64].

How to finance the DR screening program

The increase in expenditure in the curative sector has inevitably led to poor resource allocation for the prevention and health promotion of diseases that include DR. The sector-wide approach would be suitable to solve this type of a public health issue in an LMIC like Sri Lanka by involving the government, donors and stakeholders [14.55,14.54]. The priorities of the local context, flexibility of funding matched with local requirements and sustainability are some of the main concerns in program implementation [14.65]. Sufficient evidence should exist on DR screening and the number of PwDMs who require treatment to convince the decision makers to expand the screening and treatment services via the public sector. Another important aspect is that this must be initiated through the public sector as most of PwDMs attend public sector healthcare institutions for routine outpatient medical care. Initially, during this approach, donor agencies can contribute to the development of skills amongst suitable HR and the development of screening and treatment infrastructure provincially. A suggestion is to establish nine regional DR screening and treatment centres catering to each of the nine provinces in Sri Lanka.

14.3.3.3-Human resources for a DR screening program

Human resources management is an important aspect in the provision of high-quality services [14.66]. It is obvious that ophthalmologists are not an ideal category for DR screening considering their scarcity in low-income settings [14.67]. The various health system related factors would affect this decision. One major consideration in the Sri Lankan system was the ability of the selected cadre to make a clinical decision regarding PwDM according to the regulations of its ministry of health.

Physicians as primary graders through task shifting

Lack of skilled HR can stifle efforts to implement new public health strategies in LMICs [14.65]. During formative research, I identified the lack of skills on DR screening by medical officers as a major barrier. Task shifting of HR along with restructuring has been mentioned as a feasible and cost effective strategy to overcome barriers in accessing non-communicable diseases [14.68]. A systematic review on task shifting had noted that it was a practicable solution for LMICs with low resources.

This has notable policy implications [14.69]. In addition, it has been mentioned as an option to improve the efficiency of the delivery of health care services [14.70]. Therefore, in this study we developed new skills among physician graders to create a new professional cadre for DR screening in Sri Lanka. This would require carefully tailor-made training strategies without disrupting the existing systems.

Suitability of physicians as primary graders

In the current system, only qualified medical officers, residents and specialists can make decisions about patients. Para-medical and allied health staff are not allowed to make management decisions. Therefore, the training of a para-medical cadre such as optometrists would not be practical in the current system. Sri Lanka has about 87 medically qualified allopathic doctors for every 100,000 people [14.71]. This is a comparatively satisfactory ratio in an LMIC (India 0.7 per 1,000 vs 0.81 per 1,000 in Sri Lanka). The quality of health care will depend on the effective management of the available HR [14.66]. It is noted that there is no ideal universal skill mix in health care delivery [14.72]. The required mix would depend on contextual factors. In addition, it is mentioned in a review that performance of health care workers is determined by workers' knowledge and skills, motivation, provider's perception on user demand and an understanding of work responsibilities [14.73]. Therefore, in this study, I mainly considered general physicians as the most suitable primary graders in the current circumstances.

Possibility of non-physician primary graders in future

There is potential for employing a different cadre such as optometrists in DR screening. This may need a restructuring of the eye health system of Sri Lanka, without disrupting the current services. In addition, I can foresee in the future that a dedicated photographer and reader at the medical clinic would be the best solution for carrying out imaging at a program level. During the same visit, this will allow real time grading and interpretation of DR status allowing identification of individuals at risk. Those who require referral to the next level can be sent with a referral letter rather than moving

everybody to the next level and overloading the eye clinics. This would reduce the burden on the DR screening system as well as specialist eye clinics [14.74].

14.3.3.4-Data management systems for a DR screening program

To implement an efficient screening program, a proper medical information management system should be created in Sri Lanka. This is one of the major shortcomings for the implementation of a DR screening program in the public sector. The current system of record keeping is a manual documentation system that makes retrieval difficult. Most medical clinic records are kept with the patients it is not uncommon for them to be lost after a few years. Past records are important when managing chronic diseases such as DM. In addition, management decisions regarding DR is reliant on previous findings. In our feasibility study, we identified the need for very high capacity storage devices for storing fundus images and participant details. Therefore, availability of proper equipment will be important to consider when implementing a program.

14.3.4-Other important areas identified in the feasibility study when implementing a DR screening program

In the following section, I have described the factors related to service delivery and infrastructure according to the WHO health system approach. In this DR screening model, the main concerns under service delivery are: the quality of images, DTA, and referral networks. In addition, this would partly overlap with the infrastructure i.e. the imaging system used.

14.3.4.1-Research and development - How to further develop the integrated DR screening model

In this context, the development of a successful population based DR screening system would be a challenging task [14.50]. As this feasibility study was conducted at a tertiary level health facility, to test the generalizability of results, replication of this model in secondary and primary levels of service delivery may need to be considered. Therefore, further validation studies may be required in other levels of service delivery. Another consideration was that I would not be able to start DR screening in another province or district without the availability of DR treatment facilities.

14.3.4.2-Training - How to develop physician training programs on DR screening

The training of HR in LMICs should be considered as critical when launching new programs. With such training, it is said that competency-based models are more efficient than those that are time-based. Competency based models would allow for further development according to society's needs leading to a greater impact on program stakeholders. Even from the stand point of the HR being trained, competency-based methods are more efficient to avoid the training becoming a mere educational exercise [14.75]. When conducting such programs, LMICs should not aim to emulate the targets set by HICs. I followed this evidence when training the physician graders in the Western Province of Sri Lanka.

A review article stated that inadequate health worker performance is a common issue in low resource settings [14.73]. Performance is affected by factors related to the individual health worker as well as factors linked to the professional, educational, administrative, employment, socio-cultural, economic and political environment. In the training of physician graders on DR screening, my focus was on knowledge and skills [14.73]. Even though other dimensions influencing performance were not taken into consideration due to restrictions of capacity in my project at a program level, I will have to consider other dimensions such as the administrative and political environments.

14.3.4.3-Quality of the retinal images - How we can improve the quality of the retinal images

The quality of the retinal images is affected at three stages: the technical capacity of the camera; its capture by the photographer; and its display [14.76]. One study mentioned that para-professional cadres can capture high-quality images if the lens and media of the patients' eye are clear [14.77]. In this respect in the validation study, I noticed that the clarity of the cornea, lens, and of the media (vitreous gel) and pupil size were major factors affecting image quality. One major finding in my study was that, a significant proportion of technical failures were due to lens opacities. A similar finding was observed in a study conducted in India in which, out of 500 participants 153 (30.6%) had at least one eye ungradable when using nonmydriatic imaging [14.78]. Central cataracts have been reported as a cause of poor image quality even in a study conducted in an HIC such as the UK

[14.79]. In my study, there were 40 eyes (out of 1,400) that were ungradable even in the clinical reference test after mydriasis. These were found to need immediate cataract surgery. This finding highlighted the need for proper coverage in managing lens opacities, in places such as Sri Lanka. It also raised questions about what effects a high prevalence of cataracts may have on the maximum utilisation of a DR screening program.

Factors identified in the validation study that affect image quality

The technical specifications of hand-held cameras are generally inferior compared to large static table-top cameras. However, during the feasibility study, I observed that the technical specifications of the newer hand-held retinal cameras are adequate for screening purposes in a non-ophthalmic setting. A study conducted in India showed that para-professionals were capable of capturing high-quality retinal images using a hand-held portable non-mydriatic camera [14.77]. A study conducted in a high-income setting stated that the retinal field of interest; the inter-photograph interval; and the age and ethnic group of the participants are stronger predictors of the quality of non-mydriatic images captured by nurse practitioners in an emergency department [14.80]. In a future study, I can assess these factors for the Sri Lankan population.

The technique of image capturing and its effect on quality

In my study, the inter-photograph interval was very low, as there was a steady flow of PwDM in a busy medical clinic another possible reason for the high proportion of poor-quality images. In addition, there were technical factors affecting the image quality/sharpness during our image observations. The main one was the photographer's hand shake that led blurred images i.e. motion blurring, defocusing, and edge diffusion [14.81].

One disadvantage of hand-held cameras is their difficulty in controlling unavoidable movements that affect image quality. On the other hand, we noticed that the simplicity and unrestricted maneuvarability of hand-held cameras made them easier to learn to use. It was especially useful with participants who had difficulty keeping their heads on the chin-rest of a static camera, such as those

with cervical problems. In such patients, we could capture images in the positions most comfortable for them as the hand-held camera could be moved in any direction.

Other participant factors that affect image quality

In the tropical year-round sunny climate of Sri Lanka, most participants presented with 2-3mm size pupils. This made it very difficult to capture good quality retinal images. Similar observations were made in a study conducted in Andra Pradesh in India, where they reported a 34% rate of ungradability due to small pupils, the presence of cataracts and bad focusing [14.82]. In our sample, we did not observe many corneal opacities.

Even among the pseudophakics, I noticed that the image quality was low in my validation study. A possible reason is the presence of posterior capsular opacity. However, I identified that the prevalence of thick posterior capsular opacity in our sample was low. This is described in Chapter 12. When exploring the reasons for poor quality images among pseudophakics, I identified that without adjusting the camera optics to match the refractive indices of the patients, image quality is reduced. Our hand-held camera provided a range of +20D to -20D adjustment in manual or automatic mode. Physician graders mostly captured non-mydriatic images in manual mode and mydriatic when auto focusing. Therefore, I may have observed a higher ungradability even among the pseudophakic PwDM.

14.3.4.4-Required level of diagnostic accuracy of DR screening by the physician graders in this context

The next important factor is the DTA of the proposed modality. Most of the national-level DR screening programs in high-income settings recommend at least 80% sensitivity and 95% specificity in screening. However, we cannot expect the accuracy level recommended for an HIC with their sophisticated imaging infrastructure and highly-skilled trained graders. No recommended cut-off levels of DTA for a low income setting like Sri Lanka. In fact, the cut off level for diagnostic accuracy will depend on other factors such as the selected referable level of DR, the classification

system, and the number of fields used in imaging. Since there is no recommended guide, we can consider 80% sensitivity and 95 % specificity as an approximate target to achieve. However, the inability to achieve this will not mean the screening modality cannot be implemented in Sri Lanka.

How we can improve the DTA by physician graders

We followed a retinal feature-based grading system recommended by the National Health Services in the UK diabetic eye-screening program [14.83]. As a starting point, the physician graders achieved a satisfactory level of DTA in this study a major positive outcome at the time of implementation. When conducting the study there were logistical constraints relating to the availability of training resources including the unavailability of proper image reading equipment and the absence of a retinal image library/archive from Sri Lanka for teaching use. Usage of retinal images from other contexts is of questionable value when considering that various population characteristics would affect the nature and quality of images. Visualisation of delicate signs such as micro-aneurysms proved difficult in the images captured in my validation study. Considering these factors, a locally applicable DR grading training system may improve the skills and DTA of graders.

14.3.4.5-Effectiveness of the modality at population level

The effectiveness of the screening strategy would depend on the discriminative ability of the screening modality to identify asymptomatic people with DR. There should be a balance between accuracy, simplicity, accessibility, and cost. It may be a choice between a simpler, cheaper, less accurate method versus a more complex, expensive method that is more accurate but not affordable [84]. As shown in our systematic review and meta-analysis, even though the diagnostic accuracy is higher with more fields, the number of fields used depends on the availability of resources.

Another aspect of the level of DTA we achieved in this study is that it may not show the same level of DTA of physician graders who are screening at a population level. Since they were screening and grading under a facilitated environment under the research project, we can expect the DTA to vary at a population level. In addition, we selected the two best graders following the initial training program, which may lead to some selection bias in this approach. In order to generalise the DTA for physicians

in Sri Lanka, we may have to assess the DTA in a much larger sample of physicians in the region or the country as a whole. However, our method of validation would not undermine the scalability as I followed a rigorous scientific approach in the study.

14.3.4.6-How to access the target population to deliver services

One major requirement in the implementation of a screening program is to develop ways for identification, enumeration and accessing the target population. Here, one major drawback is the unavailability of a diabetic patients' register in Sri Lanka. However, it would not be difficult to develop a people with diabetes register across the island. Initially, we can propose screening of the diagnosed PwDM at the public-sector health care institutions. Each institute can develop their own PwDM register linking to a central unit at the Ministry of Health in Sri Lanka. The best option would be to develop this as a component of the VISION 2020 country program.

14.3.4.7-Need of a referral network

In the absence of a government sector general practitioner (GP) system in Sri Lanka, a comprehensive referral system is a major prerequisite before implementing a DR screening program. In Chapter 8, the PwDM described the difficulties they faced in the current referral system during the FGDs. Considering those factors, a strong link and coordination should be developed between medical clinics and eye clinics. Since the proposed DR screening modality is a system integrated with medical clinics, a need exists for a structured and robust referral network for further assessment, ocular investigations such as optical coherence tomography (OCT), and treatment. All the tertiary and higher secondary level institutions provide specialist eye care in Sri Lanka. Therefore, in the program, each screening clinic can be linked with a specialist eye clinic.

As described in formative research, in this proposed referral network, one must take into consideration the institutional barrier of having to take a separate appointment for the eye clinic. As this could discourage those referred to attend the eye clinic, an eye clinic appointment system operating within the medical clinic would be beneficial.

14.3.4.8-Need of HEI to improve referral uptake

I proposed to include an HEI to improve the uptake of referrals at the eye clinic by those who identified as having a referable level of DR. As I described in chapter 13, this HEI was acceptable to the community. I can assume that this integrated DR screening model would be more comprehensive by including an HEI to improve the referral uptake. Moreover, this HEI can be further developed with different components such as the inclusion of an HEI to improve the DR screening uptake at the medical clinic. Furthermore, I can recommend that in future the effectiveness of the current HEI can be assessed in a more scientific study using a cluster-controlled trial in Western Province.

14.4-Conclusions, limitations and recommendations

I have described the conclusions of each study, Chapter-wise below.

14.4.1-Conclusions

- The evidence in the barriers systematic review clearly suggests that the barriers and enablers are different in each income setting. The most consistent barrier across different income settings was lack of knowledge and awareness on DR and DR screening among the users. In providers point of view, lack of skilled human resources and screening infrastructure was the main barrier. Knowing the modifiable barriers in a specific context would be helpful to identify the risk groups early and to improve DRS uptake among institutional PwDM. A main recommendation of this review is to carry out an assessment of barriers and enablers in each context before implementing a DR screening program. The consumer-based health educational interventions and provider-based skills and DR screening infrastructure development would improve the access to DR screening especially in low income settings.
- The FGDs with the service users concluded that understanding how DR is conceptualised in this region and responded by the PwDM is essential to define strategies to improve uptake of DR screening services. This study shows that there are modifiable barriers to access in the

Western province of Sri Lanka. These are inter-connected personal, inter-personal, institutional, organizational and environmental barriers which hinder the uptake of DR screening services. Availability of DR screening services at a convenient location using methods acceptable, culturally and gender sensitive and relevant to PwDM together with strategies to improve the knowledge and awareness among the PwDM may facilitate uptake of screening services in this province.

- The study with the service providers showed a range of provider perceived barriers to DR screening and their recommendations to improve uptake. It highlights a combination of service delivery issues at the medical clinic level which need to be addressed, as well as the need for improved understanding of the needs at national level, with need for strong leadership commitment to implement a screening program. Training of existing non-ophthalmic human resources at medical clinic level by careful task-shifting and development screening infrastructure such as imaging systems under the funding schemes of Ministry of Health would be a feasible strategy to improve screening uptake.
- In the systematic review and meta-analysis of diagnostic test accuracy for the detection of any level of DR showed that DR screening using 2-fields delivered at non-primary care settings is a feasible approach. Dilatation of pupils did not improve the detection of any level of DR for those with gradable images, but such a wide range of ungradable were presented in these studies that this aspect must be taken into account when setting up DR screening programme. There wasn't adequate evidence in primary studies to comment on DTA of non-ophthalmological human resources on DR screening, so this aspect requires further research. Good quality digital imaging has the potential for real time interpretation of retinal images, which together with counselling for risk factors may improve the acceptability of DR screening and uptake of referral for ophthalmic assessment if conducted in a culturally acceptable way.
- In the validation study we demonstrated that the diagnostic test accuracy of the physician graders was closer to the standard practice of national level screening programs in other settings. We conclude that 2-field retinal imaging using a hand-held digital camera at a medical clinic, by physician graders, with dilatation of pupil of those who have ungradable images,

provides a valid modality to identify referable level of DR. This strategy is an accurate screening method of detection of a referable level in a health care facility-based people with diabetes who are at risk of developing sight threatening DR.

- The development of HE material in DR is a complex process, requires adaptation and development suitable to the local context. The process of adapting the health educational material is not simply translation into the appropriate language but rather an individualised tailored approach in different health services to meet the needs of various patient communities. Socio-cultural norms should be considered when defining the actionable steps. We can conclude that there is a satisfactory level of acceptability for this HEI and to deliver at a medical clinic setting would require further development of human resources and infrastructure appropriate to the intervention.

14.4.2-Overall limitations of the study components

14.4.2.1-Potential biases in the study

Of the overall research project, the main components that could lead to bias were: when conducting the systematic reviews; qualitative research; in conducting the validation study; and the assessment of the HEI. Attempts were made to minimise potential biases at the design stage. By assigning an independent co-reviewer when carrying out the systematic reviews, it was possible to obtain a more objective interpretation. As a team of sociologists were involved throughout the qualitative components of the study, the integrity and quality of the data and analyses were maximised. In conducting the validation study, the use of senior retinologists to perform all reference tests with minimal involvement from the study investigators, would have minimised a potentially major source of bias. In addition, data entry, cleaning, and analysis of the validation study were conducted by an independent team led by a local statistician.

14.4.2.2-Limitation of the study design of proposing DR screening modality

We could not assess the effectiveness of the proposed screening modality in combination with the HEI. In an ideal situation, assessing the effectiveness of the integrated DR screening modality in a cluster randomised controlled trial would have generated stronger evidence for implementation [14.85]. One important recommendation for future research is for a process evaluation to be carried out to assess the fidelity and quality of the proposed modality at population level [14.85]. This will be helpful for identifying potential failures and unexpected outcomes. Another aspect would be to assess the cost effectiveness of this modality compared to the conventional method of screening by slit lamp bio-microscopic examination.

The DTA will depend on the prevalence of the DR [14.86]. One major limitation in our validation study is the spectrum bias, due to the relatively low number of participants in the study suffering from more severe levels of DR. This was most likely due to the recruitment of an institutional sample from a tertiary centre. We did not observe a high prevalence of referable level DR in this study [14.87].

One aspect not covered in the study design was making an assessment of the service provider and of service user acceptability of the proposed screening modality [14.60]. In a future study, I would recommend carrying out a preliminary evaluation of user and provider views about the proposed modality.

14.4.2.3- Limitation of study design of development of HEI

A limitation in the component of HEI at the study design stage was it not including as assessment of the effectiveness of an intervention. Yet, it must be stressed that this decision was made due to logistical constraints. According to a review article, controlled randomised designs are highly recommended in the assessment of HEI in low-income settings [14.26]. Therefore, I would like to recommend such a method in a future study assessing the effectiveness of this HEI. It must also be noted that I could not assess the baseline knowledge and awareness of the participants prior to enrolling them on the HEI assessment. This should also be considered a limitation as their level of prior awareness could have a significant effect on their perspective.

14.4.2.4-Limitation of the overall feasibility study

One major limitation in this feasibility study is that I have not assessed and compared different DR screening modalities due to logistical constraints.

A major drawback in this overall study design was the absence of PwDM from peripheries in the Western Province of Sri Lanka. This could have led to a failure in the identification of different dimensions of barriers. This may have led to a proposal for a different DR screening modality such as mobile screening at peripheral primary care units.

Another concern was the safety and fidelity of the screening intervention in remote resource-poor settings where it could lead to an underestimation of a potential DR screening modality. In this local context, it was the first such scientific approach.

Though not discussed in this project, the next biggest concern is the PwDM at a community level, who are not attending outpatient medical care. It has been observed that in many LMICs, PwDM take over-the-counter drugs repeatedly without regularly presenting at a health care facility. Currently this is beyond the remit of this project's objectives.

14.4.3-Recommendations

- One important first step is building the leadership capacity under the Sri Lankan Ministry of Health for planning and implementation of a DR screening program. A dedicated leader in an administrative capacity with an ophthalmological clinical background would suit this position.
- At the medical clinic level, serious requirement exists for training and developing skills among physicians for DR screening using hand-held digital cameras. This can be initiated at the tertiary and secondary level public sector institutions where facilities exist to treat DR and other eye conditions identified after DR screening.
- A need exists to generate more evidence on DR and DR screening in Sri Lanka. A study on factors affecting image gradability on DR screening using digital imaging would be a very important consideration in program planning.

- In parallel with the implementation of the proposed modality, a requirement to exist to strengthen cataract surgical services. Otherwise, the delivery of DR screening services that lack cataract services will lead to frustration among those identified as having treatable lens opacities while they are undergoing DR screening.
- The feasibility of implementing the proposed modality should be assessed in a larger study by including other levels of service delivery such as primary level medical clinics in peripheral districts.
- Without affecting the current services provision, task shifting for primary DR screening should be further studied among different human resources to identify the most suitable cadre for primary DR screening. Different human resources categories can be validated in a larger study to further assess the most suitable for the proposed modality. Perhaps, this would be possible at district level by selecting a cadre suitable for that region. I would propose carrying out a feasibility study where the perception of service providers can be assessed regionally. It could decide on the best service delivery points and the categories of primary graders to be used for local DR screening.
- The procurement and provision of DR screening equipment can be done through the medical supplies division of the Ministry of Health in Sri Lanka. As there is only one central supply unit for the country, it must pass through the supplies division. There is a high possibility for securing funding for developing the infrastructure through external donors as was identified during the formative research work. However, effective coordination with donors on the purchasing of equipment and implementation of the screening program is important if it is to be successful.
- As this DR screening model is an integrated program, integration can be considered at any level of service delivery where PwDM are present. In the health system of Sri Lanka, out-patient medical clinics, diabetic clinics, endocrinology clinics and non-communicable diseases clinics are possible delivery points in initiating screening programs. Here, one challenge would be the availability of specialist eye care and

facilities for treatment. The most important facilitator for this is the availability of free eye care services within the governmental sector.

- Another important recommendation is to strengthen the specialised vitreoretinal facilities across the island when scaling up the program at a national level. Currently, there are adequate facilities in Western Province and about 10 vitreo-retinal surgeons island-wide. I propose developing provincial vitreoretinal centres in each of the nine provinces in Sri Lanka before implementing the DR screening at a program level.
- The HEI can be further developed according to the local dialects while considering the socio-cultural acceptability of each ethnic group. The human resources and technology should be further developed at medical clinic level to deliver the HEI with a view to improving referral uptake.

14.4.4-Implications for future research

The integrated DR screening modality will be useful in identifying risk groups in a non-ophthalmic setting. We used a hand-held retinal camera in this project due to its logistical and technical feasibility. In a future study, we may consider using a table-top camera with its potential for delivering higher quality images. Furthermore, these medical clinic-based imaging units can be connected with a central reading centre using the concept of tele-ophthalmology. In addition, a wider organisational and policy level approach is required to implement a regional/national level screening program. Taking Sri Lanka's free health system into account and its available resources, this is an achievable target.

In a future study, I can propose assessing the DTA using different human resources to decide on the most suitable cadre in primary grading. After assessing barriers, this type of study can be carried out at various services delivery levels. This will enable us to understand the barriers to access at various levels other than the tertiary centres in cities. Furthermore, using qualitative research, the acceptability of the integrated screening modality can be assessed amongst the service users and providers.

Assessing of the effectiveness of the HEI will be a major consideration for a future study. As this has not been assessed in Sri Lanka, or in a South Asian country in a controlled trail design, this would be very important in generating scientific evidence in a low-income setting.

References: Chapter 14

14.1. Semasinghe WM. Social Development of Sri Lanka: Achievement and Challenges. Sri Lanka J Soc Sci. 2009;01(03):283–309.

14.2. Gilbert CE, Babu RG, Sai A, Gudlavalleti V, Anchala R, Shukla R, et al. Eye care infrastructure and human resources for managing diabetic retinopathy in India : The India 11-city 9-state study. Indian J Endocrinol Metab. 2016; 20(7): 3–10. DOI:10.4103/2230-8210.179768

14.3. Murthy GVS, Das T. Diabetic care initiatives to prevent blindness from diabetic retinopathy in India. Indian J Ophthalmol. 2016;50–4.

14.4. Sabanayagam C, Yip W, Ting DS, Tan G, Wong T. Ten Emerging Trends in the Epidemiology of Diabetic Retinopathy. Ophthalmic Epidemiol. 2016;23(4):209–22. PMID: 27355693 DOI:10.1080/09286586.2016.1193618

14.5. Katulanda P, Rathnapala DAV, Sheriff R, Mathews DR . Province and ethnic specific prevalence of diabetes among Sri Lakan adults. Sri Lanka J Diabetes Endocrinol Metab. 2011;(1):2–7. DOI: http://dx.doi.org/10.4038/sjdem.v1i1.4180

14.6. Thulasiraj RD. Advocacy to improve the delivery of eye care. Community Eye Heal J. 2007;20(64):66–7. PMID:18330440

14.7. Levesque JF, Harris MF, Russell G. Patient-centred access to health care: Conceptualising access at the interface of health systems and populations. BMC Int J Equity Health 2013;12(1):1. https://doi.org/10.1186/1475-9276-12-18.

14.8. Ouwens M, Wollersheim H, Hermens R, Hulscher M, Grol R. Integrated care programmes for chronically ill patients: a review of systematic reviews. Int J Qual Heal Care. 2005;17(2):141–6. PMID:15665066 DOI:10.1093/intqhc/mzi016

14.9. Baxter S, Johnson M, Chambers D, Sutton A, Goyder E, Booth A. The effects of integrated care: A systematic review of UK and international evidence. BMC Health Serv Res. 2018;18(1):1–13. PMID: 29747651. DOI: 10.1186/s12913-018-3161-3

14.10. Mallett S, Halligan S, Thompson M, Collins GS, Altman DG. Interpreting diagnostic accuracy studies for patient care. BMJ. 2012;345:e3999. doi: https://doi.org/10.1136/bmj.e3999

14.11. Jacobs B, Ir P, Bigdeli M, Annear PL, Van Damme W. Addressing access barriers to health services : an analytical framework for selecting appropriate interventions in low-income Asian countries. Health Policy Plan. 2011;27(4): 288-300. PMID: 21565939 DOI: 10.1093/heapol/czr038

14.12. Xinzhi Z, Andersen R, Saaddine JB, Beckles, Gloria LA, Duenas MR, Lee PP. Measuring Access to Eye Care: A Public Health Perspective. Ophthalmic Epidemiol 2008;15(6):418–25. PMID: 19065435 DOI: 10.1080/09286580802399102

14.13. Fenwick E, Rees G, Pesudovs K, Dirani M, Kawasaki R, Wong TY, et al. Social and emotional impact of diabetic retinopathy : a review. Clin Exp Ophthalmol. 2012;40(1): 27–38. PMID: 21575125 DOI: 10.1111/j.1442-9071.2011.02599.x

14.14. Kashim RM, Newton P, Ojo O. Diabetic Retinopathy Screening : A Systematic Review on Patients' Non-Attendance. Int J Environ Res Public Health. 2018;15(1):157 doi:10.3390/ijerph15010157.

14.15. Lawrenson John G, Graham-Rowe E, Lorencatto F, Presseau J, Burr J, Ivers N, et al. Interventions to increase attendance for diabetic retinopathy screening. Cochrane Database Syst Rev. 2018;1:CD012054. PMID: 29333660 DOI: 10.1002/14651858.CD012054.pub2.

14.16. Strutton R, Chemin A Du, Stratton IM, Forster AS. System-level and patient-level

explanations for non-attendance at diabetic retinopathy screening in Sutton and Merton (London, UK): a qualitative analysis of a service evaluation. BMJ Open 2016;6:e010952.doi:10.1136/bmjopen-2015-010952

14.17. Pallegedara A, Grimm M. Demand for private healthcare in a universal public healthcare system: Empirical evidence from Sri Lanka. Health Policy Plan. 2017;32(9):1267–84. PMID: 28981660 DOI: 10.1093/heapol/czx085

14.18. Scanlon PH. The English National Screening Programme for diabetic retinopathy 2003–2016. Acta Diabetol. 2017;54(6):515–25. DOI: https://doi.org/10.1007/s00592-017-0974-1

14.19. Taylor-Phillips S, Mistry H, Leslie R, Todkill D, Tsertsvadze A, Connock M, et al. Extending the diabetic retinopathy screening interval beyond 1 year: systematic review. Br J Ophthalmol 2016;100(1):105–14. http://dx.doi.org/10.1136/bjophthalmol-2014-305938

14.20. Hubley J, Gilbert C. Eye health promotion and the prevention of blindness in developing countries: critical issues. Br J Ophthalmol. 2006;90(3):279–84. PMID: 16488944. doi: 10.1136/bjo.2005.078451

14.21. Blows P, Peto T, Mbulawa K. Empowering patients with diabetic retinopathy. Community Eye Heal J. 2016;28(92):14–7.

14.22. WHO. World Health Organization (Foundation Document). Health Education: Theoritical concepts, effective strategies and core competencies [Internet]. Genewa, Swisterland; 2012. Available from: http://applications.emro.who.int/dsaf/EMRPUB_2012_EN_1362.pdf. Accessed on 15 Aug 2016.

14.23. Lu Y, Serpas L, Genter P, Anderson B, Campa D, Ipp E. Divergent Perceptions of Barriers to Diabetic Retinopathy Screening Among Patients and Care Providers, Los Angeles, California, 2014-2015. Prev Chronic Dis. 2016;13(160193). PMID: 27710765 DOI: 10.5888/pcd13.160193

14.24. Gitlin LN. Introducing a new intervention: An overview of research phases and common

challenges. Am J Occup Ther. 2013;67(2):177–84. PMID: 23433272. DOI: 10.5014/ajot.2013.006742

14.25. Al Sayah F, Majumdar SR, Williams B, Robertson S, Johnson JA. Health Literacy and Health Outcomes in Diabetes: A Systematic Review. J Gen Intern Med. 2013;28(3):444–52. PMID: 23065575. DOI: 10.1007/s11606-012-2241-z

14.26. Loevinsohn B. Health education interventions in developing countries: A methodological review of published articles. Int J Epidemiol. 1990;19(4):788–94. https://doi.org/10.1093/ije/19.4.788

14.27. Kaliaperumal K. IEC Strategies for Diabetic Retinopathy. Lions Aravind Institute of Community Ophthalmology. [Internet]. Available from: http://v2020eresource.org/content/files/IEC.pdf. Accessed on 16 Aug 2017.

14.28. Noordman J, van der Weijden T, van Dulmen S. Communication-related behavior change techniques used in face-to-face lifestyle interventions in primary care: A systematic review of the literature. Patient Educ Couns. 2012;89(2):227–44. PMID: 22878028 DOI:10.1016/j.pec.2012.07.006

14.29. Wijeyaratne C, Arambepola C, Karunapema P, Periyasamy K, Hemachandra N, Ponnamperuma G, et al. Capacity-building of the allied health workforce to prevent and control diabetes : lessons learnt from the National Initiative to Reinforce and Organize General Diabetes Care in Sri Lanka (NIROGI Lanka) project. WHO South East Asia J Public Health. 2016;5(1):34–9. PMID: 28604395 DOI:10.4103/2224-3151.206550

14.30. Lawrenson JG, Graham-Rowe E, Lorencatto F, Presseau J, Burr J, Ivers N, et al. Interventions to increase attendance for diabetic retinopathy screening. Cochrane Database Syst Rev. 2018 Jan 15;1:CD012054. doi:10.1002/14651858.CD012054.pub2.

14.31. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions : an overview of reviews and development of a theoretical framework. BMC Health Serv Res. 2017;1–13.

https://doi.org/10.1186/s12913-017-2031-8

14.32. Ayala GX, Elder JP. Qualitative methods to ensure acceptability of behavioral and social interventions to the target population. J Public Health Dent. 2011;71(1):S69-79. PMID:21656958

14.33. Williams AM, Muir KW, Rosdahl JA. Readability of patient education materials in ophthalmology : a single-institution study and systematic review. BMC Ophthalmology; 2016;16:133. PMID:27487960 DOI:10.1186/s12886-016-0315-0.

14.34. Sustersic M, Gauchet A, Foote A, Bosson J. How best to use and evaluate Patient Information Leaflets given during a consultation : a systematic review of literature reviews. Health Expect. 2017;20(4):531-542. PMID: 27669682 DOI: 10.1111/hex.12487

14.35. Farrel-Miller P, Gentry P. How Effective Are Your Patient Education Materials? Guidelines for Developing and Evaluating Written Educational Materials. Diabetec Educ. 1989;15(5):418–22 PMID: 2776637 DOI: 10.1177/0145721789015005.

14.36. Latif S, Ahmed I, Shafiul M, Syed I. Exploring the potential impact of health promotion videos as a low cost intervention to reduce health inequalities : a pilot before and after study on Bangladeshis in inner-city London. London J Prim Care (Abingdon). 2016;8(4):66-71. PMID: 28250836. doi:10.1080/17571472.2016.1208382.

14.37. Denny MC, Vahidy F, Vu KYT, Sharrief AZ, Savitz SI. Video-based educational intervention associated with improved stroke literacy , self- efficacy , and patient satisfaction. PLoS One. 2017;12(3):e0171952. PMID: 28333925. DOI:10.1371/journal.pone.0171952

14.38. Abu M, Himmel W, Vormfelde S, Koschack J. Video-assisted patient education to modify behavior : A systematic review. Patient Educ Couns. 2014;97(1):16–22. PMID: 25043785 DOI:10.1016/j.pec.2014.06.015.

14.39. Gericke C, Kurowski C, Ranson M, Mills A. Intervention complexity - A conceptual framewok to inform priority-setting in health. Bull World Health Organ. 2005;84(4):285-93

PMID: 15868020 DOI: /S0042-9686200500040000.

14.40. Bauer MS, Damschroder L, Hagedorn H, Smith J, Kilbourne AM. An introduction to implementation science for the non-specialist. BMC Psychol. 2015;3:32. PMID: 26376626 DOI: 10.1186/s40359-015-0089-9

14.41. Gilson L, Lehmann U, Schneider H. Practicing governance towards equity in health systems : LMIC perspectives and experience. Int J Equity Health. 2017;1–5. https://doi.org/10.1186/s12939-017-0665-0

14.42. World Health Organization. Advocacy Strategies for Health and Development : Development Communication in Action - A Background Paper to the Inter- Agency Meeting on Advocacy Strategies for Health and Development : Development Communication in Action. 1992 Geveva. Available from http://apps.who.int/iris/bitstream/handle/10665/70051/HED_92.4_eng.pdf?sequence=1. Accessed on 16 Aug 2016.

14.43. Yamey G. What are the barriers to scaling up health interventions in low and middle income countries ? A qualitative study of academic leaders in implementation science. Global Health. 2012;8(1):11. PMID: 22643120 DOI: 10.1186/1744-8603-8-11

14.44. Durlak JA, DuPre EP. Implementation Matters : A Review of Research on the Influence of Implementation on Program Outcomes and the Factors Affecting Implementation. Am J Community Psychol. 2008;41(3-4):327–50. PMID: 18322790 DOI: 10.1007/s10464-008-9165-0

14.45. Kannuri NK, Anchala R, Murthy GVS, Gilbert CE. Strengthening diabetes retinopathy services in India : Qualitative insights into providers' perspectives : The India 11-city 9-state study. Indian J Endocr Metab. 2016;20(7):59–66. DOI: 10.4103/2230-8210.179775

14.46. Brooks A, Smith TA, Savigny D De, Lengeler C. Implementing new health interventions in developing countries : why do we lose a decade or more ? BMC Public Health.

2012;12(1):683. https://doi.org/10.1186/1471-2458-12-683.

14.47. Ridde V. Need for more and better implementation science in global health. BMJ Global Health 2016;1:e000115. doi:10.1136/bmjgh-2016-000115 2016;1–3.

14.48. Dissanayake DMSB, Niroshan WWAE, Nisansala MH, Rangani MLD. Cultural comparison in Asian countries : An Application of Greet Hofstede's Cultural Dimensions. Available from http://repository.kln.ac.lk/handle/123456789/13596. Accessed 15 Aug 2018.

14.49. Pantoja T, Opiyo N, Lewin S, Paulsen E, Ciapponi A, Cs W, et al. Implementation strategies for health systems in low-income countries : an overview of systematic reviews. Cochrane Database Syst Rev. 2017;(9):CD011086. PMID: 28895659. DOI:10.1002/14651858.CD011086.pub2

14.50. Bolster NM, Giardini ME, Bastawrous A. The Diabetic Retinopathy Screening Workflow : Potential for Smartphone Imaging. J Diabetes Sci Technol. 2015;1(2):318-24. PMID: 26596630 DOI: 10.1177/1932296815617969

14.51. Peters DH, Tran NT, Adam T. Implementation Research In Health. Alliance for Health Policy and Systems Research. World Health Organization. [Internet] Available from http://apps.who.int/iris/bitstream/handle/10665/91758/9789241506212_eng.pdf?sequence=1. Accessed on 15 Sept 2018.

14.52. Asante A, Price J, Hayen A, Jan S, Wiseman V. Equity in Health Care Financing in Low- and Middle-Income Countries : A Systematic Review of Evidence from Studies Using Benefit and Financing Incidence Analyses. PLoS One. 2016;11(4):1–20 e0152866. https://doi.org/10.1371/journal.pone.0152866

14.53. Peters DH, Paina L, Schleimann F. Sector-wide approaches (SWAps) in health : what have we learned ? Health Policy Plan. 2013;28(8):884–90. PMID: 23236010 DOI: 10.1093/heapol/czs128

14.54. Peters D, Chao S. The sector-wide approach in health:what is it? where is it leading. Int J Heal

Plann Manag. 1998;13(2):177–90. PMID: 10185508 DOI: 10.1002/(SICI)1099-1751(199804/06)13:2<177::AID-HPM504>3.0.CO;2-T

14.55. Hutton G, Tanner M. Bulletin of the World Health Organization Capacity-building for public health :The sector-wide approach: a blessing for public health? [Internet]. 2018. Available from: http://www.who.int/bulletin/volumes/82/12/editorial21204html/en/. Accesssed on 10 Oct 2018.

14.56. Poore S, Foster A, Zondervan M, Blanchet K. Planning and developing services for diabetic retinopathy in Sub-Saharan Africa. Int J Heal policy Manag. 2015;4(1):19–28. DOI: 10.15171/IJHPM.2015.04.

14.57. Bennett S, Peters DH, Bennett S, Peters DH. Assessing National Health Systems : Why and How Assessing National Health Systems : Why and How. Journal of Health systems and Reforms. 2015;1(1):9-17. https://doi.org/10.1080/23288604.2014.997107

14.58. Blanchet K, Gilbert C, Savigny D De. Rethinking eye health systems to achieve universal coverage : the role of research. Br J Ophthal. 2014;98(10):1-4 doi:10.1136/bjophthalmol-2013–303905. PMID: 24990874

14.59. Fernando D. Health care systems in transition: Sri Lanka, An overview of Sri Lanka's health care system. J Public Health Med. 2000;22(1):14–20. PMID: 10774898

14.60. Orsmond GI, Cohn ES. The distinctive features of a feasibility study: Objectives and guiding questions. OTJR Occup Particip Heal. 2015;35(3):169–77. PMID: 26594739 DOI: 10.1177/1539449215578649

14.61. Global Initiative for the Elimination of voidable Blindness. World Health Organization-Global Initiative for the Elimination of Avoidable Blindness. [Internet] Available from: http://apps.who.int/iris/bitstream/handle/10665/63748/WHO_PBL_97.61_Rev.2.pdf?sequence=1&isAllowed=y. Accessed on 15 Sept 2018.

14.62. Murthy GVS, Gupta SK, John N, Vashist P. Current status of cataract blindness and Vision

2020 : The right to sight initiative in India. Indian J Ophthalmol. 2008;55(6):489-494. PMID: 18974520

14.63. Scanlon P, Aldington S, Leal J, Luengo-Fernandez R, Oke J, Sivaprasad SS, et al. Development of a cost-effectiveness model for optimisation of the screening intervals in diabetic retinopathy screening. Heal Technol Assess. 2015;19(74):1–116. PMID: 26384314. DOI: 10.3310/hta19740

14.64. Pasquel FJ, Hendrick AM, Ryan M, Cason E, Ali MK, Narayan KMV. Cost-effectiveness of Different Diabetic Retinopathy Screening Modalities. J Diabetes Sci Technol. 2016;10(2):301-307. PMID: 26719134 doi: 10.1177/1932296815624109

14.65. Cancedda C, Farmer PE, Kerry V, Nuthulaganti T. Maximizing the Impact of Training Initiatives for Health Professionals in Low-Income Countries : Frameworks, Challenges, and Best Practices. PLoS Med. 2015;12(6):e1001840. PMID: 26079377. doi:10.1371/journal.pmed.1001840

14.66. Kabene SM, Orchard C, Howard JM, Soriano MA, Leduc R. The importance of human resources management in health care: A global context. Hum Resour Health. 2006;4:20. PMID: 16872531 DOI:10.1186/1478-4491-4-20

14.67. Resnikoff S, Felch W, Gauthier T, Spivey B. The number of ophthalmologists in practice and training worldwide : a growing gap despite more than 200 000 practitioners. Br J Ophthalmol. 2010;96(6):783–7. http://dx.doi.org/10.1136/bjophthalmol-2011-301378

14.68. Joshi R, Alim M, Kengne AP, Jan S, Maulik PK, Peiris D, et al. Task shifting for non-communicable disease management in low and middle income countries - A systematic review. PLoS One. 2014;9(8):e103754. https://doi.org/10.1371/journal.pone.0103754.

14.69. Seidman G, Atun R. Does task shifting yield cost savings and improve efficiency for health systems ? A systematic review of evidence from low-income and middle-income countries. Hum Resour Health. 2017;15(1):29. PMID: 28407810. DOI: 10.1186/s12960-017-0200-9

14.70. Fulton BD, Scheffler RM, Sparkes SP, Auh EY, Vujicic M, Soucat A. Health workforce skill mix and task shifting in low income countries : a review of recent evidence. BMC Hum Resour Health. 2011;9(1):1 https://doi.org/10.1186/1478-4491-9-1

14.71. Silva D De. How many doctors should we train for Sri Lanka ? System dynamics modelling of training needs. Ceylon Med J. 2017;62(4):233–7 https://doi.org/10.4038/cmj.v62i4.8573

14.72. Buchan J, Poz MRD . Skill mix in the health care work force: reviewing the evidence. Bull World Heal Organ. 2002;80(7):575–80. PMID: 12163922

14.73. Rowe AK, Savigny D De, Lanata CF, Victora CG. How can we achieve and maintain high-quality performance of health workers in low-resource settings ? Lancet. 2005; 366(9490):1026-35. PMID: 16168785 DOI:10.1016/S0140-6736(05)67028-6

14.74. Scanlon PH. Screening Intervals for Diabetic Retinopathy and Implications for Care. Curr Diab Rep. Current Diabetes Reports; 2017;17(96):1–8. PMID: 28875458 DOI:10.1007/s11892-017-0928-6

14.75. Gruppen LD, Mangrulkar RS, Kolars JC. The promise of competency-based education in the health professions for improving global health. Hum Resour Health. 2012;10:43. PMID: 23157696 DOI:10.1186/1478-4491-10-43

14.76. Taylor DJ, Goatman KA, Gregory A, Histed M, Martin CN, Warburton TJ, et al. Image-quality standardization for diabetic retinopathy screening. Expert Rev Ophthalmol. 2009;4(5):469–76.

14.77. Davila JR, Sengupta SS, Niziol LM, Sindal MD, Besirli CG, Upadhyaya S, et al. Predictors of photographic quality with a handheld nonmydriatic fundus cameraused for screening of vision-threatening diabetic retinopathy. Ophthalmologica. 2017;238(1–2):89–99. PMID: 28675903. DOI: 10.1159/000475773

14.78. Gupta V, Bansal R, Gupta A, Bhansali A. Sensitivity and specificity of nonmydriatic digital imaging in screening diabetic retinopathy in Indian eyes. Indian J Ophthalmol. 2014;62:851-6.

14.79. Scanlon PH, Foy C, Malhotra R, Aldington SJ. The Influence of Age , Duration of Diabetes , Cataract, and Pupil Size on. Diabetes Care. 2005;28(10):228-53. PMID: 16186278

14.80. Lamirel C, Bruce BB, Wright DW, Delaney KP, Newman NJ, blousse V. Quality of Nonmydriatic Digital Fundus Photography Obtained by Nurse Practitioners in the Emergency Department : The FOTO-ED Study. Ophthalmology. 2012;119(3):617–24. PMID: 22218140. DOI:10.1016/j.ophtha.2011.09.013.

14.81. Lin J, Weng Q, Xue L, Cao X. A retinal image sharpness metric based on histogram of edge width. Journal of Algorithms & Computational Technology. 2017;11(3):292–300. DOI: 10.1177/1748301817713184

14.82. Rani PK, Bhattarai Y, Sheeladevi S, Shivavaishnavi K. Ali MH, Babu JG. Analysis of yield of retinal imaging in a rural diabetes eye care model. Indian J Ophthalmol.2018; 66(2):233-237. PMID: 29380765. DOI: 10.4103/ijo.IJO_500_17

14.83. NHS Diabetic Eye Screening Programme Grading definitions for referable disease About Public Health England. Public Heal England [Internet]. 2017;(2016527). Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/582710/Grading_definitions_for_referrable_disease_2017_new_110117.pdf Accessed on 15 Sept 2018.

14.84. Liu SL, Mahon LW, Klar NS, Schulz DC, Gonder JR, Hramiak IM, et al. A randomised trial of non-mydriatic ultra-wide field retinal imaging versus usual care to screen for diabetic eye disease : rationale and protocol for the Clearsight trial. BMJ Open. 2017;7(8):e015382. PMID: 28775182. DOI:10.1136/bmjopen-2016-015382

14.85. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Int J Nurs

Stud. 2013;50(5):587-92. PMID: 23159157 DOI:10.1016/j.ijnurstu.2012.09.010

14.86. Leeflang M, Rutjes A, Reitsma J, Hooft L, Bossuyt P. Validation of a test's sensitivity and specificity with disease prevalence. Can Med Assoc J. 2013;185(11):537–544 DOI:10.1503 /cmaj.121286.

14.87. Stephanie A, Miller W. Spectrum Bias or Spectrum Effect ? Subgroup Variation in Diagnostic Test Evaluation. Ann Intern Med. 2002;137:598–603. PMID:12353947

BIBLIOGRAPHY

1. Abdull MM, Chandler C, Gilbert C. Glaucoma, " the silent thief of sight " : patients' perspectives and health seeking behaviour in Bauchi, Northern Nigeria. BMC Ophthalmol 2016;16(44):1-9 PMID:27102524 DOI:10.1186/s12886-016-0220-6

2. Abdulsalam S, Ibrahim A, Saidu H, Muazu M, Aliyu U, Umar H. Knowledge, Attitude, and Practice of Diabetic Retinopathy among Physicians in Northwestern Nigeria. Niger J Clin Pr. 2018;21:478–83.

3. Abu M, Himmel W, Vormfelde S, Koschack J. Video-assisted patient education to modify behavior : A systematic review. Patient Educ Couns. 2014;97(1):16–22. PMID:25043785 DOI:10.1016/j.pec.2014.06.015.

4. Adriono G, Wang D, Octavianus C, Congdon N. Use of eye care services among diabetic patients in urban Indonesia. Arch Ophthalmol. 2011;129(7):930–5. PMID:21746983. DOI:10.1001/archophthalmol.2011.147.

5. Agarwal S, Mahajan S, Kumari Rani P, Raman R, Paul PG, Kumaramanickavel G, et al. How High is the Non-Response Rate of Patients Referred for Eye Examination from Diabetic Screening Camps? Ophthalmic Epidemiol. 2005;12(6):393–4. PMID:16283991 DOI:10.1080/09286580500278418. .

6. Agency for Health Care Research and Quality. Patient Education Materials Assessment Tool for Printable Materials (PEMAT-P). How To Use the PEMAT To Assess a Material. [Internet] 2013. Available from: http://www.ahrq.gov/sites/default/files/publications/files/pemat_guide.pdf. Accessed on 01 Dec 2016.

7. Ahmed J, Ward TP, Bursell SE, Aiello LM, Cavallerano JD, Vigersky RA. The sensitivity and specificity of nonmydriatic digital stereoscopic retinal imaging in detecting diabetic

retinopathy. Diabetes Care. 2006;29(10):2205–9. DOI:10.2337/dc06-0295

8. Aikens J, Bingham R, Piette JD. Patient-provider communication and self-care behavior among type 2 diabetes patients. Diabetes Educ. 2005;31(5):681–90. PMID:16203852 DOI:10.1177/0145721705280829.

9. Al-Sabti K, Raizada S, Wani VB, Al Ajmi M, Gayed I, Sugathan TN. Efficacy and reliability of fundus digital camera as a screening tool for diabetic retinopathy in Kuwait. J Diabet Complications. 2003;17(4):229–33. PMID:12810247

10. Al-Sayah F, Majumdar SR, Williams B, Robertson S, Johnson JA. Health Literacy and Health Outcomes in Diabetes: A Systematic Review. J Gen Intern Med. 2013;28(3):444–52. PMID: 23065575. DOI:10.1007/s11606-012-2241-z

11. Amarasekara AATD, Fongkaew W, Turale S, Wimalasekara SW, Chanprasit C. An ethnographic study of diabetes health beliefs and practices in Sri Lankan adults. Int Nurs Rev. 2014;61(4):507–514. doi:10.1111/inr.12136. PMID:25363651.

12. Andermann A, Blancquaert I. Bulletin of the World Health Organization Revisiting Wilson and Jungner in the genomic age : a review of screening criteria over the past 40 years. Bull World Heal Organ. 2008;86(4):317-9. PMID:18438522.

13. Andersen RM, McCutcheon A, Aday LA, Chiu GY, Bell R. Exploring dimensions of access to medical care. Health Serv Res. 1983;18(1):49–74. PMCID: PMC1068709

14. Anderson S, Broadbent DM, Swain JYS, Vora JP, Harding SP. Ambulatory photographic screening for diabetic retinopathy in nursing homes. Eye (Lond). 2003;17(6):711–6. PMID: 12928682. DOI:10.1038/sj.eye.6700487.

15. Aptel F, Denis P, Rouberol F, Thivolet C. Screening of diabetic retinopathy: Effect of field number and mydriasis on sensitivity and specificity of digital fundus photography. Diabetes Metab. 2008;34(3):290–3. PMID:18406188 DOI:10.1016/j.diabet.2007.12.007

16. Arora S, Kurji AK, Tennant MTS. Dismantling sociocultural barriers to eye care with tele-ophthalmology: Lessons from an Alberta Cree community. Clin Investig Med. 2013;36(2):57–63. PMID:23544606

17. Asante A, Price J, Hayen A, Jan S, Wiseman V. Equity in Health Care Financing in Low- and Middle-Income Countries : A Systematic Review of Evidence from Studies Using Benefit and Financing Incidence Analyses. PLoS One. 2016;11(4):1–20 e0152866. https://doi.org/10.1371/journal.pone.0152866

18. Atun R, Bennett S, Duran A. When do vertical (stand-alone) programmes have a place in health systems ? Health Systema and Policy Analysis - WHO Regional Office for Europe. [Internet]. 2008. Available from: https://www.who.int/management/district/services/WhenDoVerticalProgrammesPlaceHealthSystems.pdf. Accessed on 19 Aug 2016.

19. Ayala GX, Elder JP. Qualitative methods to ensure acceptability of behavioral and social interventions to the target population. J Public Health Dent. 2011;71(1):S69-79. PMID: 21656958

20. Baeza M, Orozco-Beltrán D, Gil-Guillen VF, Pedrera V, Ribera MC, Pertusa S, et al. Screening for sight threatening diabetic retinopathy using non-mydriatic retinal camera in a primary care setting: To dilate or not to dilate? Int J Clin Pract. 2009;63(3):433–8. PMID: 19222628 DOI:10.1111/j.1742-1241.2008.01921.x

21. Balasuriya BMA, Sumanatilleke MR, Jayasekera TI, Wijesuriya MA SN. Prevalence of micro and macro vascular complications of diabetes detected at single visit screening. Sri Lanka J Diabetes Endocrinol Metab. 2012;2:17–20. DOI: http://dx.doi.org/10.4038/sjdem.v2i1.4328

22. Bamashmus MA, Gunaid AA. Regular Visits to a Diabetes Clinic Were Associated with Lower Magnitude of Visual Disability and Diabetic Retinopathy- A Hospital-Based Historical Cohort Study in Yemen. Diabetes Technol Ther. 2009 Jan;11(1):45-50. PMID:19132855.

DOI:10.1089/dia.2007.0299

23. Banaee T, Ansari-Astaneh MR, Pourreza H, Faal-Hosseini F, Vatanparast M, Shoeibi N, et al. Utility of 1% Tropicamide in Improving the Quality of Images for Tele-Screening of Diabetic Retinopathy in Patients with Dark Irides. Ophthalmic Epidemiol. 2017;24(4):217–21. https://doi.org/10.1080/09286586.2016.1274039.

24. Bandura A. Health promotion from the perspective of social cognitive theory. Psychol Heal. 1998;13(4):623–49. https://doi.org/10.1080/08870449808407422

25. Bandura A. Social cognitive theory: an agentic perspective. Annu Rev psychol. 2001;52:1-26. DOI:10.1146/annurev.psych.52.1.1 PMID:11148297

26. Bandura A. Toward a unifying theory of behavioural change [Internet]. Vol. 84, Psychological Review. 1977. p. 191–215. Available from: http://www.apa.org/pubs/journals/rev/. Accessed on 15 Jan 2017.

27. Bartholomew L, Parcel G, Seilheimer D, Czyzewski D, Spinelli S, Congdon B. Development of a Heallth Education Program to Promote the Self Management of Cystic Fibrosis. Heal Educ Q. 1991;18(4):429–43. PMID:1757266

28. Bauer MS, Damschroder L, Hagedorn H, Smith J, Kilbourne AM. An introduction to implementation science for the non-specialist. BMC Psychol. 2015;3:32. PMID:26376626 DOI:10.1186/s40359-015-0089-9

29. Baumeister SE, Schomerus G, Andersen RM, Tost F, Markus MRP. Trends of barriers to eye care among adults with diagnosed diabetes in Germany ,1997-2012. Nutr Metab Cardiovasc Dis. 2015;25(10):906–15. doi.org/10.1016/j.numecd.2015.07.003

30. Baxter S, Johnson M, Chambers D, Sutton A, Goyder E, Booth A. The effects of integrated care: A systematic review of UK and international evidence. BMC Health Serv Res. 2018;18(1):350. PMID:29747651 DOI:10.1186/s12913-018-3161-3

31. Beagley J, Guariguata L, Weil C, Motala AA. Global estimates of undiagnosed diabetes in adults. Diabetes Res Clin Pract. 2014;103(2):150–60. PMID:24300018 DOI:10.1016/j.diabres.2013.11.001

32. Bennett G, Tuthill A. Investigating the Barriers to the Uptake of Diabetic Retina Screen. Ir Med J. 2017;110(9):628–29 PMID:29372943.

33. Bennett S, Peters DH, Bennett S, Peters DH. Assessing National Health Systems : Why and How? Journal of Health systems and Reforms. 2015;1(1):9-17. https://doi.org/10.1080/23288604.2014.997107

34. Betancourt J, Green AR, Carrillo JE. Cultural Competence in Health Care: Emerging Frameworks and Practical Approaches. Feild Report Weil Med Coll Cornell Univeristy 2002;(576):1–24. [Internet]. Available from: http://www.etn.leeds.ac.uk/document/resources/betancourtcultural%20competence.pdf. Accessed 15 April 2016.

35. Bhargava M, Cheung CYL, Sabanayagam C, Kawasaki R, Harper CA, Lamoureux EL, et al. Accuracy of diabetic retinopathy screening by trained non-physician graders using non-mydriatic fundus camera. Singapore Med J. 2012;53(11):715–9. PMID:23192497

36. Blanchet K, Gilbert C, Lindfield R, Crook S. Eye Health Systems Assessment (EHSA): How To Connect Eye Care With The General Health. IAPB Tech Rep [Internet]. 2012;(April). Available from: http://iceh.lshtm.ac.uk/eye-health-systems-assessment/. Accessed on 19 Aug 2016.

37. Blanchet K, Gilbert C, Savigny D. Rethinking eye health systems to achieve universal coverage : the role of research. Br J Ophthal. 2014;98(10):1325-8. doi:10.1136/bjophthalmol-2013–303905. PMID:24990874

38. Blows P, Peto T, Mbulawa K. Empowering patients with diabetic retinopathy. Community Eye Heal J. 2016;28(92):14–7.

39. Bolster NM, Giardini ME, Bastawrous A. The Diabetic Retinopathy Screening Workflow : Potential for Smartphone Imaging. J Diabetes Sci Technol. 2015;10(2):318-24. DOI:10.1177/1932296815617969. PMID:26596630.

40. Boucher MC, Gresset JA, Angioi K, Olivier S. Effectiveness and safety of screening for diabetic retinopathy with two nonmydriatic digital images compared with the seven standard stereoscopic photographic fields. Can J Ophthalmol. 2003;38(7):557–68. PMID:14740797

41. Bourne RRA, Jonas JB, Bron AM, Cicinelli MV, Das A, Flaxman SR, et al. Vision Loss Expert Group of the Global Burden of Disease Study. Prevalence and causes of vision loss in high-income countries and in Eastern and Central Europe in 2015: magnitude, temporal trends and projections. Br J Ophthalmol. 2018 May;102(5):575-585. PMID:29545417 DOI:10.1136/bjophthalmol-2017-311258

42. Bowen DJ, Kreuter M, Spring B, Linnan L, Weiner D, Bakken S, et al. How we design feasibility studies. Am J Prev Med. 2010;36(5):452–7. PMID:19362699. doi:10.1016/j.amepre.2009.02.002

43. Bragge P, Gruen RL, Chau M, Forbes A, Taylor HR. Screening for Presence or Absence of Diabetic Retinopathy: a meta-analysis. Arch Ophthalmol. 2011;129(4):435–44. PMID: 21149748 DOI:10.1001/archophthalmol.2010.319

44. Brechner RJ, Cowie CC, Howie LJ, Herman WH, Will JC, Harris MI. Ophthalmic examination among adults with diagnosed diabetes mellitus. JAMA. 1993;270(14):1714–8. PMID:8411502

45. Brofenbrenner U. The Ecology of Human Development - Experiments by Nature and Design USA: Harvard University Press; 1979. 1-10 p. [Internet]. Available from: https://khoerulanwarbk.files.wordpress.com/2015/08/urie_bronfenbrenner_the_ecology_of_human_developbokos-z1.pdf. Accessed on 18 July 2016.

46. Brooks A, Smith TA, Savigny D De, Lengeler C. Implementing new health interventions in

developing countries : why do we lose a decade or more ?. BMC Public Health; 2012;12(1):683. https://doi.org/10.1186/1471-2458-12-683.

47. Buchan J, Poz MRD. Skill mix in the health care work force: reviewing the evidence. Bull World Heal Organ. 2002;80(7):575–80. PMID:12163922

48. Burgess PI, Msukwa G, Beare NAV. Diabetic retinopathy in sub-Saharan Africa: meeting the challenges of an emerging epidemic. BMC Medicine. 2013;11(1):157. PMID:23819888 DOI:10.1186/1741-7015-11-157.

49. Cancedda C, Farmer PE, Kerry V, Nuthulaganti T. Maximizing the Impact of Training Initiatives for Health Professionals in Low-Income Countries : Frameworks, Challenges, and Best Practices. PLoS Med. 2015;12(6):e1001840. PMID:26079377. doi:10.1371/journal.pmed.1001840

50. Carmichael TR, Carp GI, Welsh ND, Kalk WJ. Effective and accurate screening for diabetic retinopathy using a 60 degree mydriatic fundus camera. South African Med J. 2005;95(1):57–61. PMID:15762251

51. Cavan D, Makaroff L, Rocha J, Sylvanowicz M, Ackland P. The Diabetic Retinopathy Barometer Study: Global perspectives on access to and experiences of diabetic retinopathy screening and treatment. Diabetes Res Clin Pract. 2018;129:16–24. PMID:28499163 DOI:10.1016/j.diabres.2017.03.023

52. Census of Population and Housing 2012. Department of Census and Statistics of Sri Lanka [Internet]. 2012. Available from: http://www.statistics.gov.lk/PopHouSat/CPH2012Visualization/htdocs/index.php?usecase=indicator&action=Data&indId=. Accessed on 19 Aug 2014.

53. Centre for Diseases Control USA. The Social Ecological Model: A Framework for Violence Prevention. Division of Violence Prevention. 2015. [Internet] Available from https://www.cdc.gov/violenceprevention/pdf/sem_framewrk-a.pdf. Accessed on 15 May 2016

54. Cetin EN, Zencir M, Fenkçi S, Akin F, Yildirim C. Assessment of awareness of diabetic retinopathy and utilization of eye care services among Turkish diabetic patients. Prim Care Diabetes. 2013;7(4):297–302. PMID:23639610 DOI: 10.1016/j.pcd.2013.04.002.

55. Chakrabarthi R, Harper CA, Keeffe JE. Diabetic Retinopathy Management Guidelines. Expert Rev Ophthalmol. 2012;7(5):417–39. https://doi.org/10.1586/eop.12.52

56. Cheema A, Adeloye D, Sidhu S, Sridhar D, Chan KY. Urbanization and prevalence of type 2 diabetes in Southern Asia: A systematic analysis. J Glob Health.2014;4(1):010404. doi:10.7189/jogh.04.010404. PMID:24976963

57. Chew EY, Klein ML,Ferris III LF, Remaley NA, Murphy RP, Chantry K, et al. Association of Elevated Serum Lipid Levels with Retinal Hard Exudate in Diabetic Retinopathy: Early Treatment Diabetic Retinopathy Study (ETDRS) Report 22. Arch Ophthalmol. 1996;114(9):1079–84. PMID:8790092

58. Chou CF, Sherrod CE, Zhang X, Barker LE, Bullard KM, Crews JE, et al. Barriers to eye care among people aged 40 years and older with diagnosed diabetes, 2006-2010. Diabetes Care. 2014;37(1):180–8. PMID:24009300 doi:10.2337/dc13-1507

59. Crabb DP, Smith ND, Glen FC, Burton R, Garway-Heath DF. How does glaucoma look?: Patient perception of visual field loss. Ophthalmology. 2013;120(6):1120–6. doi.org/10.1016/j.ophtha.2012.11.043

60. Craig P, Dieppe P, Macintyre S, Health P, Unit S, Michie S. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:a1655 doi:10.1136/bmj.a1655

61. Creuzot-garcher C, Martin-phipps T, Beynat J. Effectiveness of a Mobile Diabetic Retinopathy Screening Campaign to Encourage Diabetics to Undergo Regular Ophthalmic Follow-Up. Ophthalmic Res. 2014;52(4):206-11. PMID:25402747 DOI:10.1159/000363326

62. Criel B, De Brouwere V, Dugas S. Integration of vertical programmes in multi-function health services. Studies in Health Services Organisation & Policy. 1997;3:36-40. [Internet] Available from: https://www.researchgate.net/publication/42779702_Integration_of_Vertical_Programmes_in_Multi-Function_Health_Services. Accessed on 19 Aug 2017.

63. Critical Appraisal Skills Program-CASP Check Lists [Internet]. CASP UK. 2017. Available from: http://www.casp-uk.net/casp-tools-checklists. Accessed on 01 Aug 2017.

64. da Rocha Fernandes J, Ogurtsova K, Linnenkamp U, Guariguata L, Seuring T, Zhang P, et al. IDF Diabetes atlas estimates of 2014 global health expenditures on diabetes. Diabetes Res Clin Pract. 2016;117:48–54. PMID:27329022. DOI:10.1016/j.diabres.2016.04.016

65. Dandona R, Dandona L, John RK, Mccarty CA, Rao GN. Awareness of eye diseases in an urban population in southern India. Bull World Health Organ. 2001;79(2):96-102. PMID: 11242828.

66. Davila JR, Sengupta SS, Niziol LM, Sindal MD, Besirli CG, Upadhyaya S, et al. Predictors of photographic quality with a handheld nonmydriatic fundus cameraused for screening of vision-threatening diabetic retinopathy. Ophthalmologica. 2017;238(1–2):89–99. PMID:28675903. DOI: 10.1159/000475773

67. Davis K, Schoen C, Guterman S, Shih T, Schoenbaum SC. Weinbaum I. Slowing The Growth of US Health Care Expenditures : What Are The Options? The Commonwealth Fund January 2007 [Internet]. Available from: http://people.stern.nyu.edu/wgreene/Statistics/Sicko/CommonwealthFundReport.pdf. Accessed on 15 Jan 2017.

68. De Silva AP, De Silva SHP, Haniffa R, Liyanage IK, Jayasinghe S, Katulanda P, et al. Inequalities in the prevalence of diabetes mellitus and its risk factors in Sri Lanka: A lower middle income country. Int J Equity Health. 2018;17(1):45. PMID:29665834. DOI:

10.1186/s12939-018-0759-3

69. De Silva AP, Hennadige S, De Silva P, Liyanage IK, Rajapakse LC, Saroj K, et al. Social, cultural and economical determinants of diabetes mellitus in Kalutara district, Sri Lanka: a cross sectional descriptive study. Int J Equity Health. 2012;11(1):76. https://doi.org/10.1186/1475-9276-11-76

70. Deb-Joardar N, Germain N, Thuret G, Manoli P, Garcin AF, Millot L, et al. Screening for diabetic retinopathy by ophthalmologists and endocrinologists with pupillary dilation and a nonmydriatic digital camera. Am J Ophthalmol. 2005;140(5):814-821. PMID:16310458 DOI: 10.1016/j.ajo.2005.05.051

71. Deer L, Owsley C, Campbell L, Gao L, Wood A, Girkin C. Feasibility, Patient Accepatability, and Preliminary Efficacy of a Culturally Informed, Health Promotion Program to Improve Glaucoma Medication Adherence Among African Americans-"Glaucoma Management Optimsm for African Americans Living with Glaucoma" GOAL. Curr Eye Res. 2016;41(1):50–58 PMID: 25625187. doi:10.3109/02713683.2014.1002045.

72. Denny MC, Vahidy F, Vu KYT, Sharrief AZ, Savitz SI. Video-based educational intervention associated with improved stroke literacy, self-efficacy, and patient satisfaction. PLoS One 2017;12(3):e0171952. PMID:28333925. DOI: 10.1371/journal.pone.0171952

73. Dervan E, Lillis D, Flynn L, Staines A, O'Shea D. Factors that influence the patient uptake of diabetic retinopathy screening. Ir J Med Sci. 2008;177:303–8. PMID: 18641918 DOI: 10.1007/s11845-008-0192-5

74. Ding J, Zou Y, Liu N, Jiang L, Ren X, Jia W, et al. Strategies of digital fundus photography for screening diabetic retinopathy in a diabetic population in urban China. Ophthalmic Epidemiol. 2012;19(6):414–9. PMID:23171212 DOI: 10.3109/09286586.2012.716895

75. Dissanayake DMSB, Niroshan WWAE, Nisansala MH, Rangani MLD. Cultural comparison in Asian countries : An Application of Greet Hofstede's Cultural Dimensions. [Internet].

Available from http://repository.kln.ac.lk/handle/123456789/13596. Accessed 15 Aug 2018.

76. Donabedian A. Aspects of medical care administration: specifying requirements for health care. Cambridge MA, Harvard University Press. 1973. p 343-356

77. Donnell OO. Access to health care in developing countries : breaking down demand side barriers. Cad Saude Publica. 2007;23(12):2820–34. doi.org/10.1590/S0102-311X2007001200003.

78. Drainoni M, Lee-hood E, Tobias C, Andrew J, Systems NH. Cross-Disability Experiences of Barriers to Health-Care Access Consumer Perspectives. Journal of Disability Policy Studies. 2006;17(2)101–15. https://doi.org/10.1177/10442073060170020101

79. Dudley L, Garner P. Strategies for integrating primary health services in low and middle income countries at the point of delivery. Cochrane database Syst Rev [Internet]. 2011;(7):CD003318. PMID:21735392 DOI: 10.1002/14651858.CD003318.pub3

80. Durlak JA, DuPre EP. Implementation Matters : A Review of Research on the Influence of Implementation on Program Outcomes and the Factors Affecting Implementation. Am J Community Psychol. 2008;41(3-4):327–50. PMID:18322790 DOI: 10.1007/s10464-008-9165-0

81. Early Treatment Diabetic Retinopathy Study Group. Early Photocoagulation for Diabetic Retinopathy. ETDRS Report No 9. Ophthalmology. 1991;98(5):766–785 PMID: 2062512.

82. Early Treatment Diabetic Retinopathy Study Group. Grading diabetic retinopathy from stereoscopic colour fundus photographs - An extension of the modified Airlie House classification: ETDRS report number 10. Ophthalmology. 1991;98 (5):786-806. PMID: 2062513

83. Early Treatment Diabetic Retinopathy Study Group. Photocoagulation for Diabetic Macular Edema. ETDRS Report No 1. Arh Ophthalmol. 1985;103(12):1796–1806.

doi:10.1001/archopht.1985.0105012003001. PMID:2866759

84. Economic and social statistics of Sri Lanka 2013. central Bank of Sri Lanka [Internet]. Available from: http://www.cbsl.gov.lk/pics_n_docs/10_pub/_docs/statistics/other/econ_&_ss_2013_e.pdf. Accessed on 20 Oct 2014.

85. Eijk KND, Blom JW, Gussekloo J, Polak BCP, Groeneveld Y. Diabetic retinopathy screening in patients with diabetes mellitus in primary care : Incentives and barriers to screening attendance. Diabetes Res Clin Pract. 2011;96(1):10–6. PMID:22137363 DOI: 10.1016/j.diabres.2011.11.003

86. Eiser JR, Eiser C, Riazi A. Screening for diabetic retinopathy is well received by patients and may improve self-management intentions. Diabet Med. 2001 Oct;18(10):835-41.PMID: 11678975

87. Elam AR, Lee PP. High-Risk Populations for Vision Loss and Eye Care Underutilization: A Review of the Literature and Ideas on Moving Forward. Surv Ophthalmol. 2013;58(4):348–58. DOI: 10.1016/j.survophthal.2012.07.005 PMID:23664105

88. Ellison EW. Universal eye health: Increasing access for the poorest. Community Eye Heal J. 2013;26(83):s3. PMID:24421586

89. Escoffery C, Haardoerfer R, Boing E, Udelson H, Wood R, Hartman M, et al. A systematic review of adaptations of evidence-based public health interventions globally. Implement Sci. 2018;13(1):125. PMID:30257683. DOI: 10.1186/s13012-018-0815-9.

90. Farley TF. Accuracy of Primary Care Clinicians in Screening for Diabetic Retinopathy Using Single-Image Retinal Photography. Ann Fam Med. 2008;6(5):428-34. PMID:18779547 DOI: 10.1370/afm.857

91. Farrel-Miller P, Gentry P. How Effective Are Your Patient Education Materials? Guidelines

for Developing and Evaluating Written Educational Materials. Diabetec Educ. 1989;15(5):418–22 PMID: 2776637 DOI: 10.1177/0145721789015005.

92. Fenwick E, Rees G, Pesudovs K, Dirani M, Kawasaki R, Wong TY, et al. Social and emotional impact of diabetic retinopathy : a review. Clin Exp Ophthalmol. 2012;40(1): 27–38. PMID: 21575125 DOI: 10.1111/j.1442-9071.2011.02599.x

93. Fernandes De R.J, Ogurtsova K, Linnenkamp U, Guariguata L, Seuring T, Zhang P, et al. IDF Diabetes atlas estimates of 2014 global health expenditures on diabetes. Diabetes Res Clin Pract. 2016; 117:48–54. PMID: 27329022 DOI: 10.1016/j.diabres.2016.04.016

94. Fernando D. Health care systems in transition: Sri Lanka, An overview of Sri Lanka's health care system. J Public Health Med. 2000;22(1):14–20. PMID: 10774898

95. Fernando DJ, Siribaddana S, Silva D SZ. Prevalence of retinopathy in a Sri Lankan diabetes clinic. Ceylon Med J. 1993;38(3):120–3. PMID: 7828230

96. Fikree FF. Role of gender in health disparity: the South Asian context. Bmj. 2004;328(7443):823–6. doi: https://doi.org/10.1136/bmj.328.7443.823

97. Flaxman SR, Bourne RRA, Resnikoff S, Ackland P, Braithwaite T, Cicinelli M V, et al. Global causes of blindness and distance vision impairment 1990-2020 : a systematic review and meta-analysis. Lancet Glob Health. 2017;5(12):1221–34. PMID: 29032195 DOI: 10.1016/S2214-109X(17)30393-5

98. Foreman J, Keel S, Xie J, Wijngaarden P, Taylor H, Dirani M. Adherence to diabetic eye examination Health Survey. Med J Aust. 2017;206(9):402–406 doi: 10.5694/mja16.00989.

99. Forouhi NG, Wareham NJ. Epidemiology of diabetes. Medicine (Abingdon). 2014 Dec;42(12):698-702. PMID: 25568613 DOI: 10.1016/j.mpmed.2014.09.007

100. French S, Green S, O'Connor DA, McKenzie JE, Francis JJ. Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach

using the Theoretical Domains. BMC Implement Sci. 2012;7(38):1–8. https://doi.org/10.1186/1748-5908-7-38

101. Fulton BD, Scheffler RM, Sparkes SP, Auh EY, Vujicic M, Soucat A. Health workforce skill mix and task shifting in low income countries : a review of recent evidence. BMC Hum Resour Health. 2011;9(1):1. https://doi.org/10.1186/1478-4491-9-1

102. Geneau R, Lewallen S, Bronsard A, Paul I, Courtright P. The social and family dynamics behind the uptake of cataract surgery: Findings from Kilimanjaro region, Tanzania. Br J Ophthalmol. 2005;89(11):1399–402. DOI: 10.1136/bjo.2005.075572. PMID: 16234438

103. Gerhs K, Chong L, Gusman G, Street D. Can we educate primary care physicians about diabetic retinopathy after graduation? Preliminary results of the diabetic retinopathy education study. Invest Ophthalmol Vis Sci. 1993;34:1182–5.

104. Ghisi GL, Abdallah F, Grace SL, Thomas S, Oh P. A systematic review of patient education in cardiac patients: Do they increase knowledge and promote health behavior change? Patient Educ Couns. 2014;95(2):160–74. PMID: 24529720 DOI: 10.1016/j.pec.2014.01.012.

105. Gilbert CE, Babu RG, Sai A, Gudlavalleti V, Anchala R, Shukla R, et al. Eye care infrastructure and human resources for managing diabetic retinopathy in India : The India 11-city 9-state study. Indian J Endocrinol Metab 2016; 20(7): 3–10. DOI: 10.4103/2230-8210.179768

106. Gillibrand WP, Broadbent DM, Swain JY, Harding SP, Vora JP. Knowledge levels of diabetic eye disease in people with diabetes: results of a descriptive survey. International Journal of Health Promotion and Education. 2000;38(4):141-144. doi.org/10.1080/14635240.2000.10806169

107. Gilson L, Lehmann U, Schneider H. Practicing governance towards equity in health systems : LMIC perspectives and experience. Int J Equity Health. 2017;16(1):171 https://doi.org/10.1186/s12939-017-0665-0

108. Gitlin LN. Introducing a new intervention: An overview of research phases and common challenges. Am J Occup Ther. 2013;67(2):177–84. PMID: 23433272. DOI: 10.5014/ajot.2013.006742

109. Glasson N, Larkins S, Crossland L. What do patients with diabetes and providers think of an innovative Australian model of remote diabetic retinopathy screening? A qualitative study. BMC Health Serv Res. 2017;17(1):158 PMID: 28222770 DOI:10.1186/s12913-017-2045-2

110. Global Initiative for the Elimination of voidable Blindness. World Health Organization-Global Initiative for the Elimination of Avoidable Blindness. [Internet] Available from: http://apps.who.int/iris/bitstream/handle/10665/63748/WHO_PBL_97.61_Rev.2.pdf?sequence=1&isAllowed=y. Accessed on 15 Sept 2018.

111. Gombachika BC, Heidi F, Chirwa E, Sundby J, Malata A, Maluwa A. A Social Ecological Approach to Exploring Barriers to Accessing Sexual and Reproductive Health Services among Couples Living with HIV in Southern Malawi. ISRN Public Health. 2012;2012:1–13. doi.org/10.5402/2012/825459

112. Govinda A, DeVerteuil R. Systematic review of the diagnostic accuracy of the single, two and three field digital retinal photography for screening diabetic retinopathy. JBI Libr Syst Rev. 2011;9(16):491–537 PMID: 27820519.

113. Grading diabetic retinopathy from stereoscopic colour fundus photographs - An extension of the modified Airlie House classification : ETDRS report number 10. Early Treatment Diabetic Retinopathy Study Group. Ophthalmology. 1991;98(5):786-806. PMID: 2062513

114. Graham-Rowe E, Lorencatto F, Lawrenson J, Burr J, Grimshaw J, Ivers N, et al. Barriers to and enablers of diabetic retinopathy screening attendance: a systematic review of published and greay literature. Diabet Med. 2018;35(10):1308–1319. doi: 10.1111/dme.13686. PMID: 29790594.

115. Greenwood RA, George R, Madero S. An Exploration of Cross-Cultural and Gender

Differences in East Asia, South Asia and Southeast Asia. 2016 [Internet] Available from: https://nsuworks.nova.edu/cgi/viewcontent.cgi?referer=https://www.google.lk/&httpsredir=1&article=1075&context=hcbe_facpres. Accessed on 10 Feb 2018.

116. Gruppen LD, Mangrulkar RS, Kolars JC. The promise of competency-based education in the health professions for improving global health. BMC Human Resources for Health. 2012;10:43. https://doi.org/10.1186/1478-4491-10-43

117. Guariguata L, Whiting DR, Hambleton I, Beagley J, Linnenkamp U, Shaw JE. Global estimates of diabetes prevalence for 2013 and projections for 2035. Diabetes Res Clin Pract. 2014;103(2):137–49. PMID: 24630390 DOI:10.1016/j.diabres.2013.11.002

118. Guidelines for the Development of Patient Education Materials. Report by Scotia Nova [Internet]. 2004;(March) Available from: http://www.cdha.nshealth.ca/nova-scotia-cancer-care-program-3. Accessed on 05 Jan 2018.

119. Guigui S, Lifshitz T, Levy J. Screening for diabetic retinopathy: review of current methods. Hosp Pract. 2012;40(2):64–72. PMID: 22615080 DOI: 10.3810/hp.2012.04.971.

120. Gulliford M, Morgan M. What does 'access to health care' mean. J Health Serv Res Policy. 2002;7(3):186-8. PMID: 12171751 DOI: 10.1258/135581902760082517

121. Gulliford MC, Dodhia H, Chamley M, Mccormick K, Mohamed M, Naithani S, et al. Socio-economic and ethnic inequalities in diabetes retinal screening. Diabet Med. 2010;27(3):282–8. PMID: 20536490 DOI:10.1111/j.1464-5491.2010.02946.x

122. Gupta V, Bansal R, Gupta A, Bhansali A. Sensitivity and specificity of nonmydriatic digital imaging in screening diabetic retinopathy in Indian eyes. Indian J Ophthalmol. 2014 Aug;62(8):851-6. DOI:10.4103/0301-4738.141039

123. Hall M, Felton A. The St Vincent Declaration 20 years on - defeating diabetes in the 21st century. Primary Care Diabetes. 2009;3(2):127-128. https://doi.org/10.1016/j.pcd.2009.06.003

124. Hansen AB, Sander B, Larsen M, Kleener J, Borch-Johnsen K, Klein R, et al. Screening for diabetic retinopathy using a digital non-mydriatic camera compared with standard 35-mm stereo colour transparencies. Acta Ophthalmol Scand. 2004;82(6):656–65. PMID: 15606460 DOI:10.1111/j.1600-0420.2004.00347.x

125. Harding SP, Broadbent DM, Neoh C, White MC, Vora J. Sensitivity and specificity of photography and direct ophthalmoscopy in screening for sight threatening eye disease: the Liverpool Diabetic Eye Study. BMJ. 1995;311(7013):1131–5. PMID: 7580708.

126. Hartnett ME, Key IJ, Loyacano MN, Horswell RL, DeSalvo KB. Perceived barriers to diabetic eye care - Qualitative study of patinets and physicians. Arch Ophthalmol. 2005;123:387–91. DOI: 10.1001/archopht.123.3.387 PMID:15767483.

127. Harvey JN, Craney L, Nagendran S, Ng CS. Towards comprehensive population-based screening for diabetic retinopathy: operation of the North Wales diabetic retinopathy screening programme using a central patient register and various screening methods. J Med Screen. 2006;13(2):87–92. PMID: 16792832 DOI:10.1258/096914106777589669

128. Hazavehei SMM, Jeihooni AK, Hasanzadeh A, Amini S. The Effect of Educational Program Based on BASNF Model for Eye Care in Non-insulin Dependent Diabetic Patients. J Heal Serv Res. 2010;10(2):81–90. PMID: 22911929

129. Henricsson M, Karlsson C, Ekholm L, Kaikkonen P, Sellman A, Steffert E, et al. Colour slides or digital photography in diabetes screening-a comparison. Acta Ophthalmol Scand. 2000;78(2):164–8. PMID: 10794249. doi/10.1034/j.1600-0420.2000.078002164.x/

130. Herbert HM, Jordan K, Flanagan DW. Is screening with digital imaging using one retinal view adequate? Eye (Lond). 2003;17(4):497–500. PMID: 12802350 DOI: 10.1038/sj.eye.6700409

131. Hipwell AE, Sturt J, Lindenmeyer A, Stratton I, Gadsby R, O'Hare P, et al. Attitudes, access and anguish: a qualitative interview study of staff and patients' experiences of diabetic retinopathy screening. BMJ Open. 2014;4(12): e005498. doi.org/10.1136/bmjopen-2014-

005498

132. Hofer T, Katz S. Healthy Behaviours Among Women in the United States and Ontarion: The Effect on Use of Preventive Care. Am J Public Health. 1996;86(12):1775–9.

133. Hölzel LP, Ries Z, Kriston L, Dirmaier J, Zill JM, Rummel-kluge C, et al. Effects of culture-sensitive adaptation of patient information material on usefulness in migrants : a multicentre, blinded randomised controlled trial. BMJ Open. 2016;6(11): doi: 10.1136/bmjopen-2016-012008.

134. Hongorn C, Mcpake B . How to bridge the gap in human resources for health. Lancet. 2004;364(9443):1451–6. PMID: 15488222 DOI:10.1016/S0140-6736(04)17229-2

135. Huang OS, Tay WT, Tai ES, Chb MB, Wang JJ, Saw S, et al. Lack of Awareness amongst Community Patients with Diabetes and Diabetic Retinopathy: The Singapore Malay Eye Study. Ann Acad Med Singapore. 2009;(38)12:1048–55. PMID: 20052439

136. Huang OS, Zheng Y, Tay WT, Chiang PP, Lamoureux EL, Wong TY, et al. Lack of Awareness of Common Eye Conditions in the Community. Ophthalmic Epidmiology. 2013;20(1):52–60. https://doi.org/10.3109/09286586.2012.751429

137. Hubley J, Gilbert C. Eye health promotion and the prevention of blindness in developing countries: critical issues. Br J Ophthalmol.2006;90(3):279–84. PMID: 16488944 DOI: [10.1136/bjo.2005.078451].

138. Hussain R, Rajesh B, Giridhar A, Gopalakrishnan M, Sadasivan S, James J, et al. Knowledge and awareness about diabetes mellitus and diabetic retinopathy in suburban population of a South Indian state and its practice among the patients with diabetes mellitus : A population - based study. Indian J Ophthalmol. 2016;64(4):272–6. PMID: 27221678 doi: 10.4103/0301-4738.182937.

139. Hutchinson A, McIntosh A, Peters J, Keeffe JE, Khunti K, Baker R. Effectiveness of screening

and monitoring tests for diabetic retinopathy - a systematic review. Diabet Med. 2000;17(17):495–506. PMID: 10972578

140. Hutton G, Tanner M. Bulletin of the World Health Organization Capacity-building for public health :The sector-wide approach: a blessing for public health? [Internet]. 2018. Available from: http://www.who.int/bulletin/volumes/82/12/editorial21204html/en/. Accessed on 10 Sept 2018.

141. Hwang J, Rudnisky C, Bowen S, Johnson JA. Socioeconomic factors associated with visual impairment and ophthalmic care utilization in patients with type II diabetes. Can J Ophthalmol 2015;50(2):119–26. PMID: 25863851. DOI: 10.1016/j.jcjo.2014.11.014.

142. ICO Guidelines for Diabetic Eye Care. International Council of Ophthalmology. [Internet] 2017. Available at http://www.icoph.org/downloads/ICOGuidelinesforDiabeticEyeCare.pdf. Accessed on 15 Jan 2018.

143. IDF. International Diabetes Federation Diabetes Atlas Eighth Edition 2017 [Internet]. 2017. Available from: http://www.diabetesatlas.org/resources/2017-atlas.html. Accessed 15 Jan 2017.

144. Illanasekara U, Rambodagalla S, Tennakoon S. Temporal trends in the prevalence of diabetes mellitus in a rural community in Sri Lanka. J R Soc Promot Health. 2004;124(2):92–4. PMID: 15067982

145. Illangasekara U, Rambadagalla TS. Increasing prevalence of diabetes mellitus in a rural srilankan community. J Ceylon Coll Physician. 2002;35:54–5.

146. Indications for photocoagulation treatment of diabetic retinopathy: Diabetic Retinopathy Study Report no. 14. The Diabetic Retinopathy Study Research Group. Inl Ophthalmol Clin. 1987; 27(4):239-53

147. International Diabetes Federation - Diabetes Atlas Eighth Edition 2017 [Internet]. 2017.

Available from: http://www.diabetesatlas.org/resources/2017-atlas.html. Accessed on 15 Jan 2018.

148. Irish College of Ophthalmologists. Framework for the Development of a Diabetic Retinopathy Screening Programme for Ireland. [Internet] 2008;(October). Available from: http://www.hse.ie/eng/services/publications/topics/Diabetes/Framework_for_a_Diabetic_Retinopathy_Screening_Programme_.pdf. Accessed on 19 Aug 2016.

149. Islam F, Kawasaki R, Finger R. Factors associated with participation in a diabetic retinopathy screening program in a rural district in Bangladesh. Diabetes Res Clin Pract. 2018; 144:111–117 DOI: 10.1016/j.diabres.2018. PMID: 30142363

150. Green J, Siddall H, Murdoch I. Learning to live with glaucoma:a qualitative study of diagnosis and the impact of sight loss. Soc Sci Med. 55(2):257–67. PMID: 12144140

151. Jacob B, Ir P, Bigdeli M, Annear P, Damme W. Addresing acces barriers to health services: an analytical framework for selecting appropriate interventions in low-income Asian countries. Health Policy Plan. 2011;27(4):288-300. PMID: 21565939 DOI: 10.1093/heapol/czr038

152. James M, Turner D, Broadbent D, Vora J, Harding S. Cost effectiveness analysis of screening for sight threatening diabetic eye disease. BMJ. 2000;320(7250):1627–31. PMID: 10856062

153. Jayawardena R, Ranasinghe P, Byrne NM, Soares MJ, Katulanda P, Hills AP. Prevalence and trends of the diabetes epidemic in South Asia: a systematic review and meta-analysis. BMC Public Health. 2012;12(1):380. https://doi.org/10.1186/1471-2458-12-380

154. Jennifer E. Eye care for older people. Community Eye Heal J. 2008;21(66):21–3.

155. Jenum AK, Diep LM, Holmboe-Ottesen G, Holme IMK, Kumar BN, Birkeland KI. Diabetes susceptibility in ethnic minority groups from Turkey, Vietnam, Sri Lanka and Pakistan compared with Norwegians - the association with adiposity is strongest for ethnic minority women. BMC Public Health. 2012;12(1):150. PMID: 22380873. DOI: 10.1186/1471-2458-12-

156. Jones CA, Mawani S, King KM, Allu SO, Smith M, Mohan S, et al. Tackling health literacy : adaptation of public hypertension educational materials for an Indo-Asian population in Canada. BMC Public Health. 2011;11:24 doi:10.1186/1471-2458-11-24. PMID: 21223580

157. Jones HL, Walker EA, Schechter CB, Blanco E. Vision is Preciuos: A successful behavioral inetervention to increase the rate of screening for diabetic retinopathy for inner city adults. Diabetes Educ. 2010;36(1):118–26. PMID: 20044537 doi:10.1177/0145721709356116

158. Jones S, Edwards R. Diabetic retinopathy screening: a systematic review of the economic evidence. Diabet Med. 2010;27(3):249–56. PMID: 20536486 DOI:10.1111/j.1464-5491.2009.02870.x

159. Joshi R, Alim M, Kengne AP, Jan S, Maulik PK, Peiris D, et al. Task shifting for non-communicable disease management in low and middle income countries - A systematic review. PLoS One. 2014;9(8): e103754. PMID: 25121789. DOI: 10.1371/journal.pone.0103754. https://doi.org/10.1371/journal.pone.0103754.

160. Jotheeswaran AT, Lovakanth N, Nadiga S, Anchala R, Murthy GVS, Gilbert CE. Estimating the proportion of persons with diabetes developing diabetic retinopathy in India: A systematic review and meta-analysis. Indian J Endocrinol Metab. 2016;20(7):S51-8. DOI: 10.4103/2230-8210.179774 .

161. Kaluthanthri KDMS. Ageing and the changing role of the family in Sri Lanka. Univeristy of Adelaide; 2014. [Internet] Available from: https://digital.library.adelaide.edu.au/dspace/bitstream/2440/93498/3/02whole.pdf. Accessed on 18 Feb 2018.

162. Kabene SM, Orchard C, Howard JM, Soriano MA, Leduc R. The importance of human resources management in health care: A global context. Hum Resour Health. 2006;4:20. PMID: 16872531. DOI: 10.1186/1478-4491-4-20

163. Kaliaperumal K. IEC Strategies for Diabetic Retinopathy. Lions Aravind Institute of Community Ophthalmology. [Internet]. Available from: http://v2020eresource.org/content/files/IEC.pdf. Accessed on 16 Aug 2017.

164. Kannuri NK, Anchala R, Murthy GVS, Gilbert CE. Strengthening diabetes retinopathy services in India : Qualitative insights into providers ' perspectives : The India 11 - city 9 - state study. Indian J Endocr Metab. 2016;20(7):59–66. DOI: 10.4103/2230-8210.179775

165. Kashim RM, Newton P, Ojo O. Diabetic Retinopathy Screening: A Systematic Review on Patients' Non-Attendance. Int J Environ Res Public Health. 2018;15(157):1–12 doi:10.3390/ijerph15010157.

166. Katibeh M, Ahmadieh H, Beiranvand R, Soleimanizad R, Javadi M. Awareness of the Necessity of Regular Eye Examinations among Diabetics: The Yazd Eye Study. Int J Prev Med. 2017;4(8):49 PMID: 28757926 DOI: 10.4103/ijpvm.IJPVM_218_15

167. Katibeh M, Kalantarion M, Mariotti S, Safi S, Shahraz S, Kalestrup P, et al. A Stakeholder Perspective on Diabetes Mellitus and Diabetic Retinopathy Care in Iran; A Qualitative Study. Arch Iran Med. 2017;20(5):288–294 PMID: 28510464 DOI: 0172005/AIM.006

168. Katulanda P, Ranasinghe P, Jayawardena R. Prevalence of retinopathy among adults with self-reported diabetes mellitus: the Sri Lanka diabetes and Cardiovascular Study. BMC Ophthalmol. 2014;14(1):100. PMID: 25142615. DOI: 10.1186/1471-2415-14-100

169. Katulanda P, Rathnapala DAV, Sheriff R, Mathews DR . Province and ethnic specific prevalence of diabetes among Sri Lakan adults. Sri Lanka J Diabetes Endocrinol Metab. 2011;(1):2–7. DOI: http://dx.doi.org/10.4038/sjdem.v1i1.4180

170. Katulanda P, Waniganayake YC, Ranasinghe P, Udai WM, Wijetunga A, Jayaweera M, et al. Retinopathy among young adults with Diabetes Mellitus from a tertiary care setting in Sri Lanka. BMC Endocr Disord. 2014;14(1):1–8. PMID: 24588941. doi: 10.1186/1472-6823-14-20

171. Kelly MP, Stewart E, Morgan A, Killoran A, Fischer A, Threlfall A, et al. A conceptual framework for public health : NICE's emerging approach. Public Health. 2009;123(1):e14–20. PMID: 19100588. DOI: 10.1016/j.puhe.2008.10.031.

172. Khandekar R, Lawati J Al, Barakat N. A Retrieval System for Patients with Avoidable Blindness Due to Diabetic Retinopathy who do not Present for Ophthalmic Assessment in Oman. Middle East Afr J Ophthalmol. 2011;18(2):93–7. PMID: 21731317 doi:10.4103/0974-9233.80694

173. Khandekar R, Shah S, Al Lawatti J. Retinal examination of diabetic patients: Knowledge, attitudes and practices of physicians in Oman. East Mediterr Heal J. 2008;14(4):850–7. PMID: 19166168

174. Khandekar R. Screening and Public Health Strategies for Diabetic Retinopathy in the Eastern Mediterranean Region. Middle East Afr J Ophthalmol. 2012;19(2):178–84. PMID: 22623855 DOI: 10.4103/0974-9233.95245

175. Klein BE. Overview of Epidemiologic Studies of Diabetic Retinopathy. Ophthalmic Epidemiol. 2007;14(04):179–83. PMID: 17896294. DOI:10.1080/09286580701396720

176. Klein R, Klein BE, Moss SE, Davis MD, Demets DL. The Wisconsin Epidemiologic Study of Diabetic Retinopathy: II. Prevalence and risk of diabetic retinopathy when age at diagnosis is less than 30 years. Arch Ophthalmol. 1984;102(4):520–6. PMID: 6367724

177. Klein R, Klein BEK, Moss SE, Cruickshanks KJ. The Wisconsin Epidemiologic Study of Diabetic Retinopathy : XVII. The 14-year Incidence and Progression of Diabetic retinopathy and associated risk factors in type 1 diabetes. Ophthalmology. 1998;105(10):1801–15. PMID: 9787347 DOI:10.1016/S0161-6420(98)91020-X

178. Klein R, Klein BEK. The Epidemiology of Diabetic Retinopathy [Internet]. Fifth Edit. Vols. 2–3, Retina: Fourth Edition. Elsevier Inc.; 2005. 1503-1521 p. Available from: http://dx.doi.org/10.1016/B978-1-4557-0737-9.00045-X. Accessed on 15 Jan 2016.

179. Klein R, Knudtson MD, Lee KE, Gangnon R, Klein BEK. The Wisconsin Epidemiologic Study of Diabetic Retinopathy xxii. The Twenty-Five-Year Progression of Retinopathy in Persons with Type 1 Diabetes. Diabetes. 2009;115(11):263-0279. PMID: 19068374 DOI: 10.1016/j.ophtha.2008.08.023

180. Kliner M, Fell G, Gibbons C, Dhothar M, Mookhtiar M, Cassels-Brown A. Diabetic retinopathy equity profile in a multi-ethnic, deprived population in Northern England. Eye (Lond). 2012;26(5):671–7. PMID: 22302063. doi: 10.1038/eye.2012.3 .

181. Kohner E, Stratton I, Aldington S, Holman R, Matthews D. Relationship between the severity of retinopathy and progression to photocoagulation in patients with Type 2 diabetes mellitus in the UKPDS (UKPDS 52). UK Prospect Diabetes Study Group. Diabet Med. 2001;18(3):178–84. PMID: 11318837

182. Kohner EM, Aldington SJ, Stratton IM, Manley SE, Holman RR, Mathews DR, Turner RC. United Kingdom Prospective Diabetes Study, 30: diabetic retinopathy at diagnosis of non-insulin-dependent diabetes mellitus and associated risk factors. Arch Ophthalmol. 1998;116(3):297–303. PMID: 9514482

183. Kreft D, Mcguinness M, Doblhammer G, Finger R. Diabetic retinopathy screening in incident diabetes mellitus type 2 in Germany between 2004 and 2013 - A prospective cohort study based on health claims data. PLoS One. 2018;13(4):e0195426. https://doi.org/10.1371/journal.pone.019.

184. Ku JJ, Landers J, Henderson T, Craig JE. The reliability of single-field fundus photography in screening for diabetic retinopathy: The central australian ocular health study. Med J Aust. 2013;198(2):93–6. PMID: 23373499

185. Kuo HK, Hsieh HH, Liu RT. Screening for diabetic retinopathy by one-field, non-mydriatic, 45° digital photography is inadequate. Ophthalmologica. 2005;219(5):292–6. PMID: 16123556 DOI:10.1159/000086114

186. Kurji K, Kiage D, Rudnisky CJ, Damj KF. Improving Diabetic Retinopathy Screening in Africa: Patient Satisfaction with Tele-Ophthalmology Versus Ophthalmologist Based Screening. Middle East Afr J Ophthalmol. 2013;20(1):56–60. DOI: 10.4103/0974-9233.106388

187. Lake A, Browne J, Rees G, Speight J. What factors influence uptake of retinal screening among young adults with type 2 diabetes? A qualitative study informed by the theoretical domains framework. J Diabetes Complications. 2017;31(6):997–1006 PMID: 28363730 DOI:10.1016/j.jdiacomp.20.

188. Lamirel C, Bruce BB, Wright DW, Delaney KP, Newman NJ, blousse V. Quality of Nonmydriatic Digital Fundus Photography Obtained by Nurse Practitioners in the Emergency Department : The FOTO-ED Study. Ophthalmology. 2012;119(3):617–24. PMID: 22218140. DOI:10.1016/j.ophtha.2011.09.013.

189. Lane M, Mathewson PA, Sharma HE, Palmer H, Shah P, Nightingale P, et al. Social deprivation as a risk factor for late presentation of proliferative diabetic retinopathy. Clin Ophthalmol. 2015;347–52. PMID: 25733801 DOI:10.2147/OPTH.S73272

190. Latif S, Ahmed I, Shafiul M, Syed I. Exploring the potential impact of health promotion videos as a low cost intervention to reduce health inequalities : a pilot before and after study on Bangladeshis in inner-city London. London J Prim Care (Abingdon). 2016;8(4):66-71. PMID: 28250836. doi:10.1080/17571472.2016.1208382.

191. Lawrenson JG, Graham-Rowe E, Lorencatto F, Presseau J, Burr J, Ivers N, et al. Interventions to increase attendance for diabetic retinopathy screening. Cochrane Database Syst Rev. 2018; (1):CD012054. DOI:10.1002/14651858.CD012054.pub2.

192. Leasher JL, Bourne RRA, Flaxman SR, Jonas JB, Keeffe J, Naidoo K, et al. Global Estimates on the Number of People Blind or Visually Impaired by Diabetic Retinopathy: A Meta-analysis From 1990 to 2010. Diabetes Care. 2016;39(9):1643–9. PMID: 27555623 DOI:

10.2337/dc15-2171.

193. Lee PP, Meredith LS, Whitcup SM, Spritzer K, Hays RD. A Comparison of Self-Reported Utilization of Ophthalmic Care for Diabetes in Managed Care Versus Fee-For-Service. Retina. 1998;18:356–9. PMID: 9730180

194. Lee R, Wong TY, Sabanayagam C. Epidemiology of diabetic retinopathy, diabetic macular edema and related vision loss. Eye Vis (Lond). 2015 Sep 30;2:17 PMID: 26605370 DOI:10.1186/s40662-015-0026-2

195. Leeflang M, Rutjes A, Reitsma J, Hooft L, Bossuyt P. Validation of a test's sensitivity and specificity with disease prevalence. Can Med Assoc J. 2013;185(11):537–544 DOI:10.1503 /cmaj.121286.

196. Leese GP, Boyle P, Feng Z, Emslie-Smith A, Ellis JD. Screening Uptake in a Well-Established Diabetic Retinopathy Screening Program. Diabetes Care. 2008;31(11):2131–5. PMID: 18728235 DOI:10.2337/dc08-1098

197. Legorreta A, Hassan M, Peters A, Pelletier K, Leung K. An Intervention for Enhancing Compliance With Screening Recommendations for Diabetic Retinopathy. Diabetes Care. 1997;20(4):520–3. PMID: 9096973

198. Lei X, Zeng G, Zhang Y, Li Q, Zhang J, Bai Z, et al. Association between homocysteine level and the risk of diabetic retinopathy : a systematic review and meta-analysis. Diabetol Metab Syndr. 2018;10: 61. PMID: 30083252. DOI:10.1186/s13098-018-0362-1

199. Leutz W. Five laws for integrating medical and social services: lessons from the United States and the United Kingdom. Milbank Quarterly-Journal Popul Heal Policy. 1999;77(1):77–110. PMID: 10197028

200. Levesque JF, Harris MF, Russell G. Patient-centred access to health care: Conceptualising access at the interface of health systems and populations. BMC Int J Equity Health

2013;12(1):1. https://doi.org/10.1186/1475-9276-12-18.

201. Lewis K, Patel D, Yorston D, Charteris D. A qualitative study in the United Kingdom of factors influencing attendance by patients with diabetes at ophthalmic outpatient clinics. Ophthalmic Epidemiol. 2007;14(6):375–80. PMID: 18161611 DOI:10.1080/09286580701375195

202. Liam R. O'Fallon, Frederick L. Tyson, Allen Dearry. Successful Models of Community-Based Participatory Reseach. [Internet] 2000. Available from: http://www.hud.gov/offices/lead/library/hhts/NIEHS_Successful_Models.pdf. Accessed on 10 Dec 2017.

203. Lian J, Mcghee S, Gangwani R, Lam C, Yap M, Wong D. Awareness of diabetic retinopathy and its association with attendance for systematic screening at the public primary care setting: a cross-sectional study in Hong Kong. BMJ Open. 2018;8:e019989. doi: 10.1136/bmjopen-2017-019989.

204. Lian JX, McGhee SM, Gangwani RA, Hedley AJ, Lam CL, Yap MK, et al. Screening for diabetic retinopathy with or without a copayment in a randomized controlled trial: Influence of the inverse care law. Ophthalmology. 2013;120(6):1247–53. PMID: 23583166 DOI: 10.1016/j.ophtha.2012.11.024.

205. Liesenfeld B, Kohner E, Piehlmeier W, Kluthe S, Aldington S, Et al. A Telemedical Approach to the Screening of Diabetic Retinopathy : Digital Fundus Photography. Diabetes Care. 2000;23(3):345–8. PMID: 10868863

206. Lin J, Weng Q, Xue L, Cao X. A retinal image sharpness metric based on histogram of edge width. Journal f Algorithms & Computational Technology. 2017;11(3):292–300. DOI:10.1177/1748301817713184

207. Lin S, Ramulu P, Lamoureux EL, Sabanayagam C. Addressing risk factors, screening, and preventative treatment for diabetic retinopathy in developing countries: A review. Clin Exp

Ophthalmol. 2016;44(4):300–20. PMID: 26991970. DOI:10.1111/ceo.12745

208. Lindenmeyer A, Sturt JA, Hipwell A, Stratton IM, Al-Athamneh N, Gadsby R, et al. Influence of primary care practices on patients' uptake of diabetic retinopathy screening: A qualitative case study. Br J Gen Pract. 2014;64(625):484–92. PMID: 25071061 DOI:10.3399/bjgp14X680965

209. Literacy rates by district, sex and sector. Census Popul Hous 2001 [Internet]. 2011. Available from: http://www.statistics.gov.lk/PopHouSat/PDF/Population/p9p10 Literacy rates by district, sex and sector.pdf. Accessed on 19 Aug 2016.

210. Liu SL, Mahon LW, Klar NS, Schulz DC, Gonder JR, Hramiak IM, et al. A randomised trial of non-mydriatic ultra-wide field retinal imaging versus usual care to screen for diabetic eye disease : rationale and protocol for the Clearsight trial. BMJ Open. 2017;7(8):e015382. PMID: 28775182. DOI:10.1136/bmjopen-2016-015382

211. Liu Y, Zupan N, Shiyanbola O, Swearingen R, Carlson J, Jacobson N, et al. Factors influencing patient adherence with diabetic eye screening in rural communities: A qualitative study. PLoS One. 2018;13(11): e0206742. https://doi.org/10.1371/journal.pone.020.

212. Livingston PM, McCarty CA, Wood CA, Harper AC, Keeffe JE, Taylor HR. Use of focus groups to identify health promotion strategies for the early detection of diabetic retinopathy. Aust N Z J Public Health. 1998;22(2):220–2.

213. Loevinsohn B. Health education interventions in developing countries: A methodological review of published articles. Int J Epidemiol. 1990;19(4):788–94. https://doi.org/10.1093/ije/19.4.788

214. Lopez-Bastida J, Cabrera-Lopez F, Serrano-Aguilar P. Sensitivity and specificity of digital retinal imaging for screening diabetic retinopathy. Diabet Med. 2007;24(4):403–7. PMID: 17298591 DOI:10.1111/j.1464-5491.2007.02074.x

215. Low L, Law JP, Hodson J, Mcalpine R, Colmain UO, Macewen C. Impact of socioeconomic deprivation on the development of diabetic retinopathy : a population-based, cross-sectional and longitudinal study over 12 years. BMJ Open 2015;5(4):e007290. doi:10.1136/bmjopen-2014-007290

216. Lu Y, Serpas L, Genter P, Anderson B, Campa D, Ipp E. Divergent Perceptions of Barriers to Diabetic Retinopathy Screening Among Patients and Care Providers, Los Angeles, California, 2014-2015. Prev Chronic Dis. 2016;13:e140 . PMID: 27710765 DOI:10.5888/pcd13.160193

217. Maberley D, Cruess AF, Barile G, Slakter J. Digital photographic screening for diabetic retinopathy in the James Bay Cree. Ophthalmic Epidemiol. 2002;9(3):169–78. PMID: 12045884.

218. Maberley DAL, Koushik A, Cruess AF, Cruess AF. Factors Associated with Missed with Diabetes Eye Examinations in a Cohort. Can J Public Heal. 2002;93(3):229–32. PMID: 12050993

219. Macaskill P, Gatsonis C, Deeks J, Harbord R, Takwoingi Y. Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy - Chapter 10 Analysing and Presenting Results. Cochrane DTA Handb. [Internet] 2010;1–61. Available from: http://methods.cochrane.org/sites/methods.cochrane.org.sdt/files/public/uploads/Chapter%2010%20-%20Version%201.0.pdf. Accessed 30 Sept 2015

220. Mallett S, Halligan S, Thompson M, Collins GS, Altman DG. Interpreting diagnostic accuracy studies for patient care. BMJ. 2012;345:e3999. doi: https://doi.org/10.1136/bmj.e3999

221. Marrone S. Understanding barriers to health care : a review of disparities in health care services among Indigenous populations. Int J Circumpolar Health. 2007;66(3):188–98. PMID: 17655060

222. Marshall SJ. Developing countries face double burden of disease. Bull World Heal Organ. 2004;82(7):556. PMID: 15500291

223. Maruthappu M, Hasan A, Zeltner T. Enablers and Barriers in Implementing Integrated Care. Heal Syst Reform. 2015;1(4):250–6. https://doi.org/10.1080/23288604.2015.1077301.

224. Massin P, Aubert JP, Eschwege E, Erginay A, Bourovitch JC, BenMehidi A, et al. Evaluation of a screening program for diabetic retinopathy in a primary care setting Dodia (Dépistage ophtalmologique du diabète) study. Diabetes Metab. 2005;31(2):153–62. PMID: 15959421

225. Massin P, Erginay A, Ben Mehidi A, Vicaut E, Quentel G, Victor Z, et al. Evaluation of a new non-mydriatic digital camera for detection of diabetic retinopathy. Diabet Med. 2003;20(8):635–41.

226. Mcshane KE, Smylie JK, Hastings PD, Prince C, Inuit T, Health F, et al. Evaluation of the acceptability of a CD-Rom as a health promotion tool for Inuit in Ottawa. Int J Circumpolar Heal. 2013;1(72):20573 PMID: 23717816 DOI: 10.3402/ijch.v72i0.20573

227. Mead A, Burnett S, Davey C. Diabetic retinal screening in the UK. J R Soc Med. 2001;94(3)127–9. DOI: 10.1177/014107680109400307

228. Millet C, Dodhia H . Diabetic retinopathy screening: audit of equity in participation and selected outcomes in South East London. J Med Screen. 2006;13(3):152–5. PMID: 17007657 DOI:10.1258/096914106778440608.

229. Ministry f Health Sri Lanka - Medical Statistics Unit. Annual Health Bulletin 2015 [Internet]. Annual Health Bulletin Srilanka. 2017. 35-36 p. Available from: http://www.health.gov.lk/moh_final/english/public/elfinder/files/publications/AHB/2017/AHB2015.pdf. Accessed on 19 Aug 2016.

230. Mizrachi Y, Knyazer B, Guigui S, Rosen S, Lifshitz T, Belfair N, et al. Evaluation of diabetic retinopathy screening using a non-mydriatic retinal digital camera in primary care settings in south Israel. International Ophthalmology. 2014;34(4):831-837. PMID:24292883 DOI: 10.1007/s10792-013-9887-3.

231. Moher D, Liberati A, Tetzlaff J, Altman DG, Grp P. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. Ann Intern Med. 2009;151(4):264-9. PMID: 19622511

232. Moran M, Frank L, Chatterjee J, Murphy S, Baezconde-Garbanati L. A pilot test of the acceptability and efficacy of narratve and non-narrative health education materials in a low health literacy population. J Commun Heal. 2016;9(1):40–8. PMID: 27872657 DOI: 10.1080/17538068.2015.1126995.

233. Moreton P, Stratton I, Chave S, Lipinski H, Scanlon P. Factors determining uptake of diabetic retinopathy screening in Oxfordshire. Diabet Med. 2017;34(7):993–999 PMID: 28295529 DOI:10.1111/dme.13350

234. Moss SE, Klein R, Klein BE. Factors associated with having eye examinations in persons with diabetes. Arch Fam Med. 1995;04:529–34. PMID: 7773429

235. Muecke JS, Newland HS, Ryan P, Ramsay E, Aung M, Myint S, et al. Awareness of diabetic eye disease among general practitioners and diabetic patients in Yangon, Myanmar. Clin Exp Ophthalmol. 2008;36(3):265–73. PMID: 18412597 DOI:10.1111/j.1442-9071.2008.01724.x

236. Mukamel BD, Bresnick HG, Wang Q, Dickey FC, Mukamel BD, Bresnick HG, et al. Barriers to compliance with screening guidelines for diabetic retinopathy. Ophthalmic Epidemiol. 1999;(6)1:61-72 http://dx.doi.org/10.1076/opep.6.1.61.1563 PMID: 10384685

237. Mumba M, Hall A, Lewellen S. Compliance with Eye Screening Examinations among Diabetic Patients at a Tanzanian Referral Hospital. Ophthalmic Epidemiol. 2007; 14:306–10. DOI: 10.1080/09286580701272079 PMID: 17994440

238. Munoz B, O'Leary M, Fonseca-Becker F, Rosario E, Burguess I, Anguilar M, et al. Knowledge of Diabetic Eye Disease and Vision Care Guidelines Among Hispanic Individuals in Baltimore With and Without Diabetes. Arch Ophthalmol. 2008;126(7):968–74. PMID: 18625945 doi:10.1001/archopht.126.7.968

239. Murgatroyd H, MacEwen C, Leese G. Patients' attitude towards mydriasis for diabetic eye disease screening. Scott Med J. 2006;51(4):341–5. PMID: 17137147 DOI:10.1258/RSMSMJ.51.4.35

240. Murgatroyd H. Ellingford A, Cox A, Binnie M, Ellis JD, MacEwen CJ, et al. Effect of mydriasis and different field strategies on digital image screening of diabetic eye disease. Br J Ophthalmol. 2004;88(7):920–4. PMID: 15205238. DOI: 10.1136/bjo.2003.026385.

241. Murthy GVS, Das T. Diabetic care initiatives to prevent blindness from diabetic retinopathy in India. Indian J Ophthalmol 2016;64(1):50–4. doi: 10.4103/0301-4738.178152

242. Murthy GVS, Gupta SK, John N, Vashist P. Current status of cataract blindness and Vision 2020: The right to sight initiative in India. Indian J Ophthalmol. 2008 Nov-Dec; 56(6): 489–494. PMID: 18974520

243. Murthy GVS, Malhotra S, Vashist P. Status of Eye Care in South East Asia Region. Delhi J Ophthalmol. 2013;24(2):114–8. DOI:10.7869/djo.2013.25}

244. Mwangi N, Macleod D, Gichuhi S, Muthami L, Moorman C, Bascaran C, et al. Predictors of uptake of eye examination in people living with diabetes mellitus in three counties of Kenya. Trop Med Heal. 2017;45(41):1–10 PMID: 29299019 DOI:10.1186/s41182-017-0080-7

245. Nagrebetsky A, Brettell R, Roberts N, Farmer A. Smoking cessation in adults with diabetes : a systematic review and meta-analysis of data from randomised controlled trials. BMJ Open. 2014;4:e004107. doi:10.1136/bmjopen-2013-0041072014;4(3).

246. Namperumalsamy P, Kim R, Kaliaperumal K, Sekar A, Karthika A, Nirmalan PK. A pilot study on awareness of diabetic retinopathy among non-medical persons in South India. The challenge for eye care programmes in the region. Indian J Ophthalmol. 2004;52:247–51. PMID: 15510470

247. National Institute of Health - USA. Quality Assessment Tool for Observational Cohort and

Cross-Sectional Studies [Internet]. NIH QAT. Available from: https://www.nhlbi.nih.gov/health-pro/guidelines/in-develop/cardiovascular-risk-reduction/tools/cohort. Accessed on 15 Jan 2016.

248. National Survey of Blindness, Visual Impairment, Ocular Morbidity and Disability in Sri Lanka [Internet]. 2015. Available from: https://www.iapb.org/resources/national-survey-of-blindness-and-vi-sri-lanka-2014-15/ Accessed on 15 Sept 2016.

249. NCD Risk Factor Colloboration. Worldwide trends in diabetes since 1980: A pooled analysis of 751 population-based studies with 4.4 million participants. Lancet. 2016;387(10027):1513–30. PMID: 27061677 doi:10.1016/S0140-6736(16)00618-8.

250. Neubauer AS, Kernt M, Haritoglou C, Priglinger SG, Kampik A, Ulbig MW. Nonmydriatic screening for diabetic retinopathy by ultra-widefield scanning laser ophthalmoscopy (Optomap). Graefe's Arch Clin Exp Ophthalmol. 2008;246(2):229–35. PMID: 17622548 DOI: 10.1007/s00417-007-0631-4

251. Newcomb PA, Klein R, Massoth KM. Education to Increase Ophthalmologic Care in Older Onset Diabetes Patients: Indications from the Wisconsin Epidemiologic Study of Diabetic Retinopathy. J Diabetes Complications. 1992;6(4):211–7. PMID: 1482778

252. Newcomb PA, Klein R. Factors Associated with Compliance Following Diabetic Eye Screening. Journal of Diabet Complications. 1990;4(1):8-14. PMID: 2141844 https://doi.org/10.1016/0891-6632(90)90058-D

253. Newman-Casey P, Weizer J, Heisler M, Lee P, Stein J. Systematic Review of Educational Interventions to Improve Glaucoma Medication Adherence. Semin Ophthalmol. 2013;28(3):191–201 PMID: 23697623. doi:10.3109/08820538.2013.771198.

254. NHS Diabetic Eye Screening Programme. Grading definitions for referable disease. Public Heal England [Internet]. 2017;(2016527). Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/f

ile/582710/Grading_definitions_for_referrable_disease_2017_new_110117.pdf. Accessed on 16 Aug 2016.

255. Nishad AAN, Silva J De, Mallawarachchi M, Amaratunge MS. Prevalence and associated factors for Development of Diabetic Retinopathy in Clinic Followed up Cohort of Diabetic Patients in a Hospital Set up in Sri Lanka. SAS J Med. 2015;1(4):172–5.

256. Nkumbe H. Helping older people get the eye care they need. Community Eye Heal J. 2008;21(66):26–8.

257. Noordman J, van der Weijden T, van Dulmen S. Communication-related behavior change techniques used in face-to-face lifestyle interventions in primary care: A systematic review of the literature. Patient Educ Couns. 2012;89(2):227–44. PMID: 22878028. DOI:10.1016/j.pec.2012.07.006.

258. Norgaard M, Grauslund J. Automated Screening for Diabetic Retinopathy – A Systematic Review. Ophthalmic Res. 2018;60(1):9–17 https://doi.org/10.1159/000486284. PMID: 29339646 DOI:10.1159/000486284

259. Nsiah-Kumi P, Ortmeier SR, Brown AE. Disparities in diabetic retinopathy screening and disease for racial and ethnic minority populations-a literature review. J Natl Med Assoc. 2009;101(5):430–7. PMID: 19476196.

260. Olson JA, Strachan FM, Hipwell JH, Goatman KA, McHardy KC, Forrester J V., et al. A comparative evaluation of digital imaging, retinal photography and optometrist examination in screening for diabetic retinopathy. Diabet Med. 2003;20(7):528–34. PMID: 12823232

261. Onakpoya OH, Adeoye AO, Kolawole BA. Determinants of previous dilated eye examination among type II diabetics in Southwestern Nigeria. Eur J Intern Med. 2010;21(3):176–9. DOI: 10.1016/j.ejim.2010.01.009. PMID: 20493418

262. Orsmond GI, Cohn ES. The distinctive features of a feasibility study: Objectives and guiding

questions. OTJR Occup Particip Heal. 2015;35(3):169–77. PMID: 26594739 DOI:10.1177/1539449215578649

263. Orton E, Forbes-Haley A, Tunbridge L, Cohen S. Equity of uptake of a diabetic retinopathy screening programme in a geographically and socio-economically diverse population. Public Health. 2013;127(9):814–21. PMID: 23973045 DOI: 10.1016/j.puhe.2013.04.015

264. Ouwens M, Wollersheim H, Hermens R, Hulscher M, Grol R. Integrated care programmes for chronically ill patients: a review of systematic reviews. Int J Qual Heal Care. 2005;17(2):141–6. PMID: 15665066 DOI:10.1093/intqhc/mzi016

265. Owens D, Gibbins R, Lewis P, Wall S, Allen J, Morton R. Screening for diabetic retinopathy by general practioners: Ophthalmoscopy or retinal photography as 35 mm colour transparencies? Diabet Med. 1998;15(2):170–5. PMID: 9507921 DOI: 10.1002/(SICI)1096-9136(199802)15:2<170::AID-DIA518>3.0.CO;2-H

266. Paksin-hall A, Dent ML, Dong F, Ablah E, Dent ML, Dong F, et al. Factors Contributing to Diabetes Patients Not Receiving Annual Dilated Eye Examinations. Ophthalmic Epidemiol. 2013;20(5):281–7. https://doi.org/10.3109/09286586.2013.789531

267. Pallegedara A, Grimm M. Demand for private healthcare in a universal public healthcare system: Empirical evidence from Sri Lanka. Health Policy Plan. 2017;32(9):1267–84. PMID: 28981660 DOI: 10.1093/heapol/czx085

268. Pantoja T, Opiyo N, Lewin S, Paulsen E, Ciapponi A, Cs W, et al. Implementation strategies for health systems in low-income countries : an overview of systematic reviews. Cochrane Database Syst Rev. 2017;(9):CD011086. PMID: 28895659. DOI:10.1002/14651858.CD011086.pub2

269. Panwar N, Huang P, Lee J, Keane PA, Chuan TS, Richhariya A, et al. Fundus Photography in the 21st Century-A Review of Recent Technological Advances and Their Implications for Worldwide Healthcare. Telemed J E Health. 2016; 22(3): 198-208. PMID: 26308281. DOI:

10.1089/tmj.2015.0068

270. Pasagian-macaulay, Basch CE, Zybert P, Wylie-rosett J. Ophthalmic Knowledge and Beliefs Among Women with Diabetes. Diabetes Educ. 1997;23(4):433–7. https://doi.org/10.1177/014572179702300408

271. Pascolini D, Mariotti SP. Global estimates of visual impairment: 2010. Br J Ophthalmol. 2012;96(5):614–8. PMID: 22133988 DOI:10.1136/bjophthalmol-2011-300539

272. Pasquel FJ, Hendrick AM, Ryan M, Cason E, Ali MK, Narayan KMV. Cost-effectiveness of Different Diabetic Retinopathy Screening Modalities. J Diabetes Sci Technol. 2016; 10(2): 301-307. PMID: 26719134. doi:10.1177/1932296815624109

273. Patel M. The Socioeconomics of Diabetic Retinopathy. Data from the United Kingdom quantify the societal burden of diabetic eye [Internet]. Retinal Physician. 2018. p. 1–9. Available from: https://www.retinalphysician.com/issues/2009/september-2009/the-socioeconomics-of-diabetic-retinopathy. Accessed on 16 Aug 2017.

274. Paz SH, Varma R, Klein R, Wu J, Azen SP. Noncompliance with Vision Care Guidelines in Latinos with Type 2 Diabetes Mellitus. The Los Angeles Latino Eye Study. Ophthalmology. 2006;113(8):1372–7. PMID: 16769120 DOI:10.1016/j.ophtha.2006.04.018

275. Penchansky R, Thomas J. The concept of access-Definition and relationship to consumer satisfaction. Med Care. 1981;19(2):127–40. PMID: 7206846

276. Perrier M, Boucher MC, Angioi K, Gresset JA, Olivier S. Comparison of two, three and four 45 degrees image fields obtained with the Topcon CRW6 nonmydriatic camera for screening for diabetic retinopathy. Can J Ophthalmol.2003;38(7):569–74. PMID: 14740798

277. Peters D, Chao S. The sector-wide approach in health:what is it? where is it leading. Int J Heal Plann Manag. 1998;13(2):177–90. PMID:10185508. DOI:10.1002/(SICI)1099-1751(199804/06)13:2<177::AID-HPM504>3.0.CO;2-T

278. Peters DH, Paina L, Schleimann F. Sector-wide approaches (SWAps) in health : what have we learned ?. Health Policy Plan. 2013;28(8):884–90. PMID: 23236010 DOI:10.1093/heapol/czs128

279. Peters DH, Tran NT, Adam T. Implementation Research In Health. Alliance for Health Policy and Systems Research. World Health Organization. [Internet] Available from: http://apps.who.int/iris/bitstream/handle/10665/91758/9789241506212_eng.pdf?sequence=1. Accessed on 15 Sept 2018.

280. Petticrew M, Roberts H. Systematic Reviews in the Social Sciences: A Practical Guide. Synthesising the evidence. USA:Wiley-Blackwell; 2006. p 336-342

281. Phiri R, Keeffe JE, Harper CA, Taylor HR. Comparative study of the polaroid and digital non-mydriatic cameras in the detection of referrable diabetic retinopathy in Australia. Diabet Med. 2006;23(8):867–72. DOI: 10.1111/j.1464-5491.2006.01824.x

282. Piette J, Schillinger D, Potter M, Heisler M. Dimensions of patient-provider communication and diabetes self-care in an ethnically diverse population. J Gen Intern Med. 2003;18(8):624–33. PMID: 12911644.

283. Pinidiyapathirage MJ, Kasturiratne A, Ranawaka UK, Gunasekara D, Wijekoon N, Medagoda K, et al. The burden of diabetes mellitus and impaired fasting glucose in an urban population of Sri Lanka. Diabet Med. 2013;30(3):326–32. PMID: 22998091. DOI:10.1111/dme.12013

284. Piyasena MP, Murthy G. A Situation Analysis and Mapping of Availabillity of Services for Diabetic Retinopathy in the Health Care Institutions of the Western Province of Sri Lanka. MSc Dissertation - LSHTM. [Internet]. LSHTM; 2014. Available from: https://intra.lshtm.ac.uk/library/MSc_CEH/2013-2014/107722.pdf

285. Piyasena PN, Murthy GVS. A situation analysis of diabetic eye care service delivery in health care institutions of the Western Province of Sri Lanka. Ceylon Med J. 2017;62(3):205–6. DOI: http://doi.org/10.4038/cmj.v62i3.8527

286. Poore S, Foster A, Zondervan M, Blanchet K. Planning and developing services for diabetic retinopathy in Sub-Saharan Africa. Int J Heal policy Manag. 2015;4(1):19–28. DOI: 10.15171/IJHPM.2015.04.

287. Poverty Headcount Ratio Brief : Decomposition of Consumption Poverty. Dep Census Stat Publ [Internet]. 2014; Available from: http://www.statistics.gov.lk/poverty/HIES-2012-13-News Brief.pdf. Accessed on 19 Aug 2016.

288. Preti RC, Saraiva F, Junior JAT, Takahashi WY, da Silva MER. How much information do medical practitioners and endocrinologists have about diabetic retinopathy?. Clinics (Sao Paulo). 2007;62(3):273–8. PMID: 17589667

289. Puent B, Nichols K. Patients' perspectives on noncompliance with diabetic retinopathy standard of care guidelines. Optometry. 2004;75(11):709–16. PMID: 15597813

290. Ramachandran A, Snehalatha C, Ching R, Ma W. Diabetes in South-East Asia : An update. Diabetes Res Clin Pract. 2014;103(2):231–7. PMID: 24300015 DOI:10.1016/j.diabres.2013.11.011

291. Raman R, Rani PK, Reddi Rachepalle S, Gnanamoorthy P, Uthra S, Kumaramanickavel G, et al. Prevalence of Diabetic Retinopathy in India. Sankara Nethralaya Diabetic Retinopathy Epidemiology and Molecular Genetics Study Report 2. Ophthalmology. 2009;116(2):311–8. PMID: 19084275 DOI: 10.1016/j.ophtha.2008.09.010

292. Rani PK, Bhattarai Y, Sheeladevi S, Shivavaishnavi K. Ali MH, Babu JG. Analysis of yield of retinal imaging in a rural diabetes eye care model. Indian J Ophthalmol.2018; 66(2):233-237. PMID: 29380765. DOI: 10.4103/ijo.IJO_500_17

293. Rema M, Saravanan G, Deepa R, Mohan V. Familial clustering of diabetic retinopathy in South Indian Type 2 diabetic patients. Diabet Med. 2002;19(11):910–6. PMID: 12421427

294. Resnikoff S, Felch W, Gauthier T, Spivey B. The number of ophthalmologists in practice and

training worldwide : a growing gap despite more than 200 000 practitioners. Br J Ophthalmol. 2010;96(6):783–7. http://dx.doi.org/10.1136/bjophthalmol-2011-301378

295. Richard Wormald. Delivery of eye care to the elderly: Practical considerations. Community Eye Heal J. 1999;12(29):6–7.

296. Ridde V. Need for more and better implementation science in global health. BMJ Global Health 2016;1:e000115. doi:10.1136/bmjgh-2016-000115 2016;1–3.

297. Rim TH, Byun IH, Kim HS, Lee SY, Yoon JS. Factors Associated with Diabetic Retinopathy and Nephropathy Screening in Korea: The Third and Fourth Korea National Health and Nutrition Examination Survey (KNHANES III and IV). J Korean Med Sci. 2013;(6):814–20. DOI:10.3346/jkms.2013.28.6.814 PMID: 23772143

298. Robert C, Rury R, Carole A, Irene M. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group. Lancet. 1998;352(9131):837–53. PMID: 9742976

299. Rowe AK, Savigny D De, Lanata CF, Victora CG. How can we achieve and maintain high-quality performance of health workers in low-resource settings ? Lancet. 2005; 366(9490):1026-35. PMID: 16168785 DOI:10.1016/S0140-6736(05)67028-6

300. Ruamviboonsuk P, Wongcumchang N, Surawongsin P, Panyawatananukul E, Tiensuwan M. Screening for diabetic retinopathy in rural area using single-field, digital fundus images. J Med Assoc Thai. 2005;88(2):176–80. PMID: 15962667

301. Saadine JB, Fong DS, Yao J. Factors Associated with Follow-up Eye Examinations Among Persons with Diabetes. Retina. 2008;28:195–200. DOI: 10.1097/IAE.0b013e318115169a PMID: 18301023

302. Saari JM, Summanen P, Kivelä T, Saari KM. Sensitivity and specificity of digital retinal

images in grading diabetic retinopathy. Acta Ophthalmol Scand. 2004;82(2):126–30. PMID: 15043527 DOI:10.1111/j.1600-0420.2004.00240.x

303. Sabanayagam C, Banu R, Chee M, Lee R, Wang Y, Tan G, et al. Incidence and progression of diabetic retinopathy: a systematic review. Lancet Diabetes Endocrinol. 2018;S2213-8587(18):30128–1. PMID: 30005958 DOI:10.1016/S2213–8587(18).

304. Sabanayagam C, Yip W, Ting DS, Tan G, Wong T. Ten Emerging Trends in the Epidemiology of Diabetic Retinopathy. Ophthalmic Epidemiol. 2016;23(4):209–22. PMID: 27355693 DOI: 10.1080/09286586.2016.1193618

305. Saman W. Distribution of diabetic retinopathy among diabetics in southern province of Sri Lanka. European Journal of Preventive Medicine. 2015;3(2-1):5–8. doi:10.11648/j.ejpm.s.2015030201.12

306. Samarage SM . Migration and Human Resources for Health:From Awareness to Action-Health Care System:Sri Lanka. International Organization for Migration. [Internet] Available from https://www.iom.int/jahia/webdav/site/myjahiasite/shared/shared/mainsite/microsites/IDM/workshops/Migration_and_HR_23240306/MHCW_final_report.pdf. Accessed on 19 Aug 2016.

307. Scanlon P, Aldington S, Leal J, Luengo-Fernandez R, Oke J, Sivaprasad SS, et al. Development of a cost-effectiveness model for optimisation of the screening intervals in diabetic retinopathy screening. Heal Technol Assess. 2015;19(74):1–116. PMID:26384314. DOI: 10.3310/hta19740

308. Scanlon P, Foy C, Malhotra R, Aldington S. The Influence of Age, Duration of Diabetes, Cataract, and Pupil Size on Image Quality in Digital Photographic Retinal Screening. Diabetes Care. 2005;28(10):2448-53. PMID: 16186278

309. Scanlon PH, Aldington SJ, Stratton IM. Epidemiological Issues in Diabetic Retinopathy. Middle East Afr J Ophthalmol. 2013;20(4):293–300. PMID:24339678. doi: 10.4103/0974-9233.120007

310. Scanlon PH, Carter SC, Foy C, Husband RF, Abbas J, Bachmann MO. Diabetic retinopathy and socioeconomic deprivation in Gloucestershire. J Med Screen. 2008;15(3):118–21. PMID: 18927093 DOI: 10.1258/jms.2008.008013

311. Scanlon PH, Malhotra R, Greenwood RH, Aldington SJ, Foy C, Flatman M, et al. Comparison of two reference standards in validating two field mydriatic digital photography as a method of screening for diabetic retinopathy. Br J Ophthalmol. 2003;87(10):1258–63.

312. Scanlon PH, Malhotra R, Thomas G, Foyt C, Kirkpatrick JN, Lewis-Barned N, et al. The effectiveness of screening for diabetic retinopathy by digital imaging photography and technician ophthalmoscopy. Diabet Med. 2003;20(6):467–74. PMID:12786681

313. Scanlon PH, Stratton IM, Leese GP, Bachmann MO, Land M, Jones C. et al. Screening attendance, age group and diabetic retinopathy level at first screen. Diabet Med. 2016;33(7):904-11. PMID: 26337435 DOI: 10.1111/dme.12957

314. Scanlon PH. Screening Intervals for Diabetic Retinopathy and Implications for Care. Current Diabetes Reports. 2017;17(96):1–8. PMID:28875458. DOI: 10.1007/s11892-017-0928-6

315. Scanlon PH. The English National Screening Programme for diabetic retinopathy 2003–2016. Acta Diabetol. 2017;54(6):515–25. PMID: 28224275 DOI: 10.1007/s00592-017-0974-1 PMID: 28224275

316. Schillinger D, Piette J, Grumback K, Wang F, Wilson C, Daher C, et al. Closing the loop: Physician communication with diabetic patients who have low health literacy. Arch Intern Med. 2003;163(1):83–90. PMID: 12523921

317. Schmid KL, Schmid LM, Pedersen C. Knowledge of the ocular effects of diabetes among the general population of Australia and the members of. Clin Exp Optom. 2003;86(2):91–103. PMID: 12643805

318. Schoenfeld ER, Greene JM, Wu SY, Leske C. Patterns of Adherence to Diabetes Vision Care

Guidelines Baseline Findings from the Diabetic Retinopathy awareness program. Ophthalmology. 2001;108(03):563–71. PMID: 11237912

319. Seidman G, Atun R. Does task shifting yield cost savings and improve efficiency for health systems ? A systematic review of evidence from low-income and middle-income countries. Hum Resources Heal. 2017;15(1):29. PMID: 28407810. DOI: 10.1186/s12960-017-0200-9

320. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions : an overview of reviews and development of a theoretical framework. BMC Health Services Research; 2017;1–13. https://doi.org/10.1186/s12913-017-2031-8

321. Semasinghe WM. Social Development of Sri Lanka: Achievement and Challenges. Sri Lanka J Soc Sci. 2009;01(03):283–309.

322. Shah M, Noor A, Ormsby G, Chakrabarti R, Harper C, Islam F, et al. Attitude and perceptions of eye care workers and health adminsitrators regarding task sharing in screening and detection for management of diabetic retinopathy in Pakistan. Ophthalmic Epidemiol. 2018;25(2):169–75. PMID: 28976241 DOI: 10.1080/09286586.2017.1381273

323. Shamoon H, Zybert P, Basch CE, Walker EA, Howard CJ. The Effect of Health Education on the rate of ophthalmic examinations among African Americans with diabetes mellitus. Am J Public Health. 1999;89(12): 1878–1882. PMID: 10589324.

324. Shaw JE, Sicree RA, Zimmet PZ . Global estimates of the prevalence of diabetes for 2010 and 2030. Diabetes Res Clin Pract. 2010;87(1):04-14. PMID: 19896746. DOI: 10.1016/j.diabres.2009.10.007.

325. Shaw RL, Larkin M, Flowers P. Expanding the evidence within evidence-based healthcare: thinking about the context, acceptability and feasibility of interventions. Evid Based Med. 2014;19(6):201–3. PMID: 24799447 DOI: 10.1136/eb-2014-101791.

326. Shaw S, Rosen R, Rumbold B. What is integrated care? [Internet]. Research Report Nuffield

Trust. 2011. Available from: http://www.nuffieldtrust.org.uk/sites/files/nuffield/publication/what_is_integrated_care_research_report_june11.pdf. Accessed on 19 Aug 2016.

327. Sheppler CR, Lambert WE, Gardiner SK, Becker TM, Mansberger SL. Predicting adherence to diabetic eye examinations: Development of the compliance with annual diabetic eye exams survey. Ophthalmology. 2014;121(6):1212–9. PMID:24518614 DOI:10.1016/j.ophtha.2013.12.016

328. Shi L, Wu H, Dong J, Jiang K, Lu X, Shi J. Telemedicine for detecting diabetic retinopathy: a systematic review and meta-analysis. Br J Ophthalmol. 2015;99(6):823–31. PMID: 25563767. DOI: 10.1136/bjophthalmol-2014-305631.

329. Shi R, Zhao L, Wang F, Liu F, Chen Z, Li R, et al. Effects of lipid-lowering agents on diabetic retinopathy: a Meta-analysis and systematic review. Int J Ophthalmol. 2018;11(2):287–95. PMID: 29487821. DOI: 10.18240/ijo.2018.02.18.

330. Shiffman R, Jacobsen G, Nussbaun J, Desai U, Carey D, Glasser D, et al. Comparison of a Digital Retinal Imaging System and Seven-Field Stereo Colour Fundus Photography to Detect Diabetic Retinopathy in the Primary Care Environment. Ophthalmic Surgery, Laser and Imaging. 2005;36:46–57. PMID: 15688971

331. Shih HCh, Chou P, Chen SJ, Liu JH, Lee FL, Liu CM, et al. A Community Based Study of the Willingness to pay associated with Screening for Diabetic Retinopathy among Type 2 Diabetes in Kinmen, Taiwan. J Epidemiol. 2007;17(6):186–95. PMID: 18094517

332. Shoemaker SJ, Wolf MS, Brach C. Development of the Patient Education Materials Assessment Tool (PEMAT): A new measure of understandability and actionability for print and audiovisual patient information. Patient Educ Couns. 2014;96(3):395-403. PMID: 24973195 doi:10.1016/j.pec.2014.05.027.

333. Silva D De. How many doctors should we train for Sri Lanka? System dynamics modelling of

training needs. Ceylon Medical Journal. 2017;62(4):233–37. DOI: http://doi.org/10.4038/cmj.v62i4.8573

334. Sivaprasad S, Gupta B, Crosby-Nwaobi R, Evans J. Prevalence of Diabetic Retinopathy in Various Ethnic Groups: A Worldwide Perspective. Surv Ophthalmol. 2012;57(4):347–70. PMID: 22542913 DOI:10.1016/j.survophthal.2012.01.004

335. Smithto H, Caroline H, Smith T. Feasibility studies-Their importance in the design of clinical trials. J Physiother Pain Assoc. 2013;(35):12–7.

336. Sri Lanka-Addressing the Needs of an Aging Population-Document of the World Bank May 28, 2008 [Internet]. Available from: http://siteresources.worldbank.org/INTSRILANKA/Resources/LKAgingFullRep.pdf. Accessed on 19 Aug 2014.

337. Srinivasan N, John D, Rebekah G, Kujur E, Paul P, John S. Diabetes and Diabetic Retinopathy: Knowledge, Attitude, Practice (KAP) among Diabetic Patients in A Tertiary Eye Care Centre. J Clin Diagn Res. 2017;11(7):1–7 PMID:28892947 DOI: 10.7860/JCDR/2017/27027.10174

338. Stefansson E. Prevention of diabetic blindness. Br J Ophthalmol. 2006;90(1):2–3. PMID: 16361653 doi:10.1136/bjo.2005.082065.

339. Stephanie A, Miller W. Spectrum Bias or Spectrum Effect ? Subgroup Variation in Diagnostic Test Evaluation. Ann Intern Med. 2002;137:598–603. PMID: 12353947

340. Storey PP, Murchinson AP, Pizzi LT, Hark LA, Dai Y, Leiby BE, et al. Impact of Physician Communication on Diabetic Eye Examination Adherence: Results from a Retrospective Cohort Analysis. Retina. 2016; 36:20–7. PMID:26098386 DOI:10.1097/IAE.0000000000000652

341. Stratton I, Kohner E, Aldington S, Turner R, Holman R, Manley S, et al. UKPDS 50. Risk

factors for incidence and progression of retinopathy in type 11 diabetes over 6 years from diagnosis. Diabetologia. 2001;44(2):156–63 PMID: 11270671 DOI: 10.1007/s001250051594.

342. Strutton R, Chemin A Du, Stratton IM, Forster AS. System-level and patient-level explanations for non-attendance at diabetic retinopathy screening in Sutton and Merton (London,UK): a qualitative analysis of a service evaluation. BMJ Open 2016;6:e010952.doi:10.1136/bmjopen-2015-010952

343. Suansilpong A, Rawdaree P. Accuracy of Single-Feild Nonmydriatic Digital Fundus Image in Screening for Diabetic Retinopathy. J Med Assoc Thai. 2008;91(9):1397–403. PMID: 18843870

344. Sundling V, Gulbrandsen P, Straand J. Sensitivity and specificity of Norwegian optometrists' evaluation of diabetic retinopathy in single-field retinal images-a cross-sectional experimental study. BMC Health Serv Res. 2013;13:17. https://doi.org/10.1186/1472-6963-13-17

345. Sureshkumar K, Murthy GVS, Munuswamy S, Goenka S, Kuper H. "Care for Stroke", a web-based, smartphone-enabled educational intervention for management of physical disabilities following stroke: feasibility in the Indian context. BMJ Innov. 2015;1(3):127–36. DOI:10.1136/bmjinnov-2015-000056

346. Sustersic M, Gauchet A, Foote A, Bosson J. How best to use and evaluate Patient Information Leaflets given during a consultation : a systematic review of literature reviews. Health Expect. 2017;20(4):531–42. PMID: 27669682. DOI: 10.1111/hex.12487

347. Swanson M. Retinopathy screening in individuals with type 2 diabetes: who, how, how often, and at what cost-an epidemiologic review. Optometry. 2005;76(11):636–46. PMID: 16298316 DOI: 10.1016/j.optm.2005.08.019

348. Taylor DJ, Goatman KA, Gregory A, Histed M, Martin CN, Warburton TJ, et al. Image-quality standardization for diabetic retinopathy screening. Expert Rev Ophthalmol. 2009;4(5):469–76.

349. Taylor DJ, Scoyoc LV, Hawley S. Health Insurance and Mammography: Would a Medi Care buy-in Take Us to Universal Screening. Health Serv Res. 2002;37(6):1469–86. PMID: 12546282

350. Taylor SP, Nicolle C, Maguire M. Cross-cultural communication barriers in health care. Nurs Stand. 2013;27(31):35-49. PMID:23641636.

351. Taylor-Phillips S, Mistry H, Leslie R, Todkill D, Tsertsvadze A, Connock M, et al. Extending the diabetic retinopathy screening interval beyond 1 year: systematic review. Br J Ophthalmol. 2016;100(1):105–14. PMID:25586713. DOI: 10.1136/bjophthalmol-2014-305938.

352. Thapa R, Paudyal G, Maharjan N, Bernstein P. Demographics and awareness of diabetic retinopathy among diabetic patients attending the vitreo-retinal service at a tertiary eye care center in Nepal. Nepal J Ophthalmol. 2012;4(1):10–6. PMID: 22343990. DOI:10.3126/nepjoph.v4i1.5844.

353. The Diabetes Control and Complications Trial Research Group. The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med. 1993;329(14):977–86. PMID: 8366922 DOI:10.1056/NEJM199309303291401

354. The Diabetic Retinopathy Screening Implementation Group - Diabetic Retinopathy Screening Services in Scotland:Recommendations for Implementation [Internet]. 2003. Available from: http://www.ndrs-wp.scot.nhs.uk/wp-content/uploads/2013/04/Recommendations-for-Implementing-DRS.pdf Accessed on 15 Sep 2017

355. The Diabetic Retinopathy Srudy Research Group. Indications for photocoagulation treatment of diabetic retinopathy: Diabetic Retinopathy Study Report no. 14. Int Ophthalmol Clin.1987; (27)4:239–53. PMID: 2447027

356. The Diabetic Retinopathy Study Research Group. Photocoagulation treatment of proliferative diabetic retinopathy. Clinical application of Diabetic Retinopathy Study (DRS) findings, DRS

Report Number 8. Ophthalmology. 1981;88(7):583–600 PMID: 7196564.

357. The Diabetic Retinopathy Study Research Group. Photocoagulation Treatment of Proliferative Diabetic Retinopathy. Ophthalmology.1976;88(7):583–600. doi.org/10.1016/S0161-6420(81)34978-1

358. The Diabetic Retinopathy Study Research Group. Photocoagulation Treatment of Proliferative Diabetic Retinopathy. Second Report of Diabetic Retinopathy Study Findings. Ophthalmology 1978;85(1):82-106. PMID:345173 https://doi.org/10.1016/S0161-6420(78)35693-1

359. The Diabetic Retinopathy Vitrectomy Study Research Group. Early Vitrectomy for Severe Proliferative Diabetic Retinopathy in Eyes with Useful Vision. Results of a randomized trail--Diabetic Retinopathy Vitrectomy Study Report 3. Ophthalmology. 1988;95(10):1307–20.

360. The Diabetic Retinopathy Vitrectomy Study Research Group. Early Vitrectomy for Severe Vitreous Hemorrhage in Diabetic Retinopathy. Two-Year Results of a Randomized Trial-Diabetic Retinopathy Vitrectomy Study Report 2. Arch Ophthalmol. 1985;103(11):1644–1652 PMID: 2865943 doi:10.1001/archopht.1985.01050110038020.

361. The Royal College of Ophthalmologists Diabetic Retinopathy Guidelines. Version 2013;2012(July) [Internet]. Available from: https://www.rcophth.ac.uk/wp-content/uploads/2014/12/2013-SCI-301-FINAL-DR-GUIDELINES-DEC-2012-updated-July-2013.pdf. Accessed on 15 Jan 2016

362. The Saint Vincent Declaration. Acta Ophthalmol Scand. 1997;75(S223):63. Available from: http://onlinelibrary.wiley.com/doi/10.1111/j.1600-0420.1997.tb00440.x/pdf. Accessed on 15 Aug 2016.

363. The World Bank- Data-Sri Lanka [Internet]. Available from: http://data.worldbank.org/country/sri-lanka. Accessed on 19 Aug 2014.

364. The World Health Organisation Frame Work : Health Services Development. [Internet] 2017

http://www.wpro.who.int/health_services/health_systems_framework/en/. Accessed on 12 Feb 2018.

365. The Writing Team for the Diabetes Conrol and Complications Trial. Effect of Intensive Therapy on the Microvascular Complications of Type 1 Diabetes mellitus. JAMA Ophthalmol. 2002;287(19):2563–2569 PMID: 12020338.

366. Thulasiraj RD. Advocacy to improve the delivery of eye care. Community Eye Heal J. 2007;20(64):66–7. PMID: 18330440

367. Ting D, Cheung G, Wong T. Diabetic retinopathy: global prevalence, major risk factors, screening practices and public health challenges : a review. Clin Exp Ophthalmol. 2016;44(4):260–277. PMID: 26716602 doi: 10.1111/ceo.12696.

368. Tong A, Sainsbury P, Craig J. Consolidated criterio for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus group. Int J Qual Heal Care. 2007;19(6):349–57. https://doi.org/10.1093/intqhc/mzm042

369. Tran K, Mendel TA, Holbrook KL, Yates PA. Construction of an inexpensive, hand-held fundus camera through modification of a consumer "point-and-shoot" camera. Investig Ophthalmol Vis Sci. 2012;53(12):7600–7. doi: 10.1167/iovs.12-10449. PMID: 23049089

370. Tran KT, Mendel TA, Holbrook KL, Yates PA. Construction of an inexpensive, hand-held fundus camera through modification of a consumer "point-and-shoot" camera. Investig Ophthalmol Vis Sci. 2012;53(12):7600–7607. DOI:10.1167/iovs.12-10449

371. Trento M, Bajardi M, Borgo E, Passera P, Maurino M, Gibbins R, et al. Perceptions of diabetic retinopathy and screening procedures among diabetic people. Diabet Med. 2002;19(10):810–3. PMID:12358866

372. Tsiachristas A, Stein KV, Evers S, Mölken MR. Performing Economic Evaluation of Integrated Care : Highway to Hell or Stairway to Heaven? Int J Integr Care. 2016;16(4):3

DOI: http://doi.org/10.5334/ijic.2472

373. Tu K, Palmer P, Sen S, Matthew P, Khaleel A. Comparison of optometry vs digital photography screening for diabetic retinopathy in a single district. Eye. 2004;18(July 2002):3–8. DOI:10.1038/sj.eye.6700497

374. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonyl ureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet. 1998;352(9131):837–53. PMID: 9742976

375. UNDP. UNDP's role and leadership on achieving the MDGs in Sri Lanka. United Nations. 2018-07-05. [Internet] Available from: http://www.lk.undp.org/content/srilanka/en/home/post-2015/mdgoverview.html. Accessed on 05th July 2018.

376. UNICEF. Understanding the Social Ecological Model (SEM) and Communication for Development_Module 1. 2015 [Internet]. Available from: https://www.unicef.org/earlychildhood/files/Module_1_-_MNCHN_C4D_Guide.docx Accessed on 15 June 2016.

377. vanEijk KND, Blom JW, Gussekloo J, Polak BCP, Groeneveld Y. Diabetic retinopathy screening in patients with diabetes mellitus in primary care: Incentives and barriers to screening attendance. Diabetes Res Clin Pract. 2011;96(1):10–6. PMID:22137363 DOI:10.1016/j.diabres.2011.11.003

378. vonElm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. PLoS Med. 2007;4(10):e296. https://doi.org/10.1371/journal.pmed.

379. Walker EA, Basch CE, Howard C, Zybert PA, Kromholz WN, Shamoon H. Incentives and Barriers to RetinoDathv Screening Among African-Amer&an/ With Diabetes. J Diabetes Complications. 1997;11(5)298-306 PMID:9424171

380. Wang D, Ding X, He M, Yan L, Kuang J, Geng Q, et al. Use of eye care services among diabetic patients in Urban and Rural China. Ophthalmology. 2010;117(9):1755–62. PMID: 20471689 DOI: 10.1016/j.ophtha.2010.01.019

381. Wang X, Tang L, Gao L, Yang Y, Cao D, Li Y. Myopia and diabetic retinopathy: A systematic review and meta-analysis. Diabetes Res Clin Pract. 2015;111:1–9. PMID: 26531140 DOI: 10.1016/j.diabres.2015.10.020

382. Whitehead D. A social cognitive model for health education/health promotion practice. J Adv Nurs. 2001;36(3):417–25. PMID:11686756

383. Whiting DR, Guariguata L, Weil C, Shaw J. IDF Diabetes Atlas: Global estimates of the prevalence of diabetes for 2011 and 2030. Diabetes Res Clin Pract. 2011;94(3):311–21. PMID: 22079683 DOI: 10.1016/j.diabres.2011.10.029

384. Whiting PF, Rutjes AWS, Westwood ME, Mallet S, Deeks JJ, Reitsma JB, et al. Research and Reporting Methods Accuracy Studies. Ann Intern Med. 2011;155(4):529–36. PMID: 22007046. DOI:10.7326/0003-4819-155-8-201110180-00009

385. WHO. World Health Organization (Foundation Document). Health Education: Theoritical concepts, effective strategies and core competencies [Internet]. Genewa, Swisterland; 2012. Available from: http://applications.emro.who.int/dsaf/EMRPUB_2012_EN_1362.pdf. Accessed on 15 Aug 2016.

386. Wijeyaratne C, Arambepola C, Karunapema P, Periyasamy K, Hemachandra N, Ponnamperuma G, et al. Capacity-building of the allied health workforce to prevent and control diabetes : lessons learnt from the National Initiative to Reinforce and Organize General Diabetes Care in Sri Lanka (NIROGI Lanka) project. WHO South East Asia J Public Health.2016;5(1):34–9. PMID: 28604395 DOI: 10.4103/2224-3151.206550

387. Williams A, Liu P, Muir K, Waxman E. Behavioural economics and diabetic eye exams. Prev Med (Baltim). 2018;112(March):76–87. PMID: 29626555 DOI: 10.1016/j.ypmed.2018.04.006

388. Williams AM, Muir KW, Rosdahl JA. Readability of patient education materials in ophthalmology : a single-institution study and systematic review. BMC Ophthalmology; 2016;16:133. PMID: 27487960 DOI: 10.1186/s12886-016-0315-0.

389. Williams R, Airey M, Baxter H, Forrester J, Kennedy-Martin T, Girach A. Epidemiology of diabetic retinopathy and macular oedema : a systematic review. Eye. 2004;18(10):963–83. PMID: 15232600 DOI: 10.1038/sj.eye.6701476

390. Wilson J, G Jungenr. Principles and Practice of Screening of Disease [Internet]. 1968. Available from: http://www.who.int/bulletin/volumes/86/4/07-050112bp.pdf. Accessed on 16 Aug 2016.

391. Wong TY, Yau J, Rogers S, Kawasaki R, Lamoureux EL, Kowalski J. Global Prevalence of Diabetic Retinopathy: Pooled Data from Population studies from the United States, Australia, Europe and Asia. Meta Eye Group. Investig Ophthalmol Vis Sci. 2011;52(14):4818.

392. World Health Organisation (WHO). Integrated care models: An overview. Health Service Delivery Program [Internet]. 2016;42. Available from: http://www.euro.who.int/__data/assets/pdf_file/0005/322475/Integrated-care-models-overview.pdf Accessed on 19 Aug 2016.

393. World Health Organisation. Integrated health services-what and why? Tech Br No 1 [Internet]. 2008;(1):1–10. Available from: https://www.who.int/healthsystems/technical_brief_final.pdf Accessed on 16 Aug 2016.

394. World Health Organisation. Shanghai Declaration on Health Promotion in the 2030 Agenda for Sustainable Development. [Internet]. 2016;1–2. Available from: http://www.who.int/healthpromotion/conferences/9gchp/shanghai-declaration.pdf?ua=1. Accesssed on 16 Aug 2017.

395. World Health Organization. Advocacy Strategies for Health and Development: Development Communication in Action - A Background Paper to the Inter- Agency Meeting on Advocacy

Strategies for Health and Development : Development Communication in Action. [Internet] 1992 Geveva. Available from: http://apps.who.int/iris/bitstream/handle/10665/70051/HED_92.4_eng.pdf?sequence=1. Accessed on 16 Aug 2016.

396. World Health Organization. Health - United Nations Sustainable Development. WHO [Internet]. 2010;1–92. Available from: https://www.who.int/who-un/about/sdg/en/. Accessed on 19 Aug 2016.

397. World Health Organization. Prevention of blindness from diabetes mellitus. Geneva WHO [Internet]. 2005;1–48. Availablefrom: https://www.who.int/blindness/Prevention%20of%20Blindness%20from%20Diabetes%20Mellitus-with-cover-small.pdf?ua=1. Accessed on 18 Jan 2016.

398. World Health Organization. Universal Eye Health-A Global Action Plan 2014-2019 [Internet]. 2013. Available from: https://www.who.int/blindness/AP2014_19_English.pdf?ua=1. Accessed on 16 Aug 2016.

399. Xinzhi Z, Andersen R, Saaddine JB, Beckles, Gloria LA, Duenas MR, Lee PP. Measuring Access to Eye Care: A Public Health Perspective. Ophthalmic Epidemiol 2008;15(6):418–25. PMID: 19065435 DOI: 10.1080/09286580802399102

400. Xiong Y, Liu L, Chen Y, Zhao J. Survey on the awareness of diabetic retinopathy among people with diabetes in the Songnan community of Shanghai. Int Eye Sci. 2015;15(7):1117-21.

401. Yamey G. What are the barriers to scaling up health interventions in low and middle income countries ? A qualitative study of academic leaders in implementation science. Global Health. 2012;8(1):11. PMID: 22643120 DOI: 10.1186/1744-8603-8-11

402. Yan X, Liu T, Gruber L, He M, Congdon N, FL F, et al. Attitudes of Physicians, Patients, and Village Health Workers Toward Glaucoma and Diabetic Retinopathy in Rural China: a focus group study. Arch Ophthalmol. 2012;130(6):761-70. PMID: 22801838 DOI:

10.1001/archophthalmol.2012.145.

403. Yau JWY, Rogers SL, Kawasaki R, Lamoureux EL, Kowalski JW, Bek T, et al. Global prevalence and major risk factors of diabetic retinopathy. Diabetes Care. 2012;35(3):556–64. http://dx.doi.org/10.2337/dc11-1909. PMID: 22301125.

404. Yau JWY, Rogers SL, Kawasaki R, Lamoureux EL, Kowalski JW, Bek T, et al. Global prevalence and major risk factors of diabetic retinopathy. Diabetes Care. 2012;35:556–64. doi.org/10.2337/dc11-1909

405. Yeo ST, Edwards RT, Fargher EA, Luzio SD, Thomas RL, Owens DR. Preferences of people with diabetes for diabetic retinopathy screening: A discrete choice experiment. Diabet Med. 2012;29(7):869–77. PMID: 22414336 DOI: 10.1111/j.1464-5491.2012.03636.x

406. Yeo ST, Edwards RT, Luzio SD, Charles JM, Thomas RL, Peters JM, et al. Diabetic retinopathy screening: Perspectives of people with diabetes, screening intervals and costs of attending screening. Diabet Med. 2012;29(7):878–85. PMID: 22414383 DOI:10.1111/j.1464-5491.2012.03637.x

407. Zabetian A, Sanchez IM, Narayan KMV, Hwang CK, Ali MK. Global rural diabetes prevalence: A systematic review and meta-analysis covering 1990-2012. Diabetes Res Clin Pract. 2014;104(2):206–12. PMID: 24507869 DOI: 10.1016/j.diabres.2014.01.005

408. Zhang K, Ferreyra HA, Grob S, Bedell M, Zhang JJ. Chapter 46 - Diabetic Retinopathy: Genetics and Etiologic Mechanisms [Internet]. Fifth Edition. Vol. 1, Retina. Elsevier Inc. p 925-939. Available from: https://www.sciencedirect.com/science/article/pii/B9781455707379000461?via%3Dihub. Accessed on 15 Jan 2017.

409. Zhang P, Zhang X, Brown J, Vistisen D, Sicree R, Shaw J, et al. Global healthcare expenditure on diabetes for 2010 and 2030. Diabetes Res Clin Pract. 2010;87(3):293–301. PMID: 20171754 DOI:10.1016/j.diabres.2010.01.026

410. Zhang X, Norris SL, Saadine J, Chowdhury FM, Horsley T, Kanjilal S, et al. Effectiveness of Interventions to Promote Screening for Diabetic Retinopathy. Am J Prev Med. 2007;33(4):318–35. PMID:17888859 DOI: 10.1016/j.amepre.2007.05.002

411. Zhang X, Williams DE, Beckles GL, Gregg EW, Barker L, Luo H, et al. Diabetic retinopathy, dilated eye examination, and eye care education among African Americans, 1997 and 2004. J Natl Med Assoc. 2009;101(10):1015–21. PMID: 19860301

412. Zheng Y, He M, Congdon N. The worldwide epidemic of diabetic retinopathy. Indian J Ophthalmol. 2018;60(5):2005–8. PMID: 22944754 DOI:10.4103/0301-4738.100542

413. Zhou Y, Zhang Y, Shi K, Wang C. Body mass index and risk of diabetic retinopathy-A meta-analysis and systematic review. Medicine (Baltimore). 2017;96(22):e6754. PMID: 28562529. DOI:10.1097/MD.0000000000006754

414. Zhu W, Meng Y, Wu Y, Xu M, Lu J. Association of alcohol intake with risk of diabetic retinopathy : a meta- analysis of observational studies. Sci Rep. 2017 Jan 31;7(1):4. PMID: 28127054 DOI: 10.1038/s41598-017-00034-w

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Appendix 11

11.1 - Journal copyright statements and co-author permission letters

Illustrative Material

Health educational intervention video and leaflet contain in a CD-ROM in the backcover.

APPENDICES

Appendix 1 - Ethics Approval Letters

1.1 - Ethics approval (formative research) from the London School of Hygiene and Tropical Medicine - UK

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

Observational / Interventions Research Ethics Committee

Dr. Mapa Mudiyanselage Prabhath Nishantha Piyasena

LSHTM

4 October 2016

Dear Dr. Mapa Mudiyanselage Prabhath Nishantha Piyasena

LSHTM Ethics Ref: 11789 **Study Title:** A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka (Phase before Upgrade)

Thank you for responding to the Observational Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received,

where relevant. **Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Local Approval	Local Ethics_NEH ERC Approval	01/03/2016	V1.1
Protocol / Proposal	A1_Formative Research_Topic Guide_V1.16_V1.2	01/08/2016	V1.2
Protocol / Proposal	A2_Formative Research Questionnair V1.16_V1.2	01/08/2016	V1.2
Investigator CV	Investigator CV	01/08/2016	V1.2
Information Sheet	1_Consent Form Diabetic Patient_English Language_V1.2	01/08/2016	V1.2
Information Sheet	2_Consent Form Service Provider_English Language_V1.2	01/08/2016	V1.2
Information Sheet	4_Information Leaflet Participants_Qualitative Study_English Langiage_V1.2	01/08/2016	V1.2
Information Sheet	6_Consent Forms Translated_Local Language_Sinhalese_V1.2_All	01/08/2016	V1.2

Information Sheet	7_Information Sheets_Translated_Sinhala_V1.2	01/08/2016	V1.2
Information Sheet	8_Consent Forms Translated_Local Language_ Tamil_All V1.2	01/08/2016	V1.2
Information Sheet	9_Information Sheets_Translated Tamil_V1.2	01/08/2016	V1.2
Investigator CV	Supervisor CV_ProfGVS Murthy	09/08/2016	V1.2
Covering Letter	LSHTM Ethics_Reply Letter_Sept_2016_V1.17	28/09/2016	V1.17
Protocol / Proposal	Prabhath_Project Proposal_V1.17_SEPT_ LSHTM_ERC_Revised	28/09/2016	V1.17

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

[redacted]

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

1.2 - Ethics approval (phase after upgrading) from the London School of Hygiene and Tropical Medicine - UK

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

Observational / Interventions Research Ethics Committee

Dr. Mapa Mudiyanselage Prabhath Nishantha Piyasena
LSHTM

19 May 2017

Dear Dr. Mapa Mudiyanselage Prabhath Nishantha Piyasena

Study Title: A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka (Phase after Upgrading)

LSHTM Ethics Ref: 12072

Thank you for responding to the Observational Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been re-

ceived, where relevant. **Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Local Approval	Local Ethics_NEH ERC Approval	16/02/2016	V1.1
Protocol / Proposal	1_Data Collection Form_DRS Validation_V1.18	12/02/2017	V1.18
Protocol / Proposal	2_Data Collection Form_DRS Grading_V1.18	12/02/2017	V1.18
Protocol / Proposal	3_Data Collection Form_HE Intervention_V1.18	12/02/2017	V1.18
Protocol / Proposal	4_Data Collection Form_HE Intervention_V1.18	12/02/2017	V1.18
Protocol / Proposal	14_Topic Guide_HE Intervention_User_V1.18	12/02/2017	V1.18
Protocol / Proposal	15_Topic Guide_HE Intervention_Provider_V1.18	12/02/2017	V1.18
Protocol / Proposal	5_6_7_HE Intervention Development Guides_V1.18	12/02/2017	V1.18
Investigator CV	Supervisor CV_ProfGVS Murthy	12/02/2017	V1.18
Investigator CV	Investigator CV	12/02/2017	V1.18
Covering Letter	LSHTM Ethics Clarifications Letter_May_2017_ProfGV	07/05/2017	V1.19
Protocol / Proposal	Study Protocol_Phase after Upgrading_V1.19_Revised_May_2017	07/05/2017	V1.19

Information Sheet	Information Sheet_8_Validation Study_V1.3	07/05/2017	V1.3
Information Sheet	Information Sheet_9_1_HE Intervention_V1.3	07/05/2017	V1.3
Information Sheet	Information Sheet_9_2_HE Intervention_V1.3	07/05/2017	V1.3
Information Sheet	Information Sheet_10.1_Participatory Workshop_V1.3	07/05/2017	V1.3
Information Sheet	Information Sheet_10.2_Stake Holder Meeting_V1.3	07/05/2017	V1.3
Information Sheet	Consent Form_11_DRS Validation_V1.3	07/05/2017	V1.3
Information Sheet	Consent Form_12_HE Intervention_Provider_V1.3	07/05/2017	V1.3
Information Sheet	Consent Form_13_HE Intervention_User_V1.3	07/05/2017	V1.3

Information Sheet	Consent Form_14_1_HE Intervention_Stake Holder_V1.3	07/05/2017	V1.3
Information Sheet	Consent Form_14_2_HE Partcipatory Workshop_V1.3	07/05/2017	V1.3
Local Approval	NEH_ERC_Amendments_Approval	07/05/2017	V1.18

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

1.3 - Ethics approval (full proposal) from the National Eye Hospital - Sri Lanka

National Eye Hospital
Sri Lanka

National Eye Hospital, Deans Road, Colombo 10, Sri Lanka - Tel 0112693911 -(Ext 300) - Email: nehercsecretary@gmail.com web: nationaleyehospital.health.gov.lk

15th February, 2016

Dr. M.M.P.N. Piyasena,
Medical Officer,
National Eye Hospital,
Colombo 10.

Dear Dr. Piyasena,

Reference No. ERC/NEH/2016/28

Project Title:- A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

Thank you for submitting the above research proposal, which was evaluated by the members of the Ethics Review Committee of the National Eye Hospital at its meeting, held on 12.02.2016. The following documents were reviewed:

1. Completed application form
2. Study protocol
3. Patient information documents and consent forms
4. Investigator's curriculum vitae
5. Data collection form

I am pleased to inform you that the Ethics Review Committee members approved the conduct of this study for stages 1, 2 and 3 as per submitted protocol. The following members participated:

- Dr. Sriyani Nanayakkara – NEH/affiliate member
- Dr. M. Radhakrishnan - Non-affiliate member (Secretary)
- Ms. Fazna Ajward - NEH/affiliate member
- Dr. D. Wijewardena - NEH/affiliate member
- Dr. Kapila Banduthilake - NEH/affiliate member
- Dr. Charith Fonseka - NEH/affiliate member (Chairman)
- Eng. Lalith Wikremarathna - Non-affiliate member

It was noted that neither you nor a member of your research team was present at the meeting when the research study was reviewed.
Thank you.

Yours sincerely,

[redacted]

Secretary
Ethics Review Committee
National Eye Hospital
Colombo, Sri Lanka.

Dr. M. Radhakrishnan,
Secretary,
Ethics Review Committee,
National Eye Hospital.

1.4 - Ethics approval (phase after upgrading) from the National Eye Hospital - Sri Lanka

National Eye Hospital
Sri Lanka

National Eye Hospital, Deans Road, Colombo 10, Sri Lanka - Tel 0112693911 -(Ext 300) - Email: nehercsecretary@gmail.com web: nationaleyehospital.health.gov.lk

10th March 2017

Dr. M.M.P.N. Piyasena,
Medical Officer,
Vitreo-retina Unit,
National Eye Hospital,
Colombo 10.

Dear Dr. M.M.P.N. Piyasena,

Reference No. ERC/NEH/2017/32

Project Title - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka. (Phase after upgrading)

Thank you for submitting the above research proposal which was evaluated by the members of the Ethics Review Committee at its meeting, held on 10.03.2017.
The following documents were reviewed:

1. Completed application form
2. Study protocol Version V1.18©
3. Patient information documents and consent forms
4. Investigator's curriculum vitae
5. Clinical data collection form

I am pleased to inform you that the Ethics Review Committee members approved the conduct of this study as per submitted protocol. The following members participated:

- Dr. Aruna Fernando – Non-affiliate member
- Dr. M. Radhakrishnan - Non-affiliate member (Secretary)
- Dr. Kapila Banduthilake - NEH/affiliate member
- Rev. Dr. Noel Dias - Non-affiliate member
- Ms. Sanduni Ruwandima - NEH/affiliate member

It was noted that neither you nor a member of your research team was present at the meeting when the research study was reviewed.

Thank you.

Yours sincerely,

[redacted]

Secretary
Ethics Review Committee
National Eye Hospital
Colombo, Sri Lanka.

Dr. M. Radhakrishnan,
Secretary,
Ethics Review Committee,
National Eye Hospital.

National Eye Hospital, Deans Road, Colombo 10, Sri Lanka - Tel 0112693911 Email: ehcolombo.erc@gmail.com

Appendix 2 - Data collection questionnaire schedules

A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

2.1 - Baseline Data Collection (FGD - Service Users) – Questionnaire

1.Patient code number | 2. Date DD / MM / YYYY

3.Name of the health care institution attending

4.District of the health care institution

A. Demographic Data of the Diabetic Patient -

5.Date of birth DD / MM / YYYY | 6. Age | 7. Gender

1	Male	
2	Female	

8.Place of residence By the address

9. Distance to the healthcare institution Km

10.Ethnic Group

1	Sinhalese	
2	Tamil	
3	Moors	
4	Other	

11. Main Language

1	Sinhalese	
2	Tamil	
3	Moors	
2	Other	

12.Educational Attainment

1	No Schooling	
2	Primary	
3	Secondary	
4	GCE O/L	
5	GCE A/L	
6	Degree and Above	

13. Level of Household income

1	<30,220 LKR	
2	<41,478 LKR	
3	>69,880 LKR	

B. Past Medical History -

History of Diabetes

14.Age at the diagnosis Yrs | 15. Duration of DM Yrs

16.Glycaemic control FBS | 17. HbA1c

18.Other comorbidities

1	Hypertension	
2	Hypercholesterolemia	
3	Ischaemic heart diseases	
4	Renal disorders	
5	Neuropathy	
6	Leg / peripheral ulcers	
7	Other……..	

C. Past Ocular History –

History Related to Past DR Screening (only)

18.Presenting VA R L

19. BCVA R L

20.Mode of referral for DR screening if underwent

1	Self – Other symptoms	
2	Self – Due to DM / DR	
3	Physician / GP referral	
4	Optometrist	
5	Other	

21.Last eye examination – Method of examination

22. Date of Ex DD / MM / YYYY

(as reported by the patient)

1	Direct Ophthalmoscope	
2	Slit lamp examination	
3	Indirect ophthalmoscopy	
4	Retinal Imaging - Mydriatic	
5	Retinal Imaging - Nonmyd	
6	No funduscopy	

23.Details of Follow-up – Frequency of follow up - DR screening or treatment

1	6/12	
2	1 year	
3	>1 year	
4	No follow-up	

24.Past DR treatment

1	DR Laser	
2	AntiVEGF – Intravitreal	
3	TPPV	
4	Other	

Name of the Investigator: …… Date: ……

A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

2.2 - Data entry form of diabetic retinopathy screening intervention validation study

PART 1

1. Date of examination

2. Participant's ID

3. Name of the study centre

Research Assistant's Notes -

A. Participant characteristics – *(to be filled by research assistant)* -

4. Date of Birth

5. Age

6. Gender

Female	1
Male	2

7. Status of employment

Employed	1
Unemployed	2
Retired	3

8. Type of occupation

Skilled labour	1
Unskilled labour	2
Service worker	3
Professional	4
Administrative	5
Managerial	6
Security / Armed forces	7

9. Place of Residence *(by District)*

Colombo	1
Gampaha	2
Kalutara	3

10. Category of residential area *(by Divisional secretariat division-DS)*

Estate sector	1
Rural	2
Urban	3

11. Level of Education

No schooling	1
Primary (Grade 1 to 5)	2
Secondary (Grade 6 to 10)	3
GCE (O/L) (Grade 11)	4
GCE (A/L) (Grade 12)	5
Degree and above	6

12. Level of Income (Household income)

<30,220 (Monthly)	1
<41,478 (Monthly)	2
>69,880 (Monthly)	3

13. Ethnic group

Sinhalese	1
Tamil	2
Moor	3
Other	4

14. Main Language

Sinhala	1
Tamil	2
English	3
Other	4

B. Past Medical History – *(to be filled by research assistant) -*

15. Age at diagnosis of diabetes

16. Current treatment of diabetes

Diet only	1
Oral anti-diabetic medication	2
Insulin injections	3
Oral medication + Insulin injections	4

17. Glycaemic control FBS

18. HbA1c

19. Other comorbidities

Hypertension	1
Hypercholesterolemia	2
Ischaemic heart diseases	3
Renal disorders	4
Neuropathy	5
Leg / peripheral ulcers	6
Other ……..	7
Other ……...	8
Other ……..	9

20. Frequency of attending to the medical clinic

Weeks ……	1
Months ……...	2
Once a year	3

21. Duration of attending to the medical clinic Yrs Months

C. Ocular History – *(to be filled by research assistant)*

22.Past ocular history *(* related to diabetic retinopathy screening and treatment only – except history of cataract surgery)*

Intervention	Right Eye		Left Eye	
Previous DR screening	Yes	1	Yes	1
	No	2	No	2
Cataract Surgery with IOL	Yes	1	Yes	1
	No	2	No	2
Laser Treatment	Yes	1	Yes	1
	No	2	No	2

Intravitreal injections	Yes	1	Yes	1
	No	2	No	2
Pars plana vitrectomy	Yes	1	Yes	1
	No	2	No	2
Other (related to DR)	Yes	1	Yes	1
	No	2	No	2

D. Examination –

*(*Presenting VA – to be checked and filled by research assistants)*

23. Whether wearing spectacles at presentation / not ?

Yes	1
No	2

24.Presenting visual acuity (without pin hole)

Log-MAR	Visual acuity	Right Eye	Left Eye
0.00	6/6	1	1
0.20	6/9	2	2
0.30	6/12	3	3
0.50	6/18	4	4
0.60	6/24	5	5
0.80	6/36	6	6
1.00	6/60 – 4/60	7	7
1.10	3/60 – 1/60	8	8
	CF / HM	9	9
	PL	10	10
	NPL	11	11

Name and signature of the research assistant: …… Date : ……..

Anterior segment examination – *(Question No: 25 to 28 - to be filled by the main investigator) -*

25. Cornea

	Right eye	Left eye
Clear	1	1
Not clear	2	2
If not clear – reason		
Scarring present	3	3
Corneal graft present	4	4
Other ……	5	5

26. Status of the pupil

	Right Eye	Left Eye
Pharmacologically dilated	1	1
Pharmacologically not dilated	2	2

27. Size of the pupil when examining

	Right Eye	Left Eye
1mm	1	1
2 mm	2	2
3mm	3	3
4 mm	4	4
5 mm	5	5
6 mm	6	6
Fully dilated	7	7

28. Lens status

	Right Eye	Left Eye
Clear	1	1
Not clear	2	2
If not clear – reason		
Lens opacity present	1	1
Posterior capsular opacity present	2	2
Other ……	3	3
Status of lens		
Phakic	1	1
Aphakic	2	2
Pseudophakic	3	3

Name and signature of the main investigator - …….

Date - ……...

(* Instructions - Part 1 of the questionnaire schedule should be completed and filed separately before presenting patients for imaging by graders).

PART 2 - Data Entry Form of Diabetic Retinopathy Screening Intervention Validation Study - INDEX TEST

1. Date of examination

2. Participant's ID

Code -

Decode -

3. Grader ID

4. Code of the study centre

*(*Instructions - separate data entry forms should be used for each participant by each grader in each test)*

E. Imaging -

1.Mode of imaging –

Non-mydriatic (index test)	1
Mydriatic (index test)	2

2.Status of success of imaging –

	Right Eye		Left Eye	
Field 1	Yes	1	Yes	1
	No	2	No	2
Field 2	Yes	1	Yes	1
	No	2	No	2

3. If not successful – Reason for not imaging -

Reason	Right Eye	Left Eye
Small pupil size	1	1
Corneal opacity	2	2
Lens opacity	3	3
Media opacity	4	4
Participant not coopera-tive	5	5
Technical problem in camera	6	6
Other	7	7
Other	8	8

Code -
Decode -

F. Grading -

4. Diabetic retinopathy grading chart -**encircle the correct category / tick the signs according to the quadrant*

Grading Scheme	**Right Eye OD**				**Left Eye OS**			
Mode of Imaging	***MYD / NON-MYD***				***MYD / NON-MYD***			
Gradability	***Gradable / Not gradable***				***Gradable / Not gradable***			
**(encircle the %)*	*100%*	*75%*	*50%*	*<50%*	*100%*	*75%*	*50%*	*<50%*
Signs	Upper temporal [UT]	Lower temporal [LT]	Upper nasal [UN]	Lower nasal [LN]	Upper temporal [UT]	Lower temporal [LT]	Upper nasal [UN]	Lower nasal [LN]
1.Micro aneurysms								
2.Hard exudates								
3.Cotton wool spots								
4.Intra retinal haemorrhages								
5.Venous beading								
6.IRMA								
7.NVD								
8.NVE								
9.Tractional bands / Fibrosis / TRD								
10.Other								
1.Macular oedema * (signs according to protocol)								

5.Final grading

Category		**Right Eye**	**Left Eye**
No DR –	**R0**	**R0**	**R0**
Mild NPDR -	**R1**	**R1**	**R1**
Moderate NPDR –	**R2**	**R2**	**R2**
Severe NPDR –	**R3**	**R3**	**R3**
PDR –	**R4**	**R4**	**R4**
Macular oedema absent –	**M0**	**M0**	**M0**
Macular oedema present –	**M1**	**M1**	**M1**

Signature of the Index grader - …… Date : ……

Completeness checked by - …… Date : ……

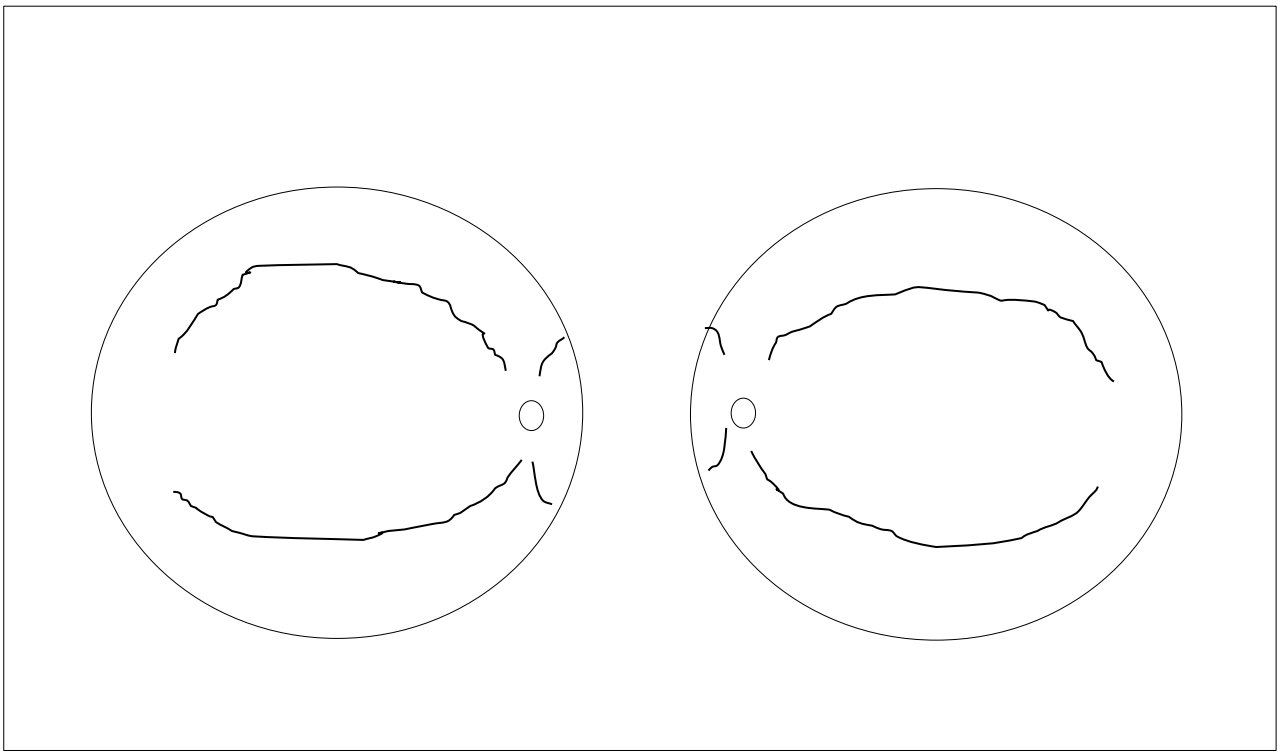
Code -
Decode -

(Instructions – to be continued with the appendix 2 in a separate data entry form for the reference test grader)*

G. Fundus diagram of the REFERENCE TEST

Indirect Ophthalmoscopy and 90D Slit Lamp Biomicroscopic Examination Findings -

Right Eye OD **Left Eye**



Grading Scheme	**Right Eye OD**				**Left Eye OS**			
Signs	Upper temporal [UT]	Lower temporal [LT]	Upper nasal [UN]	Lower nasal [LN]	Upper temporal [UT]	Lower temporal [LT]	Upper nasal [UN]	Lower nasal [LN]
1.Micro aneurysms								
2.Hard exudates								
3.Cottonwool spots								
4.Intra retinal HA								
5.Venous beading								
6.IRMA								
7.NVD								
8.NVE								
9.Tractional bands / Fibrosis / TRD								
10.Other								
1.Macular oedema								

Final Grading – REFERENCE TEST -

Category		Right Eye	Left Eye
No DR –	**R0**	**R0**	**R0**
Mild NPDR -	**R1**	**R1**	**R1**
Moderate NPDR –	**R2**	**R2**	**R2**
Severe NPDR –	**R3**	**R3**	**R3**
PDR –	**R4**	**R4**	**R4**
Ungradable	**R9**	**R9**	**R9**
Macular oedema absent –	**M0**	**M0**	**M0**
Macular oedema present –	**M1**	**M1**	**M1**

Management Plan (VRS Opinion)

……

……

……

Remarks –

……

Follow up plan

……

……

……

……

Name of the Reference test grader –

Dr. Kapila Baduthilake
Consultatant VR Surgeon
National Eye Hospital – Colombo

Signature - …… Date - ……

2.3 - Pilot study of assessment of feasibility and acceptability of a health educational intervention to improve the referral uptake – Baseline characteristics of the participants

A. Participant characteristics-

1. Study ID of the participant _____ 2. Date _____

3. Institution code _____

4. Date of Birth _____ 5. Age _____

6.

Female	1
Male	2

Gender

7. Status of employment

Employed	1
Unemployed	2
Retired	3

8. Type of occupation

Skilled labour	1
Unskilled labour	2
Service worker	3
Professional	4
Administrative	5
Managerial	6
Security / Armed forces	7

9. Place of Residence *(by District)*

Colombo	1
Gampaha	2
Kalutara	3

10. Category of residential area *(by Divisional secretariat division-DS)*

Estate sector	1
Rural	2
Urban	3

11. Level of Education

No schooling	1
Primary (Grade 1 to 5)	2
Secondary (Grade 6 to 10)	3
GCE (O/L) (Grade 11)	4
GCE (A/L) (Grade 12)	5
Degree and above	6

12. Level of Income (Household)

Estate Rs<30,220 (Monthly)	1
Rural Rs<41,478 (Monthly)	2
Urban Rs>69,880 (Monthly)	3

13. Ethnic group

Sinhalese	1
Tamil	2
Moor	3
Other	4

14. Main Language

Sinhala	1
Tamil	2
English	3
Other	4

B. Past Medical History -

15. Age at diagnosis of diabetes

16. Current treatment of diabetes

Diet only	1
Oral anti-diabetic medication	2
Insulin injections	3
Oral medication + Insulin injections	4

17. Glycaemic control FBS 18. HbA1c

19. Other comorbidities

Hypertension	1
Hypercholesterolemia	2
Ischaemic heart diseases	3
Renal disorders	4
Neuropathy	5
Leg / peripheral ulcers	6
Other ……..	7
Other ……...	8
Other ……..	9

20. Frequency of attending to the medical clinic

Weeks ……	1
Months ……...	2
Once a year	3

21. Duration of attending to the medical clinic Yrs Months

C. Ocular History –

22.Past ocular history (* related to diabetic retinopathy screening and treatment only – except history of cataract surgery)

Intervention	Right Eye		Left Eye	
Previous DR screening	Yes	1	Yes	1
	No	2	No	2
Cataract Surgery with IOL	Yes	1	Yes	1
	No	2	No	2
Laser Treatment	Yes	1	Yes	1
	No	2	No	2
Intravitreal injections	Yes	1	Yes	1
	No	2	No	2

Pars plana vitrectomy	Yes	1	Yes	1
	No	2	No	2
Other (related to DR)	Yes	1	Yes	1
	No	2	No	2

D. Examination – (**Presenting VA – checked and filled by research assistants)*

23. Whether wearing spectacles at presentation / not?

Yes	1
No	2

24. Presenting visual acuity (without pin hole)

Visual acuity	Right Eye	Left Eye
6/6	1	1
6/12	2	2
6/18	3	3
6/24	4	4
6/36	5	5
6/60 – 4/60	6	6
3/60 – 1/60	7	7
CF / HM	8	8
PL	9	9
NPL	10	10

25. Level of diabetic retinopathy

(By physician graders)

Category	Right Eye	Left Eye
No DR	1	1
Mild NPDR	2	2
Moderate NPDR	3	3
Severe NPDR	4	4
PDR	5	5
Adv PDR with tractions	6	6
Tractional Retinal Detachment	7	7
Macular oedema present	1	1
Macular oedema absent	2	2

Name and signature of research assistant: …….

Date: ……..

Appendix 3 - Information sheets

3.1- Information sheet - FGD - service users

Information Sheet to the Participants of the Formative Research - Focus Group Discussion (People with diabetes) English Language – Version 1.2

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

Good morning! Let me introduce myself. I am a medical officer attached to the National Eye Hospital – Colombo and a research fellow under the International Centre for Eye Health and London School of Hygiene and Tropical Medicine - United Kingdom. I am carrying out a feasibility study on the development of an integrated diabetic retinopathy screening program in the Western province of Sri Lanka.

I would like to invite you to participate in this focus group discussions which is concerned with identifying the difficulties you faced when accessing eye screening for diabetic eye diseases.

What is the purpose of the study?

Even though the current prevalence of diabetes is as high about 20% that is 1 in 5 adults can have diabetes, in the Western region, no active methodical screening for eye complications is available. One of the complications of diabetes is diabetic retinopathy which may lead to loss of vision.

Every person with diabetes of a long duration is at risk of developing this eye condition. Most of the available research studies have shown that early screening and detection of sight threatening diabetic eye disease will help in preventing the vision loss.

What am I doing this project?

Therefore, there is a need for improving the services for diabetic eye screening in the Western province of Sri Lanka.

This project would be part of my research degree at the London School of Hygiene and Tropical Medicine – UK.

Why do you have to take part in this study?

As you have been on treatment for diabetes / as you have been on treatment for diabetic eye problems; you have been selected to provide your views on barriers / difficulties you faced in accessing screening services.

Your views regarding the barriers to access / challenges in obtaining these services of diabetic retinopathy screening services in the Western province Sri Lanka will be collected in this focus group discussion.

What will happen to me if I take part?

Your contribution for this research study as a person with detected diabetes / as a person undergoing treatment for diabetic eye diseases will be very helpful to develop a successful diabetic retinopathy screening program for the Western province – Sri Lanka in the near future.

What would happen if I do not take part?

You are free ask any questions, explanations and clarifications regarding this survey. Your participation is entirely voluntary. You have a right to withdraw from the interview / discussion at any time. Further this information sheet will be given to you with investigator contact details for future contacts.

This interview / discussion will be conducted confidentially. It will take about 45 minutes to 1 hour to complete the interview / discussion. There will be no representation of the participants' names or institution name in the analysis and publication of data. We may need to voice record this discussion / interview in order to analyse and prepare transcripts of your views regarding eye screening after completing this survey.

The voice clip of this interview / focus group discussion will be recorded and stored anonymously following your consent and it will be only accessible to the principal investigator during the analysis. There will be no indication your identification details or institution identification details when storing these data records for the analysis.

What should I do to participate this discussion?

If you are satisfied and willing to participate in this research study, please sign the consent form after reading. Again, you have time to go through any questions. I would greatly appreciate your cooperation in conducting this interview / focus group discussion since this would be a valuable study on prevention of diabetes related visual loss in Sri Lanka in future.

How can I contact the research team or investigators afterwards?

You can have this information sheet with the contact details below.

Name of the Investigator – Dr.M.M.P.N.Piyasena
Contact Details - Vitreo retinal unit, National Eye Hospital, Colombo, Sri Lanka
Contact Number – 0772 968 881
Email – Prabhath.piyasena@lshtm.ac.uk

Thank you very much for your cooperation.

3.2 - Information sheet - SSI - service provider

Information Sheet to the Participants of the Formative Research - Semi Structured Interviews (Service Providers) English Language – Version 1.2

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

Good morning Sir / Madam let me introduce myself. I am a medical officer attached to the National Eye Hospital – Colombo and a research fellow under the International Centre for Eye Health and London School of Hygiene and Tropical Medicine - United Kingdom. I am carrying out a feasibility study on the development of an integrated diabetic retinopathy screening program in the Western province of Sri Lanka.

I would like to invite you to participate in this semi structured interviews which is concerned with identifying the difficulties you faced when providing services for diabetic eye diseases under this health care institution in the government sector.

What is the purpose of the study?

Even though the current prevalence of diabetes is as high as 18.6% in the Western region, no active systematic screening for eye complications is available. One of the complications of diabetes is diabetic retinopathy which may lead to loss of vision. Every person with diabetes of a long duration is at risk of developing "Diabetic Retinopathy" (DR).

Most of the available research studies have shown that early screening and detection of sight threatening diabetic eye disease will help in preventing the vision loss due to diabetic retinopathy. Further there is evidence that health educational interventions will improve the uptake of screening services.

However, we understand that there are gaps in provision of these services in the Western province.

What am I doing this project?

Therefore, there is a need for improving the services for diabetic eye screening in the Western province of Sri Lanka. I would expect your views regarding this issue in order to identify solutions to the problems you faced.

This project would be part of my research degree at the London School of Hygiene and Tropical Medicine – UK.

Why do you have to take part in this study?

As you are the experts in this from this region, I would greatly appreciate your views regarding this public health problem.

As you have been engaging in service provision for diabetics; you have been selected to provide your views on barriers in accessing screening services / provision of screening services in the Western region.

Your views regarding the barriers to access / challenges in provision of diabetic retinopathy screening services in the Western province Sri Lanka will be collected in this interview and those will be use to develop a feasible DR screening modality for this region.

What will happen to me if I take part?

Your contribution for this research study as a service provider engage in managing diabetics will be very helpful to develop a successful diabetic retinopathy screening program for the Western province – Sri Lanka in the near future.

You are free ask any questions, explanations and clarifications regarding this survey. Your participation is entirely voluntary. You have a right to withdraw from the interview / discussion at any time. Further this information sheet will be given to you with investigator contact details for future contacts.

What are the steps in this study?

This interview / discussion will be conducted confidentially. It will take about 30 - 45 minutes to complete the interview / discussion. There will be no representation of the participants' names or institution name in the analysis and publication of data.

We may need to voice record this discussion / interview following your consent, in order to analyse and prepare transcripts of your views regarding DR screening after completing this survey.

Will your participation in this project remain confidential?

The voice clip of this interview will be recorded and stored anonymously following your consent and it will be only accessible to the principal investigator during the analysis.

There will be no indication your identification details or institution identification details when storing these data records for the analysis.

If you are satisfied and willing to participate in this research study, please sign the consent form after reading. Again, you have time to go through any questions. I would greatly appreciate your cooperation in conducting this interview / focus group discussion since this would be a valuable study on prevention of diabetes related visual loss in Sri Lanka in future.

Please not my contact details for future correspondence.

Name of the Investigator – Dr.M.M.P.N.Piyasena
Contact Details - Vitreo retinal unit, National Eye Hospital, Colombo, Sri Lanka
Contact Number – 0772 968 881
Email – Prabhath.piyasena@lshtm.ac.uk

Thank you very much for your cooperation.

3.3 - Information sheet - Validation of screening intervention

Information Sheet to the Participants of the Validation of Diabetic Retinopathy Screening Intervention – English Language – Version 1.3

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

I would like to invite you to participate in this research project which is concerned with the screening of people with diabetes for their eye complication called "diabetic retinopathy".

What is the purpose of the study?

Diabetic retinopathy will lead to blindness if not treated on time. Screening would help to identify the changes in the back of your eye ("retina") early, enabling you to undergo treatment in advance. There is no systematic diabetic retinopathy screening programs in the Western province of Sri Lanka.

As you have been on treatment for diabetes you have been selected to test a method of screening your eyes to detect the abnormal findings early.

Why am I (investigator) doing this project?

This project would be part of my research degree at the London School of Hygiene and Tropical Medicine – UK

Do you have to take part in the study?

No, your participation in this project is entirely voluntary. Similarly, if you do agree to participate you are free to withdraw at any time during the project if you change your mind.

What will happen to me if I take part?

The screening modality entails taking photographs of the back of your eye by your physician at medical clinic using a retinal camera. You will be enrolled to the study following informed consent.

It will take about 1/2hr – 1 hr to take the retinal images at the medical clinic and another 1 – 2 hours to examine your eyes by consultant retinologist at retinal clinic.

What are the steps in this study?

- Two views of each eye (2 retinal fields) will be taken for this assessment. There will be a flash of light while taking the photo. Two physicians will examine you at this step.
- Initial set of images will be taken without dilatation of your pupils. Afterwards, your pupils will be dilated using an eye drop to have a better visualisation.
- These drops will cause some irritation for few minutes and you may see blurred images till the effect of the eye drops wears off (few hours). After adequate dilatation of pupils another set of images (same 2 retinal fields in each eye, by two physicians) will be taken.
- The next step is examination of your eyes by a consultant retinologists at the retinal clinic. A research assistant will accompany you for this examination.

- If you have any problems in attending to the retinal clinic on the same day, we can provide you an appointment to come within couple of days. Further we would like to receive your contact details to see whether you have attended the said clinic during the given time period.
- In the eye clinic a retinologist will perform full examination of your eyes and you will be referred for treatment if required.
-

Will your participation in the project remain confidential?

Your name will not be recorded on the questionnaire and the information will not be disclosed to other parties. The data and retinal images will be stored anonymously and will be only accessible to the principal investigator.

What are the possible disadvantages and risks of taking part in the study?

There is no potential harm or disadvantages with regard to the interventions in this study except a rare possibility of getting an episode of rise in your eye pressure following dilatation of pupils. It can happen when we put eye drops to dilate your pupils. Those who have a narrow angle for drainage of watery discharge in the foremost part of the eye are more prone to this. However, this is a very rare occasion where less 1% of the people have this condition and vulnerable to rise in eye pressure.

If you are about to get such situation you will have symptoms such as eye pain, redness, nausea, headache and vomiting. If you have any of these symptoms you should inform the investigator / research assistants as quick as possible. We would keep you under observation for these features and if you face such rare adverse event, we will take the responsibility of treating you at the 24-hour casualty eye department.

In addition, there will be blurring of vision for few hours after the dilatation of pupils. You would not be able to carry out fine tasks such as reading, driving during this time period. Although the study procedures may give you useful information about your sight they cannot be used for diagnostic purposes. Therefore, this would not a substitute for regular visits to your eye specialist / optician.

What if there is any problem?

Any complaint or concern about the aspects of the way you have been dealt with during the course of the study will be addressed. Please contact investigator if there is any concern.

Contact details –

Name of the Investigator – Dr.M.M.P.N.Piyasena
Contact Details - Vitreo retinal unit, National Eye Hospital, Colombo, Sri Lanka
Contact Number – 0772 968 881
Email – Prabhath.piyasena@lshtm.ac.uk

Expenses or payments –

There will be no costs incur to you by the study procedures. If you are willing to obtain, you are entitling to receive a payment for your travelling expenses and for the loss of earnings.

Thank you very much for your cooperation.

3.4 - Information sheet - participatory workshops

Information Sheet to the Participants of the Participatory Workshop – Health Educational Intervention Development - English Language – Version 1.3

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

I would like to invite you to participate in this participatory work shop which is concerned with development of a local context specific health educational intervention in improving the uptake of services at ophthalmologist's clinic by those who have been identified as having referable level diabetic retinopathy.

What is the purpose of the study?

Diabetic retinopathy will lead to blindness if not treated on time. Ophthalmologists have experienced that people with diabetic retinopathy do not attend for their assessment visits / treatment at ophthalmologist's clinic timely despite been referred.

There is no properly developed health educational material/methods on diabetic retinopathy in local languages in Sri Lanka.

Therefore, we are going to adopt globally available health educational interventions/material in local languages. In this participatory work shop we would expect your active participation in development and assessment of acceptability and comprehension of the most suitable health educational material/interventions for the local context.

You have been selected to participate in this workshop as you have been identified as having diabetes.

Why am I (investigator) doing this project?

This project would be part of my research degree at the London School of Hygiene and Tropical Medicine – UK

Do you have to take part in the study?

No, Your participation in this workshop is entirely voluntary. Similarly if you do agree to participate you are free to withdraw at any time during the workshop if you change your mind.

What will happen to me if I take part?

The health educational intervention development workshop will be conducted on 4 days.

One session will last about 3 - 4 hours. You will be enrolled to the study following informed consent and you will work in 4 groups.

During the workshops we would expect you to express your views/ideas regarding the current problems, acceptability and comprehension of the health educational interventions.

First, your ideas about how we should do this will be discussed. Afterwards you will be given some sample educational material to criticise.

Afterwards you will be asked to further develop the health educational intervention appropriate to local context based on your ideas, as a group activity. There will be facilitators throughout the workshop if you have any further questions. We expect you to gather your ideas and views as a group and present to us on the final day.

What is schedule of this workshop?

- Day 1 – Introduction, identification of needs of people with diabetes with regard to health education and exposure to available material.
- Day 2 – Development of health educational material/intervention by incorporating participants' ideas.
- Day 3 and 4 - Presentation of views and ideas as a group (either of days).

Will your participation in the project remain confidential?

Your name will not be recorded in this workshop. Your ideas and views regarding the health educational material/intervention will be documented/recorded by the moderators anonymously and will be only accessible to the principal investigator.

Further, you will be asked few questions about details of education, past medical history and past ocular history. In addition we would like to receive your contact details if there is any need of future correspondence.

What are the possible disadvantages and risks of taking part in the study?

There is no potential harm or disadvantages in participating this workshop. We can discuss and adjust the time schedule of the workshop depend on your availability.

What if there is any problem?

Any complaint or concern about the aspects of the way you have been dealt with during the course of the study will be addressed.

Please contact investigator if there is any concern.

Contact details –

Name of the Investigator – Dr.M.M.P.N.Piyasena
Contact Details - Vitreo retinal unit, National Eye Hospital, Colombo, Sri Lanka
Contact Number – 0772 968 881
Email – Prabhath.piyasena@lshtm.ac.uk

Expenses or payments –

There will be no costs incur to you by the study procedures. If you are willing to obtain, you are entitle to receive a payment for your travelling expenses and for the loss of earnings.

Thank you very much for your cooperation.

3.5 - Information sheet - stakeholders meeting

Information Sheet to the Participants of the Stake Holders Meeting – Health Educational Intervention Development – English Language – Version 1.3

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

I would like to invite you to participate in this stake holders meeting which is concerned with development of a local context specific health educational intervention to improve the uptake of services at ophthalmologist's clinic by those who have identified as having referable diabetic retinopathy at medical clinics.

What is the purpose of this meeting?

Diabetic retinopathy will lead to blindness if not treated on time. Ophthalmologists have experienced that people with diabetic retinopathy do not attend for their assessment visits / treatment at ophthalmologist's clinic timely despite been referred.

There is no properly developed health educational material/methods on diabetic retinopathy in local languages in Sri Lanka.

Therefore we are going to adopt globally available health educational interventions/material in local languages.

In this stakeholder meeting we would expect your opinion on adaptation, further development and content evaluation of health educational interventions / material.

Why am I (investigator) doing this project?

This project would be part of my research degree at the London School of Hygiene and Tropical Medicine – UK

What is the time schedule of the meeting?

The stake holders meeting will be conducted on 2 days. One meeting would last for about 3-4 hours.

- 1st meeting – preliminary adaptation of the selected health educational interventions by reviewing the sample material (objectives – define the target group, content, mode of delivery, location of delivery and personnel involved)
- 2nd meeting – assessment of content validity

Will your participation in the project remain confidential?

Your name will not be recorded in this workshop. Your ideas and views regarding development of the health educational material/intervention will be documented/recorded by the moderators anonymously and will be only accessible to the principal investigator.

Further we may use quotations made by you in the health educational material anonymously in future following informed consent.

Please contact investigator if there is any concern.

Contact details –

Name of the Investigator – Dr.M.M.P.N.Piyasena
Contact Details - Vitreo retinal unit, National Eye Hospital, Colombo, Sri Lanka
Contact Number – 0772 968 881
Email – Prabhath.piyasena@lshtm.ac.uk

Thank you very much for your cooperation.

3.6 - Information sheet - pilot testing of the health educational intervention - service user

Information Sheet to the Participants of the Pilot Study of Health Educational Intervention - English Language – Version 1.3

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

I would like to invite you to participate in this research project which is concerned with pilot testing of a local context specific health educational method to improve the uptake of services at eye clinics by those who have been identified as having referable level diabetic retinopathy at medical clinics.

What is the purpose of the study?

Diabetic retinopathy will lead to blindness if not treated on time. Ophthalmologists have experienced that people with diabetic retinopathy do not attend for their assessment visits / treatment at ophthalmologist's clinic timely despite been referred.

There is no properly developed health educational material/methods on diabetic retinopathy in local languages in Sri Lanka. Therefore we are going to pilot test a local context specific health educational intervention to improve the uptake.

You have been selected to test a method of health education as you have been identified as having referable level of diabetic retinopathy by your physician.

Why am I (investigator) doing this project?

This project would be part of my research degree at the London School of Hygiene and Tropical Medicine – UK.

Do you have to take part in the study?

No, Your participation in this project is entirely voluntary. Similarly if you do agree to participate you are free to withdraw at any time during the project if you change your mind.

What will happen to me if I take part?

Once you have been identified as having referable level of diabetic retinopathy, you will be enrolled to the study following informed consent. Research assistants will fill a questionnaire schedule of your baseline information and pre-test your knowledge in diabetic retinopathy. This will take about 1/2 – 1 hour.

After pre-testing the knowledge an educator / physician will deliver the health educational intervention suggesting you to seek care at next level of ophthalmologist's clinic.

Afterwards you will be called back for another appointment with in a period of 4 weeks to post test your knowledge (using a questionnaire schedule) and to assess the comprehension and acceptability of the delivered intervention (using semi-structured interviews). This whole process will take about 1-2 hours.

What are the steps in this study?

- Collection of baseline demographic and clinical data using a questionnaire schedule by research assistants.
- Pre testing of knowledge, attitude and practice.
- Delivery of the health educational intervention by your physician/educators at medical clinic.
- You will be referred to an ophthalmologist's/retinologist's clinic for assessment/treatment.
- Assessment of acceptability of the intervention with in a period of 4 weeks using semi-structured interviews. (Here we would like to audio record your answers for future analysis following informed consent)
- Post testing of knowledge, attitude and practice components at 4 weeks.
-

Will your participation in the project remain confidential?

Your name will not be recorded on the questionnaire schedules or in semi-structured interviews. We would like to receive your contact details for correspondence.

The interviews will be audio recorded and records will be saved anonymously following your consent. The important statements made by you during the interview will be quoted in the analysis without giving identification to any personal details.

What are the possible disadvantages and risks of taking part in the study?

There is no potential harm or disadvantages with regard to the health educational intervention delivered in this pilot study.

What if there is any problem?

Any complaint or concern about the aspects of the way you have been dealt with during the course of the study will be addressed.

Please contact investigator if there is any concern.

Contact details –

Name of the Investigator – Dr.M.M.P.N.Piyasena
Contact Details - Vitreo retinal unit, National Eye Hospital, Colombo, Sri Lanka
Contact Number – 0772 968 881
Email – Prabhath.piyasena@lshtm.ac.uk

Expenses or payments –

There will be no costs incur to you by the study procedures. If you are willing to obtain, you are entitle to receive a payment for your travelling expenses and for the loss of earnings.

Thank you very much for your cooperation.

3.7 - Information sheet - pilot testing of the health educational intervention - service provider

Information Sheet to the Participants of the Study of Assessment of Feasibility and Acceptability of Health Educational Intervention among Service Providers - English Language – Version 1.3

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

I would like to invite you to participate in this research project which is concerned with assessment of feasibility and acceptability of a local context specific health educational method to improve the uptake of services at eye clinics by those who have been identified as having referable level diabetic retinopathy at medical clinics.

What is the purpose of the study?

Diabetic retinopathy will lead to blindness if not treated on time. Ophthalmologists have experienced that people with diabetic retinopathy do not attend for their assessment visits / treatment at ophthalmologist's clinic timely despite been referred.

There is no properly developed health educational material/methods on diabetic retinopathy in local languages in Sri Lanka. Therefore we developed and piloted a local context specific health educational intervention to improve the uptake.

You have been selected to assess the feasibility and acceptability of this method of health education as you are involved in managing patients with diabetes / diabetic retinopathy in this institution.

Why am I (investigator) doing this project?

This project would be part of my research degree at the London School of Hygiene and Tropical Medicine – UK.

Do you have to take part in the study?

No, Your participation in this project is entirely voluntary. Similarly if you do agree to participate you are free to withdraw at any time during the interview if you change your mind.

What are the steps in this study?

If you do agree to participate in this interview, we will ask you a set of pre-designed questions about feasibility and acceptability of the health educational intervention piloted in this clinic to improve the uptake of services at ophthalmologist's clinic.

If you need we can provide adequate time to go through the health educational intervention.

It will take about 1/2hr – 1 hr to conduct the interview. We would like to record your answers following informed consent for future analysis. If not, a moderator will document your answers.

Will your participation in the project remain confidential?

Your name and institution name will not be recorded / documented in semi-structured interviews.

The interview will be audio recorded and records will be saved anonymously following your consent.

The important statements made by you during the interview will be quoted in the analysis without giving identification to any personal details with your consent.

What if there is any problem?

Any complaint or concern about the aspects of the way you have been dealt with during the course of the study will be addressed.

Please contact investigator if there is any concern.

Contact details –

Name of the Investigator – Dr.M.M.P.N.Piyasena
Contact Details - Vitreo retinal unit, National Eye Hospital, Colombo, Sri Lanka
Contact Number – 0772 968 881
Email – Prabhath.piyasena@lshtm.ac.uk

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Thank you very much for your cooperation.

Appendix 4 - Consent Forms

4.1 - Consent form - FGD - service user

Consent Form for Participation of Persons with Diabetes in the Study – Version 1.2 - English Language

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

Name of the Investigator – …….. *Date* - ……..

This is to certify that I have read / has been read out to me the study information sheet in my language and being satisfied with the information.

I …… hereby willingly agree to participate as a volunteer in this research study as a diabetic patient / diabetic retinopathy patient attending to the public sector / private sector health care institution in the Western province of Sri Lanka.
(Name of hospital - ……..)

- The objectives of the research project has been fully explained to me by the investigator ……. on …… and I am satisfied with the explanations. A copy of the information about this survey has been provided to me and discussed in detail with me.

- I have been given an opportunity to ask questions, and all such questions and inquiries have been answered to my satisfaction.

- I understand that I am free to decline to answer any specific items or questions in interviews, focus group discussions or questionnaires.

- I understand that all data will remain confidential with regard to my identity. Further I understand that this study involves audio recording of the interview / discussion with the researchers.

- I understand that the voice records will be transcribed by the principle investigator and the transcriptions will not reflect my identity. Further these transcripts may be reproduced in whole or part for use in written products that result from this study.

- I understand that participation in this research project is voluntary and not a requirement or a condition for being the recipient of any kind of benefits or services.

- I understand that the approximate length of time required for participation in this research project; interview / focus group discussion is …… minutes to ……. minutes.

- I understand that if I have any questions concerning the purposes or the procedures associated with this survey; I can stop participating, refuse consent or ask further questions during or later in this study.

- I understand that I am free to withdraw my consent and discontinue participation at any time.

Consent for Participation –

Signature of Subject (patient) ……. Date ……

Consent for audio recording of the focus group discussions –

Audio recording consent – Available / Not Available

I hereby give my consent for audio recording of the discussion

Signature of the Subject (patient) …… Date …….

Consent for usage of anonymised quotations – Available / Not available

I hereby give my consent for use of anonymised quotes from the workshop.

Signature of Participant - …… Date ……..

Consent for photography

I hereby provide my consent for photography and inclusion of those in the thesis / publication material.

Signature of the Subject (patient) …… Date …….

Signature of the witness:

I, the undersigned, have defined and fully explained the survey to the above participant.

Signature of Investigator ……..... Date …….

4.2 - Consent form - SSI - service provider

Consent Form for Participation of the Service Providers in the Study - Version1.2 – English Language

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

Name of the Investigator – …….. *Date* - ……..

This is to certify that I have read / has been read out to me the study information sheet in my language and being satisfied with the information.

I …… hereby willingly agree to participate as a volunteer in this research study as a service provider in diabetic care / eye care under a public sector / private sector health care institution in the Western province of Sri Lanka.

(Name of hospital - ……..)

- The objectives of the research project has been fully explained to me by the investigator ……. on …… and I am satisfied with the explanations. A copy of the information about this survey has been provided to me and discussed in detail with me.

- I have been given an opportunity to ask questions, and all such questions and inquiries have been answered to my satisfaction.

- I understand that I am free to decline to answer any specific items or questions in the semi structured interviews / in depth interviews or in questionnaires.

- I understand that all data will remain confidential with regard to my / institutional identity. Further I understand that this study involves audio recording of the interview / discussion with the researchers.

- I understand that the voice records will be stored and transcribed by the principle investigator and the transcriptions will not reflect my / institutional identity. Further these transcripts may be reproduced in whole or part for use in written products that result from this study.

- I understand that participation in this research project is voluntary and not a requirement or a condition for being the recipient of any kind of benefits or services.

- I understand that the approximate length of time required for participation in this research project; interview / in depth interview is …… minutes to ……. minutes.

- I understand that if I have any questions concerning the purposes or the procedures associated with this survey; I can stop participating, refuse consent or ask further questions during or later in this study.

- I understand that I am free to withdraw my consent and discontinue participation at any time.

Consent for Participation –

Signature of Subject (patient) ……. Date ……

Consent for audio recording of the interviews – Audio re-

cording consent – Available / Not Available

I hereby give my consent for audio recording of the discussion

Signature of the Subject (patient) …… Date …….

Consent for usage of anonymised quotations – Available / Not available

I hereby give my consent for use of anonymised quotes from the workshop.

Signature of Participant - …… Date ……..

Signature of the witness -

I, the undersigned, have defined and fully explained the survey to the above participant.

Signature of Investigator ……..... Date ……

4.3 - Consent form - screening modality validation study

Consent Form for Participation of Persons with Diabetes in the Study of Diabetic Retinopathy Screening Intervention Validation – Version 1.3 - English Language

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

Name of the Investigator – …….. Date - ……..

This is to certify that I have read / has been read out to me the study information sheet in my language and being satisfied with the information.

I ……. hereby willingly agree to participate as a volunteer in this research study as a diabetic patient / diabetic retinopathy patient attending to the public sector health care institution in the Western province of Sri Lanka.
(Name of hospital - …….)

- The objectives of the research project has been fully explained to me by the investigator ……. (name) on …… and I am satisfied with the explanations. A copy of the information about this survey has been provided to me and discussed in detail with me.

- I have been given an opportunity to ask questions, and all such questions and inquiries have been answered to my satisfaction.

- I understand that I am free to decline to answer any specific items or questions in interviews, discussions or questionnaires and free to decide whether to participate or not in any procedures involve in the diabetic retinopathy screening intervention validation study.

- I understand that all data will remain confidential with regard to my identity.

- I understand that participation in this research project is voluntary and not a requirement or a condition for being the recipient of any kind of benefits or services.

- I understand that the approximate length of time required for participation in this validation study is ……. to ……. Hours.

- I understand that if I have any questions concerning the purposes or the procedures associated with this survey; I can stop participating, refuse consent or ask further questions during or later in this study.

- I understand that I am free to withdraw my consent and discontinue participation at any time.

- I understand that there is a possibility of anonymised data of this study will be held in a data repository after finishing this project.

Signature of Participant - ……. Date ……

Consent for photography

I hereby provide my consent for photography and inclusion of those in the thesis / publication material.

Signature of the Subject (patient) …… Date …….

Signature of the witness:

I, the undersigned, have defined and fully explained the survey to the above participant.

Signature of Investigator ……..... Date …….

I have received a sum of LKR ……..……
(In words) as participation cost.

Signature of the Participant ……. Date: ……

Voucher Number: ……..

Signature of witness:

Signature of the Investigator ……. Date ……

4.4 - Consent form - participatory work shops

Consent Form for Participants of Participatory Work Shop on the Development of Health Educational Intervention - Version1.3 – English Language

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

Name of the Investigator – ……. Date - ……..……

This is to certify that I have read / has been read out to me the study information sheet in my language and being satisfied with the information.

I …… hereby willingly agree to participate as a volunteer in this participatory workshop as a person with diabetes attending a public sector health care institution in the Western province of Sri Lanka.
(Name of hospital - ……..)

- The objectives of the research project have been fully explained to me by the investigator ……..….. (name) on …… and I am satisfied with the explanations. A copy of the information about this survey has been provided to me and discussed in detail with me.

- I have been given an opportunity to ask questions, and all such questions and inquiries have been answered to my satisfaction.

- I understand that I am free to decline to answer any specific items or questions in this workshop.

- I understand that all opinions given in the meeting remain confidential with regard to my / institutional identity. Further I understand that this study involves adaptation and development of a health educational material / intervention using participants' opinions.

- I understand that participation in this workshop is voluntary and not a requirement or a condition for being the recipient of any kind of benefits or services.

- I understand that the approximate length of time required for participation in this participatory study is 3-4 hours per session and 3 sessions in total.

- I understand that if I have any questions concerning the purposes or the procedures associated with this study; I can stop participating, refuse consent, or ask further questions during or later in this study.

- I understand that I am free to withdraw my consent and discontinue participation at any time.

- I understand that there is a possibility of anonymised data of this study will be held in a data repository after finishing this project.

Consent for Participation –

Signature of Participant - ……. Date ……

Consent for audio recording of the opinions –

Audio recording consent – Available / Not Available

I hereby give my consent for audio recording my ideas / opinions during this workshop.

Signature of Participant - …… Date …….

Consent for usage of anonymised quotations – Available / Not available

I hereby give my consent for use of anonymised quotes from the workshop.

Signature of Participant - …… Date ……..

Consent for photography

I hereby provide my consent for photography and inclusion of those in the thesis / publication material.

Signature of the Subject (patient) …… Date …….

Signature of the witness -

I, the undersigned, have defined and fully explained the survey to the above participant.

Signature of Investigator ……..... Date …….

I have received a sum of LKR ……..……
(In words) as participation cost.

Signature of the Participant ……. Date: ……

Voucher number : ……

Signature of witness:

Signature of the Investigator ……. Date ……

4.5 - Consent form - stakeholders meeting

Consent Form for Participation of Stake Holders in Development of Health Educational Intervention - Version1.3 – English Language

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

Name of the Investigator – ……. *Date* - ……..……

This is to certify that I have read / has been read out to me the study information sheet in my language and being satisfied with the information.

I …… hereby willingly agree to participate as a volunteer in this research study as a service provider in health care / diabetic care / eye care under a public / private sector health care institution / organisation in the Western province of Sri Lanka. (Name of hospital/Organisation- ……..)

- The objectives of the research project have been fully explained to me by the investigator ……..….. (name) on …… and I am satisfied with the explanations. A copy of the information about this survey has been provided to me and discussed in detail with me.

- I have been given an opportunity to ask questions, and all such questions and inquiries have been answered to my satisfaction.

- I understand that I am free to decline to answer any specific items or questions in this stake holders meeting.

- I understand that all opinions given in the meeting remain confidential with regard to my / institutional identity. Further I understand that this study involves adaptation and development of a health educational material / intervention using the stake holder's opinions.

- I understand that participation in this stake holder's meeting is voluntary and not a requirement or a condition for being the recipient of any kind of benefits or services.

- I understand that the approximate length of time required for participation in this study is 3-4 hours per session. (2 sessions in total).

- I understand that if I have any questions concerning the purposes or the procedures associated with this study; I can stop participating, refuse consent, or ask further questions during or later in this study.

- I understand that I am free to withdraw my consent and discontinue participation at any time.

- I understand that there is a possibility of anonymised data of this study will be held in a data repository after finishing this project.

Consent for Participation –

Signature of Participant - ……. Date ……

Consent for audio recording of the opinions –

Audio recording consent – Available / Not Available

I hereby give my consent for audio recording my opinions during this meeting.

Signature of Participant - …… Date …….

Consent for usage of anonymised quotations – Available / Not available

I hereby give my consent for use of anonymised quotes from the meeting.

Signature of Participant - …… Date ……..

Signature of the witness -

I, the undersigned, have defined and fully explained the survey to the above participant.

Signature of Investigator ……..... Date …….

4.6 - Consent form - health educational intervention assessment - service user

Consent Form for Participation of Persons with Referable Level Diabetic Retinopathy in Piloting of Health Educational Intervention – Version 1.3 - English Language

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

Name of the Investigator – …… *Date* - ……

This is to certify that I have read / has been read out to me the study information sheet in my language and being satisfied with the information.

I ……. hereby willingly agree to participate as a volunteer in this pilot test of health educational intervention as a diabetic patient attending to the public sector health care institution in the Western province of Sri Lanka.

(Name of hospital - …….)

- The objectives of the research project have been fully explained to me by the investigator …… (name) on …… and I am satisfied with the explanations. A copy of the information about this survey has been provided to me and discussed in detail with me.

- I have been given an opportunity to ask questions, and all such questions and inquiries have been answered to my satisfaction.

- I understand that I am free to decline to participate in this pilot study or to decline to answer any specific items in questionnaires or semi-structured interviews.

- I understand that all data will remain confidential with regard to my identity. Further I understand that this study involves audio recording of the interview with the researchers.

- I understand that the voice records will be transcribed by the principle investigator and the transcriptions will not reflect my identity. Further these transcripts may be reproduced in whole or part for use in written products that result from this study.

- I understand that participation in this study is voluntary and not a requirement or a condition for being the recipient of any kind of benefits or services.

- I understand that the approximate length of time required for participation in the pilot study for pre-testing knowledge and delivery of the health educational intervention is 1/2hr to 1 hr. In addition I understand that I will be interviewed and post-test the knowledge again (takes about 1/2hr to 1 hr) with in a period of 4 weeks following the visit to retinologist's / ophthalmologist's clinic.

- I understand that if I have any questions concerning the purposes or the procedures associated with this study; I can stop participating, refuse consent, or ask further questions during or later in this study.

- I understand that I am free to withdraw my consent and discontinue participation at any time.

- I understand that there is a possibility of anonymised data of this study will be held in a data repository after finishing this project.

Consent for Participation –

Signature of Participant ……. Date ……

Consent for audio recording of the semi-structured interviews –

Audio recording consent – Available / Not Available

I hereby give my consent for audio recording of the semi-structured interview -

Signature of the Participant …… Date …….

I hereby give my consent for usage of quotations from interviews.

Signature of the Participant - …… Date ……

Signature of the witness:

I, the undersigned, have defined and fully explained the survey to the above participant.

Signature of Investigator ……..... Date ……

I have received a sum of LKR ……..……
(In words) as participation cost.

Signature of the Participant ……. Date: ……

Voucher number : ……

Signature of witness:

Signature of the Investigator ……. Date ……

4.7 - Consent form - health educational intervention assessment - service provider

Consent Form for Participation of Service Providers in Pilot Study of Health Educational Intervention (Assessment of Feasibility and Acceptability) Version1.2 – English Language

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

Name of the Investigator – ……. Date - ……..……

This is to certify that I have read / has been read out to me the study information sheet in my language and being satisfied with the information.

I …… hereby willingly agree to participate as a volunteer in this research study as a service provider in diabetic care / eye care under a public sector health care institution in the Western province of Sri Lanka.

(Name of hospital - ……..)

- The objectives of the research project have been fully explained to me by the investigator ……..….. (name) on …… and I am satisfied with the explanations. A copy of the information about this survey has been provided to me and discussed in detail with me.

- I have been given an opportunity to ask questions, and all such questions and inquiries have been answered to my satisfaction.

- I understand that I am free to decline to answer any specific items or questions in the semi structured interviews or in questionnaires.

- I understand that all data will remain confidential with regard to my / institutional identity. Further I understand that this study involves audio recording of the interview / discussion with the researchers.

- I understand that the voice records will be stored and transcribed by the principle investigator and the transcriptions will not reflect my / institutional identity. Further these transcripts may be reproduced in whole or part for use in written products that result from this study.

- I understand that participation in this research project is voluntary and not a requirement or a condition for being the recipient of any kind of benefits or services.

- I understand that the approximate length of time required for participation in this research project; semi structured interview is 20 minutes to 30 minutes.

- I understand that if I have any questions concerning the purposes or the procedures associated with this survey; I can stop participating, refuse consent, or ask further questions during or later in this study.

- I understand that I am free to withdraw my consent and discontinue participation at any time.

- I understand that there is a possibility of anonymised data of this study will be held in a data repository after finishing this project.

Consent for Participation –

Signature of Service provider ……. Date ……

Consent for audio recording of the interviews –

Audio recording consent – Available / Not Available

I hereby give my consent for audio recording of the discussion

Signature of Service provider …… Date …….

I hereby give my consent for usage of quotations from interviews.

Signature of the Participant - …… Date ……

Signature of the witness -

I, the undersigned, have defined and fully explained the survey to the above participant.

Signature of Investigator ……..... Date …….

4.8 - Annexure for Consent for Photography and or Video Filming

Consent Form for Photography and or Video Filming - Version 1. 1 - English Language

Title of the Research Project - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

For a participant' consent to inclusion of images / video clips in the Thesis.

[*Instructions to the research assistants - attached this form to the main consent form when phography / video filming is required]

I ……. (print full name here) give my consent for the material of me to appear in a research degree student thesis / publication. I confirm that I have seen the photo/s or video/s that appear me in the thesis / publication.

In addition, I understand the following.

- The material will be appeared in the thesis / publication without my name attached however I understand that complete anonimity can not be guranteed.
- The material may show or include detail related to my medical condition that I have, had or may have in the future.
- The thesis / article may be published and availabe online that can be accessed by anyone.
- I will not receive any finanacial benefit by apprearing in this photo / video clip.
- The thesis / article may also be used in full or part in other publicationas and products published by relevent or other publishers.
- I can revoke my consent at any time before publication, but once the article / thesis has been committed to publication, it will not be possible to revoke the consent.
- This consent from will be retained securely and confidence by the main investigator at the colloborating institution in accordance with the law, for no longer than necessary.

Signature of the participant - ……. Date - …….

Siganture of the witness: I, the undersigned have defined and fully explained the purpose of photography / video filming to the above participant.

Signature of the investigator: ……. Date - ……

Position : ……..

Appendix 5

5.1 - S1 Table. PRISMA check list

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	01
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	04-05
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	06-09
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	09
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	10-11
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	11-12
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	11
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	11
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	11-12

Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	14
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	12-14
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	12-13
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	N/A

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	14-15
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	14-15
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	15
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A

Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	32-33
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	32-33
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	34
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	36

5.2 - S2 Table. Search strategy of barriers to access systematic review

Medline / Ovid	EMBASE / Ovid	Cochrane
1.exp Patient Acceptance of health care/ 2.exp Attitude to health/ 3.exp health behavior/ 4.(Uptake or barrier$ or attend$ or accept$ or adhere$ or participate or facilitat$ or enable$).tw. 5.(motivat$ or staisf$ or takeup$ or consent$ or promot$).tw. 6.(complie$ or comply or compliance$ or noncompliance$ or non compliance$).tw.	1. exp randomized controlled trial/ 2. exp randomization/ 3. exp double blind procedure/ 4. exp single blind procedure/ 5. or/1-4 6. (animal or animal experiment).sh. 7. human.sh. 8. 6 and 7 9. 6 not 8 10. 5 not 9 11. exp clinical trial/ 12. (clin$ adj3 trial$).tw.	#1 MeSH descriptor: [Diabetes Mellitus] explode all trees #2 MeSH descriptor: [Diabetes Complications] explode all trees #3 MeSH descriptor: [Diabetic Retinopathy] explode all trees #4 (diabet* or proliferative or non-proliferative) near/4 retinopath* #5 diabet* near/3 (eye* or vision or visual* or sight*) #6 retinopath* near/3 (eye* or vision or visual* or sight*) #7 DR near/3 (eye* or vision or visual* or sight*) #8 #1 or #2 or #3 or #4 or #5 or #6 or #7 #9 MeSH descriptor: [Mass Screening] explode all trees #10 MeSH descriptor: [Vision Tests] explode all trees #11 MeSH descriptor: [Telemedicine] explode all trees #12 MeSH descriptor: [Photography] explode all trees

7.(encourag$ discourage$ or reluctan$ or nonrespon$ or non respon$ or refuse$).tw. 8.(non-attend$ or non attend$ or dropout or drop out or apath$).tw. 9.Health Education/ 10.exp Patient Education as Topic/ 11.exp Health Promotion/ 12.(educat$ adj2 (information or material or leaflet)).tw. 13.Socioeconomic Factors/ 14.exp Poverty/ 15.Social Class/ 16.((school or education$) adj3 (status or level or attain$ or achieve$)).tw. 17.Uncompensated Care/ 18.Reimbursement Mechanisms/ 29.Reimbursement, Incentive/ 20.(financial or pay or payment or copayment or paid or fee or fees or monetary or incentiv$).tw. 21.Healthcare Disparities/ 22.Health Status Disparities/ 23.exp Medically Underserved Area/ 24.Rural Population/ 25.Urban Population/ 26.exp Ethnic Groups/ 27.Minority Groups/ 28.Vulnerable Populations/ 29.((health$ or social$ or racial$ or ethnic$) adj5 (inequalit$ or inequit$ or disparit$ or equit$ or disadvantage$ or depriv$)).tw.	13. random$.tw. 14. exp placebo/ 15. placebo$.tw. 16. ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask$)).tw. 17. exp experimental design/ 18. exp crossover procedure/ 19. exp control group/ 20. exp latin square design/ 21. or/11-20 22. 21 not 9 23. 22 not 10 24. exp comparative study/ 25. exp evaluation/ 26. exp prospective study/ 27. (control$ or prospectiv$ or volunteer$).tw. 28. or/24-27 29. 28 not 9 30. 29 not (10 or 22) 31. 10 or 23 or 30 32. "randomized controlled trial (topic)"/ 33. 31 or 32 34. exp diabetes mellitus/ 35. exp diabetic retinopathy/ 36. ((diabet$ or proliferative or non-proliferative) adj4 retinopath$).tw. 37. diabetic retinopathy.kw. 38. (diabet$ adj3 (eye$ or vision or visual$ or sight$)).tw. 39. (retinopath$ adj3 (eye$ or vision or visual$ or sight$)).tw. 40. (DR adj3 (eye$ or vision or visual$ or sight$)).tw. 41. or/34-40 42. exp Screening/ 43. exp Vision Test/ 44. Eye Examination/ 45. Telemedicine/ 46. Photography/ 47. Eye Photography/	#13 MeSH descriptor: [Ophthalmoscopes] explode all trees #14 MeSH descriptor: [Ophthalmoscopy] explode all trees #15 ophthalmoscop* or fundoscop* or funduscop*:ti #16 (exam* or photo* or imag*) near/3 fundus #17 photography or retinography #18 (mydriatic or digital or retina* or fundus or steroscopic) near/3 camera* #19 (mydriatic or digital or retina* or fundus or steroscopic) near/3 imag* #20 screen$.tw. #21 (eye* or retina* or ophthalm*) near/4 exam* #22 (eye* or vision or retinopathy or ophthalmic) near/4 test* #23 (eye* or retina* or ophthalm*) near/4 visit* #24 MeSH descriptor: [Office Visits] this term only #25 (telemedicine* or telemonitor* or telescreen* or telehealth or teleophthalmology) #26 #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 #27 MeSH descriptor: [Quality of Health Care] explode all trees #28 MeSH descriptor: [Quality of Health Care] this term only #29 MeSH descriptor: [Quality Improvement] this term only #30 MeSH descriptor: [Delivery of Health Care] this term only #31 MeSH descriptor: [Delivery of Health Care, Integrated] this term only #32 service delivery #33 decision making #34 consensus near/3 (process* or discuss) #35 stakeholder* #36 MeSH descriptor: [Quality Control] this term only #37 MeSH descriptor: [Total Quality Management] this term only #38 MeSH descriptor: [Quality Indicators, Health Care] this term only #39 MeSH descriptor: [Quality Assurance, Health Care] this term only #40 quality assurance #41 quality near/2 improv* #42 total quality #43 continuous quality #44 quality management #45 (organisation* near/3 cultur*) #46 MeSH descriptor: [Disease Management] this term only

30.(disadvant$ or marginali$ or underserved or under served or impoverish$ or minorit$ or racial$ or ethnic$).tw. 31.exp culture/ 32.sex factors/ 33. ((gender or women$) adj4 (inequalit$ or inequit$ or disparit$ or equit$ or disadvantage$)).tw. (34 –error) 35. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 36 .exp Diabetic Retinopathy/ 37.exp Diabetes Complications/ 38.((diabet$ or proliferative non-proliferative) adj4 retinopath$).tw. 39 .(diabet$ adj4 (eye$ or vision or visual$)).tw. 40 .(retinopath$ adj3 (sight$ or vision or visual$)).tw. 41 .(DR adj3 (sight or vision or visual$)).tw. 42 or/36-41 43 exp mass screening/ 44 .exp vision tests/ 45 .exp telemedicine/ 46 .exp Photography/ 47 exp ophthalmoscopes/ 48 .exp ophthalmoscopy/ 49. (ophthalmoscop$ or fundoscop$ or funduscop$).ti.	48. Ophthalmoscopy/ 49. (ophthalmoscop$ or fundoscop$ or funduscop$).ti. 50. ((exam$ or photo$ or imag$) adj3 fundus).tw. 51. (photography or retinography).tw. 52. ((mydriatic or digital or retina$ or fundus or steroscopic) adj3 camera).tw. 53. ((mydriatic or digital or retina$ or fundus or steroscopic) adj3 imag$).tw. 54. screen$.tw. 55. ((eye$ or retina$ or ophthalm$) adj4 exam$).tw. 56. ((eye or vision or retinopathy or ophthalmic) adj4 test$).tw. 57. ((eye$ or retina$ or ophthalm$) adj4 visit$).tw. 58. (telemedicine$ or telemonitor$ or telescreen$ or telehealth or teleophthalmology).tw. 59. or/42-58 60. Health Care Quality/ 61. Quality Improvement/ 62. Health Care Delivery/ 63. Integrated Health Care System/ 64. service delivery.tw. 65. decision making.tw. 66. (consensus adj3 (process$ or discuss)).tw. 67. stakeholder$.tw. 68. Quality Control/ 69. Total Quality Management/ 70. quality assurance.tw. 71. (quality adj2 improv$).tw. 72. total quality.tw. 73. continuous quality.tw. 74. quality management.tw. 75. (organisation$ adj3 cultur$).tw. 76. disease management/ 77. program evaluation/ 78. ((provider$ or program$) adj3 (monitor$ or evaluate$ or modif$ or practice)).tw. 79. (implement$ adj3 (improve$ or change$ or effort$ or issue$ or impede$ or glossary or tool$ or innovation$ or outcome$ or	#47 MeSH descriptor: [Program Evaluation] this term only #48 (provider* or program*) near/3 (monitor* or evaluate* or modif* or practice) #49 implement* near/3 (improve* or change* or effort* or issue* or impede* or glossary or tool* or innovation* or outcome* or driv* or examin* or reexamin* or scale* or strateg* or advis* or expert*) #50 needs near/3 assess* #51 (education* or learn*) near/5 (continu* or material* or meeting or collaborat*) #52 MeSH descriptor: [Medical Audit] explode all trees #53 audit or feedback or compliance or adherence or training or innovation:ti #54 guideline* near/3 (clinical or practice or implement* or promot*) #55 MeSH descriptor: [Health Services Accessibility] explode all trees #56 outreach near/2 (service$ or visit*) #57 intervention* near/3 (no or usual or routine or target* or tailor* or mediat*) #58 usual care #59 #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54 or #55 or #56 or #57 or #58 #60 MeSH descriptor: [Reminder Systems] explode all trees #61 remind* #62 improve* near/3 (attend* or visit* or intervention* or adhere*) #63 increas* near/3 (attend* or visit* or intervention* or adhere*) #64 appointment* near/3 (miss* or fail* or remind* or follow up) #65 MeSH descriptor: [Telephone] this term only #66 telephone* #67 MeSH descriptor: [Cell Phones] this term only #68 MeSH descriptor: [Mobile Applications] this term only #69 MeSH descriptor: [Remote Consultation] this term only #70 m-health or e-health or g-health or u-health #71 phone* near/1 (smart or cell) #72 smartphone* or cellphone* #73 hand held device*

50 .((photo$ or imag$) adj3 fundus).tw 52 .((mydiatric or digital or retina$ or funduc or stereoscopic) adj3 camera).tw. 53 .((mydiatric or digital or retina$ or fundus or stereoscopic) adj3 imag$).tw. 54 .Screen$.tw. 55 .((eye$ or retina$ or ophthalm$) adj4 exam$).tw. 56 .((eye$ or vision or ophthalmic) adj4 test$).tw. 57 .((eye$ or retina$ or ophthalm$) adj4 visit$).tw. 58 .Office visits/ 59 .(telemedicine$ or telemonitor$ or telescreen$).tw. 60 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 61 35 and 42 and 60	driv$ or examin$ or reexamin$ or scale$ or strateg$ or advis$ or expert$)).tw. 80. (need$ adj3 assess$).tw. 81. ((education$ or learn$) adj5 (continu$ or material$ or meeting or collaborat$)).tw. 82. Medical audit/ 83. (audit or feedback or compliance or adherence or training or innovation).ti. 84. (guideline$ adj3 (clinical or practice or implement$ or promot$)).tw. 85. (outreach adj2 (service$ or visit$)).tw. 86. (intervention$ adj3 (no or usual or routine or target$ or tailor$ or mediat$)).tw. 87. usual care.tw. 88. reminder system/ 89. remind$.tw. 90. (improve$ adj3 (attend$ or visit$ or intervention$ or adhere$)).tw. 91. (increas$ adj3 (attend$ or visit$ or intervention$ or adhere$)).tw. 92. (appointment$ adj3 (miss$ or fail$ or remind$ or follow up)).tw. 93. telephone/ 94. telephone.tw. 95. Mobile Phone/ 96. Mobile Application/ 97. Teleconsultation/ 98. (m-health or e-health or g-health or u-health).tw. 99. (phone$ adj1 (smart or cell)).tw. 100. (smartphone$ or cellphone$).tw. 101. (hand adj1 held device$).tw. 102. (mobile adj2 (health or healthcare or phone$ or device$ or monitor$ or comput$ or app or apps or application)).tw. 103. Internet/ 104. Social Network/ 105. (email$ or text$ or message$).tw.	#74 mobile near/2 (health or healthcare or phone* or device* or monitor* or comput* or app or apps or application) #75 MeSH descriptor: [Internet] this term only #76 MeSH descriptor: [Social Networking] this term only #77 email* or text* or message* #78 letter or mail or mailed or print* or brochure* or newsletter* #79 #60 or #61 or #62 or #63 or #64 or #65 or #66 or #67 or #68 or #69 or #70 or #71 or #72 or #73 or #74 or #75 or #76 or #77 or #78 #80 MeSH descriptor: [Primary Health Care] this term only #81 MeSH descriptor: [General Practitioners] this term only #82 MeSH descriptor: [Physicians, Family] this term only #83 MeSH descriptor: [Physicians, Primary Care] this term only #84 MeSH descriptor: [Primary Prevention] this term only #85 MeSH descriptor: [Preventive Health Services] this term only #86 MeSH descriptor: [Community Health Services] this term only #87 MeSH descriptor: [Nurses, Community Health] this term only #88 MeSH descriptor: [Health Services, Indigenous] this term only #89 MeSH descriptor: [Rural Health Services] explode all trees #90 MeSH descriptor: [Mobile Health Units] this term only #91 Ophthalmologist* or Optometrist* or Optician* or Orthopist* or Refractionists #92 (Ophthalmic or eye) near/3 (surgeon* or nurse* or technician* or officer* or assistant* or staff*) #93 MeSH descriptor: [Physician's Practice Patterns] this term only #94 MeSH descriptor: [Professional Practice] this term only #95 MeSH descriptor: [Education, Medical, Continuing] this term only #96 MeSH descriptor: [Nurses] explode all trees #97 MeSH descriptor: [Specialties, Nursing] this term only #98 MeSH descriptor: [Nurse's Role] this term only #99 MeSH descriptor: [Education, Nursing, Continuing] this term only #100 nurse or nurses #101 MeSH descriptor: [Pharmacists] this term only #102 pharmacist* #103 (role or roles) near/3 expan* #104 task* near/3 shift* #105 MeSH descriptor: [Medical Records Systems, Computerized] explode all trees

	106. (letter or mail or mailed or print$ or brochure$ or newsletter$).tw. 107. Primary Health Care/ 108. General Practitioner/ 109. Primary Prevention/ 110. Preventive Health Service/ 111. Community Care/ 112. Community Health Nursing/ 113. exp Transcultural Care/ 114. Rural Health Care/ 115. Ophthalmologist/ 116. (Ophthalmologist$ or Optometrist$ or Optician$ or Orthopist$ or Refractionists).tw. 117. ((Ophthalmic or eye) adj3 (surgeon$ or nurse$ or technician$ or officer$ or assistant$ or staff$)).tw. 118. Clinical Practice/ 119. Professional Practice/ 120. Continuing Education/ 121. (professional adj3 (practice or develop$ or educat)).tw. 122. Nurse/ 123. Nursing Discipline/ 124. Nurse Attitude/ 125. Nursing Education/ 126. (nurse or nurses).tw. 127. pharmacist/ 128. pharmacist$.tw. 129. ((role or roles) adj3 expan$).tw. 130. (task$ adj3 shift$).tw. 131. Electronic Medical Record/ 132. Information System/ 133. Data Base/ 134. Computer System/ 135. Hospital Information System/ 136. ((health or healthcare) adj4 (record or management system$)).tw. 137. (decision adj5 support).ti. 138. cost benefit analysis/	#106 MeSH descriptor: [Management Information Systems] this term only #107 MeSH descriptor: [Database Management Systems] this term only #108 MeSH descriptor: [Computer Systems] this term only #109 MeSH descriptor: [Point-of-Care Systems] this term only #110 MeSH descriptor: [Hospital Information Systems] this term only #111 (health or healthcare) near/4 (record or management system*) #112 (decision near/5 support) .ti. #113 #80 or #81 or #82 or #83 or #84 or #85 or #86 or #87 or #88 or #89 or #90 or #91 or #92 or #93 or #94 or #95 or #96 or #97 or #98 or #99 or #100 or #101 or #102 or #103 or #104 or #105 or #106 or #107 or #108 or #109 or #110 or #111 or #112 #114 MeSH descriptor: [Economics] this term only #115 MeSH descriptor: [Costs and Cost Analysis] this term only #116 MeSH descriptor: [Cost Allocation] this term only #117 MeSH descriptor: [Cost-Benefit Analysis] this term only #118 MeSH descriptor: [Cost Control] this term only #119 MeSH descriptor: [Cost Savings] this term only #120 MeSH descriptor: [Cost of Illness] explode all trees #121 MeSH descriptor: [Cost Sharing] this term only #122 MeSH descriptor: [Deductibles and Coinsurance] this term only #123 MeSH descriptor: [Medical Savings Accounts] this term only #124 MeSH descriptor: [Health Care Costs] this term only #125 MeSH descriptor: [Direct Service Costs] this term only #126 MeSH descriptor: [Drug Costs] this term only #127 MeSH descriptor: [Employer Health Costs] this term only #128 MeSH descriptor: [Hospital Costs] this term only #129 MeSH descriptor: [Health Expenditures] this term only #130 MeSH descriptor: [Capital Expenditures] this term only #131 MeSH descriptor: [Economics, Hospital] explode all trees #132 MeSH descriptor: [Economics, Medical] explode all trees #133 MeSH descriptor: [Economics, Nursing] this term only #134 MeSH descriptor: [Economics, Pharmaceutical] this term only #135 MeSH descriptor: [Fees and Charges] explode all trees #136 MeSH descriptor: [Budgets] explode all trees #137 low* near/2 cost* #138 high* near/2 cost* #139 (health care or healthcare) near/2 cost*

	139. cost effectiveness analysis/ 140. cost of illness/ 141. cost control/ 142. economic aspect/ 143. financial management/ 144. health care cost/ 145. health care financing/ 146. health economics/ 147. hospital cost/ 148. (fiscal or financial or finance or funding).tw. 149. cost minimization analysis/ 150. (cost adj estimate$).mp. 151. (cost adj variable$).mp. 152. (unit adj cost$).mp. 153. (economic$ or pharmacoeconomic$ or price$ or pricing).tw. 154. exp Reimbursement/ 155. (financial or economic or pay or payment or copayment or paid or fee or fees or monetary or money or cash or incentiv$ or disincentiv$).tw. 156. (insurance adj3 (health$ or scheme$)).tw. 157. or/60-156 158. exp Patient Attitude/ 159. exp Health Behaviour/ 160. (barrier$ or obstacle$ or facilitat$ or enable$).tw. 161. (uptake or takeup or attend$ or accept$ or adhere$ or attitude$ or participat$ or facilitat$ or utilisat$ or utilizat$).tw. 162. (complie$ or comply or compliance$ or noncompliance$ or non compliance$).tw. 163. (encourag$ or discourage$ or reluctan$ or nonrespon$ or non respon$ or refuse$).tw. 164. (non-attend$ or non attend$ or dropout or drop out or apath$).tw. 165. Health Education/ 166. exp Patient Education/ 167. Diabetes Education/ 168. Help Seeking Behavior/	#140 fiscal or funding or financial or finance #141 cost near/2 estimate* #142 cost near/2 variable* #143 unit near/2 cost* #144 economic* or pharmacoeconomic* or price* or pricing #145 MeSH descriptor: [Uncompensated Care] this term only #146 MeSH descriptor: [Reimbursement Mechanisms] this term only #147 MeSH descriptor: [Reimbursement, Incentive] this term only #148 insurance near/3 (health or scheme*) #149 financial or economic or pay or payment or copayment or paid or fee or fees or monetary or money or cash or incentiv* or disincentiv* #150 #114 or #115 or #116 or #117 or #118 or #119 or #120 or #121 or #122 or #123 or #124 or #125 or #126 or #127 or #128 or #129 or #130 or #131 or #132 or #133 or #134 or #135 or #136 or #137 or #138 or #139 or #140 or #141 or #142 or #143 or #144 or #145 or #146 or #147 or #148 or #149 #151 #59 or #79 or #113 or #150 #152 MeSH descriptor: [Patient Acceptance of Health Care] explode all trees #153 MeSH descriptor: [Attitude to Health] explode all trees #154 MeSH descriptor: [Health Behavior] explode all trees #155 barrier* or obstacle* or facilitat* or enable* #156 uptake or takeup or attend* or accept* or adhere* or attitude* or participat* or facilitat* or utilisat* or utilizat* #157 complie* or comply or compliance* or noncompliance* or non compliance* #158 encourag* or discourage* or reluctan* or nonrespon* or non respon* or refuse* or refusal #159 non-attend* or non attend* or dropout or drop out or apath* #160 MeSH descriptor: [Health Education] this term only #161 MeSH descriptor: [Patient Education as Topic] explode all trees #162 MeSH descriptor: [Health Promotion] explode all trees #163 health near/2 (promotion* or knowledge or belief*) #164 educat* near/2 (intervention* or information or material or leaflet) #165 MeSH descriptor: [Socioeconomic Factors] this term only #166 MeSH descriptor: [Poverty] explode all trees #167 MeSH descriptor: [Social Class] this term only

	169. Patient Participation/ 170. Patient Decision Making/ 171. exp Health Promotion/ 172. (health adj2 (promotion$ or knowledge or belief$)).tw. 173. (educat$ adj2 (intervention$ or information or material or leaflet)).tw. 174. exp Socioeconomics/ 175. Income/ 176. Social Class/ 177. Social Status/ 178. Educational Status/ 179. ((school or education$) adj3 (status or level$ or attain$ or achieve$)).tw. 180. Employment/ 181. Health Care Disparity/ 182. Health Disparity/ 183. Rural Population/ 184. Rural Area/ 185. Urban Population/ 186. Urban Area/ 187. exp Ethnic Group/ 188. Ethnicity/ 189. Race Difference/ 190. Minority Groups/ 191. Vulnerable Populations/ 192. ((health$ or social$ or racial$ or ethnic$) adj5 (inequalit$ or inequit$ or disparit$ or equit$ or disadvantage$ or depriv$)).tw. 193. (disadvant$ or marginali$ or underserved or under served or impoverish$ or minorit$ or racial$ or ethnic$).tw. 194. or/158-193 195. 157 or 194 196. 33 and 41 and 59 and 195 197. (ranibizumab or bevacizumab or avastin or aflibercept or photocoagulation or coronary or cardiovascular).ti. 198. (blood glucose or blood pressure).ti. 199. (macula$ adj2 (oedema or edema)).ti.	#168 MeSH descriptor: [Educational Status] this term only #169 (school or education*) near/3 (status or level* or attain* or achieve*) #170 MeSH descriptor: [Employment] this term only #171 MeSH descriptor: [Healthcare Disparities] this term only #172 MeSH descriptor: [Health Status Disparities] this term only #173 MeSH descriptor: [Medically Underserved Area] explode all trees #174 MeSH descriptor: [Rural Population] this term only #175 MeSH descriptor: [Urban Population] this term only #176 MeSH descriptor: [Ethnic Groups] explode all trees #177 MeSH descriptor: [Minority Groups] this term only #178 MeSH descriptor: [Vulnerable Populations] this term only #179 (health* or social* or racial* or ethnic*) near/5 (inequalit* or inequit* or disparit* or equit* or disadvantage* or depriv*) #180 disadvant* or marginali* or underserved or under served or impoverish* or minorit* or racial* or ethnic* #181 #152 or #153 or #154 or #155 or #156 or #157 or #158 or #159 or #160 or #161 or #162 or #163 or #164 or #165 or #166 or #167 or #168 or #169 or #170 or #171 or #172 or #173 or #174 or #175 or #176 or #177 or #178 or #179 or #180 #182 #151 or #181 #183 #8 and #26 and #182 #184 (ranibizumab or bevacizumab or avastin or aflibercept or photocoagulation or coronary or cardiovascular):ti #185 blood glucose or blood pressure:ti #186 macula* near/2 (oedema or edema):ti #187 #184 or #185 or #186 #188 #183 not #187

	200. (cataract or intraocular or glaucoma).ti. 201. macula$ degeneration.ti. 202. nerve fiber layer.ti. 203. or/197-202 204. 196 not 203	

5.3 - S3 Tables. Methodological quality and applicability assessment of the included studies

Table 1. Methodological quality assessment of cross-sectional studies

	1.Research question or objectives clearly stated	*2.Study population clearly specified and defined*	*3.Participation rate of eligible persons at least 50%*	*4.All the subjects recruited from similar populations in the same time period*	*5.Inclusion and exclusion criteria prespecified and applied uniformly*	*6.Sample size justification, power description, or variance and effect estimates provided*	*7.Exposure(s) of interest measured prior to the outcome(s) being measured*	*8.Timeframe sufficient to see an association between exposure and outcome*	*9.For exposures that can vary in amount or level, the study examined different levels of the exposure related to outcome*	*10.Exposure measures clearly defined, valid, reliable, and implemented consistently across all study participants*	*11.Exposure(s) assessed more than once over time*	*12.Outcome measures clearly defined, valid, reliable, and implemented consistently across all study participants*	*13.Outcome assessors blinded to the exposure status of participants*	*14.Loss to follow-up after baseline 20% or less*	*15.Key potential confounding variables measured and adjusted statistically*
1.Abdulsalam S et al (2018) (Nigeria)	Yes	Yes	Yes	Yes	Yes	Yes	N/A	N/A	N/A	N/A	N/A	Yes	N/A	N/A	N/A
2.Adriono G et al (2011) (Indonesia)	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	No	No	No	N/A	Yes

3.Agarwal S et al (2005) (India)	Yes	Yes	N/A	Yes	Not reported	N/A	N/A	N/A	N/A	N/A	N/A	Yes	N/A	N/A	N/A
4.Anderson S et al (2003) (UK)	Yes	Yes	Yes	Yes	Yes	N/A	N/A	N/A	N/A	N/A	N/A	No	N/A	N/A	N/A
5.Baumeister SE et al (2015) (Germany)	No	Yes	N/A	Yes	Yes	N/A	N/A	N/A	Yes	No	N/A	No	Not reported	N/A	Yes
6.Bennet GH et al (2018) (Ireland)	No	Yes	Yes	Yes	Not reported	Not reported	N/A	N/A	N/A	N/A	N/A	Yes	N/A	No	No
7.Brechner RJ et al (1993) (USA)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	Yes	No	N/A	No	N/A	N/A	Yes
8.Cetin EN et al (2013) (Turkey)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	Yes	Yes	N/A	No	N/A	N/A	Yes
9.Creuzot GC et al (2014)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	No	Yes	N/A	No	No	No	Yes
10.Dervan E et al (2008) (Ireland)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	Yes	Yes	N/A	No	N/A	N/A	Yes
11.Eiser JR et al (2001) (UK)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	Yes	No	N/A	No	N/A	N/A	Yes
12.Foreman J et al (2017) (Australia)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	N/A	N/A	N/A	Yes	N/A	N/A	N/A
13.Gillibrand WP et al (2000) (UK)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	N/A	N/A	N/A	No	N/A	N/A	No
14.Gulliford MC et al (2010) (UK)	Yes	Yes	N/A	Yes	Yes	No	N/A	N/A	Yes	No	N/A	Yes	N/A	N/A	Yes

15.Harvey JN et al (2006) (UK)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	N/A	Yes	N/A	Yes	Not reported	N/A	No
16.Huang OS et al (2009) (Singapore)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	Yes	Yes	N/A	Yes	Yes	N/A	Yes
17.Hwang J et al (2015) (Canada)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	Yes	Yes	N/A	No	N/A	N/A	Yes
18.Islam FMA et al (2018) (Bangladesh)	Yes	Yes	Not Reported	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	N/A	N/A	Yes
19.Katibeh M et al (2017) (Iran) 2nd Article	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
20.Khandekar R et al (2008) (Oman)	Yes	Yes	Yes	Yes	Yes	Yes	N/A	N/A	N/A	N/A	N/A	Yes	N/A	N/A	N/A
21.Kurji K et al (2013)	Yes	Yes	No	Yes	Yes	No	N/A	N/A	N/A	N/A	N/A	Yes	N/A	No	No
22.Lee PP et al (1998)	Yes	Yes	Yes	Yes	No	No	N/A	N/A	N/A	Yes	N/A	Yes	N/A	Yes	Yes
23.Leese GP et al (2008) (UK)	Yes	Yes	N/A	Yes	Yes	N/A	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
24.Lian J et al (2018) (Hong Kong)	Yes	Yes	Yes	Yes	Yes	No	Yes	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
25.Moreton RBR et al (2017) (UK)	Yes	Yes	N/A	Yes	Yes	N/A	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes

26.Moss SE et al (1995) (USA)	Yes	Yes	No	Yes	Yes	No	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
27.Muecke JS et al (2008) (Myanmar)	Yes	No	No	Yes	No	No	N/A	N/A	Yes	Not Reported	N/A	Not Reported	N/A	N/A	Not Reported
28.Mukamel DB et al (1999) (USA)	Yes	Yes	N/A	Yes	Yes	No	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
29.Mumba M et al (2007)	Yes	Yes	Yes	Yes	No	No	N/A	N/A	N/A	N/A	N/A	Yes	N/A	Yes	Yes
30.Munoz B et al (2008) (USA)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
31.Murgatroyd H et al (2006) (UK)	Yes	No	Not reported	Yes	Not reported	No	N/A	N/A	N/A	Yes	N/A	Not Reported	N/A	N/A	No
32.Mwangi N et al (2017) (Kenya)	Yes	Yes	Yes	Yes	Yes	Yes	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
33.Namperumalsamy P et al (2004) (India)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	N/A	N/A	N/A	Yes	N/A	N/A	No
34.Newcomb PA et al (1990) (USA)	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Not reported	Yes	Yes
35.Newcomb PA et al (1992)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	Yes	No	Yes	Yes
36.Onakpoya OH et al (2010) (Nigeria)	Yes	Yes	Not reported	Yes	Not reported	No	N/A	N/A	Yes	Yes	N/A	No	N/A	N/A	No

37.Orton E et al (2013) (UK) (Audit)	Yes	Yes	N/A	Yes	Yes	N/A	Yes	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
38.Paksin Hall A et al (2013) (USA)	Yes	Yes	Not reported	Yes	Yes	N/A	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
39.Pasagian MA et al (1997)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	N/A	N/A	N/A	Yes	N/A	N/A	No
40.Paz SH et al (2006) (USA)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
41.Puent BD et al (2004) (USA)	Yes	Yes	No	Yes	Yes	N/A	N/A	N/A	N/A	N/A	N/A	Yes	N/A	N/A	N/A
42.Rim TH et al (2013) (Korea)	Yes	Yes	Yes	Yes	Yes	Not reported	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
43.Saadine JB et al (2008) (USA)	Yes	Yes	N/A	Yes	Yes	Not reported	N/A	N/A	Yes	Yeso	N/A	Yes	N/A	N/A	Yes
44.Scanlon PH et al (2008) (UK)	Yes	Yes	N/A	Yes	Yes	N/A	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
45.Scanlon PH et al (2016) (UK)	Yes	Yes	N/A	N/A	Yes	N/A	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
46.Schmid KL et al (2003) (Australia)	Yes	Yes	No	No	N/A	Not reported	N/A	N/A	Yes	Yes	N/A	Yes	Not reported	N/A	No
47.Schoenfeld ER et al (2001) (USA)	Yes	Yes	Not Reported	Yes	Yes	Not reported	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes

48.Sheppler CR et al (2014)	Yes	Yes	Yes	Yes	Yes	No	N/A	N/A	N/A	N/A	N/A	Yes	N/A	Yes	Yes
49.Shih HC et al (2007) (Taiwan)	Yes	Yes	No	No	No	Not reported	N/A	N/A	Yes	Yes	N/A	No	N/A	N/A	Yes
50.Srinivasan NK et al (2017) (India)	Yes	Yes	Not reported	Yes	Yes	No	N/A	N/A	No	Yes	N/A	Yes	N/A	N/A	Yes
51.Thapa R et al (2012) (Nepal)	Yes	Yes	Not reported	Yes	Yes	Not reported	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
52.Trento M et al (2002) (UK and Italy)	Yes	Yes	Yes	No	Yes	Not reported	N/A	N/A	No	Yes	N/A	Yes	N/A	N/A	No
53-a*. Van Ejik KN et al (2012) (Netherland) (Quantitative component)	Yes	Yes	Yes	Yes	Yes	Not reported	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	No
54.Walker EA et al (1997) (USA)	Yes	Yes	Yes	Yes	Yes	Not reported	N/A	N/A	N/A	N/A	N/A	Yes	N/A	N/A	N/A
55.Wang D et al (2010) (China)	Yes	Yes	Yes	Yes	Yes	Not reported	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
56.Xiong Y et al (2015) (China)	Yes	Yes	Not reported	Yes	Yes	Not reported	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes

57.Yeo ST et al (2012) (UK) First	Yes	Yes	Yes	Yes	Yes	Not reported	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes
58.Yeo ST et al (2012) (UK) Second	Yes	Yes	No	Yes	Yes	Not reported	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	No
59.Zhang X et al (2009) (USA)	Yes	Yes	Yes	No	Yes	Not reported	N/A	N/A	Yes	Yes	N/A	Yes	N/A	N/A	Yes

Table 2. Methodological quality assessment of cohort studies

	(A) Validity of study results								*(B) Results*			*(C) General applicability of results*		
	1.Addressed a clearly focused issue (discontinue if ' No')	*2.Acceptable method of cohort Recruitment (discontinue if ' No')*	*3.Exposure accurately measured to minimise bias*	*4.Outcome accurately measured to minimise bias*	*5.Identified all important confounding factors*	*6.Taken account of the confounding factors in the design and/or analysis*	*7.Complete enough follow up of subjects*	*8.Long enough follow up of subjects*	*9.Significance of the outcome difference between exposure groups given*	*10.Precision of the estimate mentioned*	*11.Results are believable*	*12.Results applicable to the general population*	*13.Study results fit with other available evidence*	*14.Implications of the study for practice noted*
60.Bamashmus MA et al (2009) (Yemen)	Yes	No	Yes	Yes	Yes	No	N/A (historical cohort)	N/A (historical cohort)	Yes	Yes	Yes	Not Reported	Not Reported	No
61.Kreft D et al (2018) (Germany)	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
62.Maberley DA et al (2002) (Canada)	Yes	No	No	Yes	Yes	Yes	Yes	Not Reported	Yes	No	Yes	Not Reported	Not Reported	Yes

63.Storey PP et al (2016) (USA)	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Not Reported	Not Reported	Yes

Table 3. Methodological quality assessment of case control studies

	(A) Validity of trial results						*(B) Results*			*(C) General applicability of results*	
	1.Addressed a clearly focused issue (discontinue if ' No')	*2.Used an appropriate method to answer the question (discontinue if ' No')*	*3. Acceptable method of case Recruitment*	*4.Acceptable method of selecting controls*	*5. Exposure accurately measured minimising bias*	*6.Taken account of the confounding factors in the design and/or analysis*	*7.Estimate and/or significance of the difference in risk between groups given*	*8.Precision of the estimate mentioned*	*9.Results are believable*	*10.Results applicable to the general population*	*11.Study results fit with other available evidence*
64.Lane M et al (2015) (UK)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Not Reported	Not Reported

Table 4. Methodological quality assessment of RCTs

	(A) Validity of trial results						*(B) Results*		*(C) General applicability of results*		
	1.Addressed a clearly focused issue (discontinue if ' No')	*2.Randomised assignment of patients to treatments (discontinue if ' No')*	*3. Patients, health workers and study personnel blinded*	*4.Groups similar at start of the trial*	*5. Groups treated equally other than for the intervention*	*6.All patients entered in the trial properly accounted for at conclusion*	*7.Treatment effect size mentioned*	*8.Precision of the treatment effect size mentioned*	*9. Results applicable to the general population*	*10.All clinically important outcomes considered*	*11.Benefits worth the harms and costs*
65.Basch CE et al (1999) (USA)	Yes	Yes	Yes (not patients)	Yes	Yes	Yes	Yes	Yes	No	No	No
66.Lian JX et al (2013) (Hong Kong)	Yes	Yes	Yes (not patients)	Yes	Yes	Yes	Yes	Yes	No	No	Yes
67.Hazavehei SMM et al (2010) (Iran)	Yes	No	Not Reported	No	Not Reported	Not Reported	Yes	No	Not Reported	No	Not Reported

Table 5. Methodological quality assessment of qualitative research

	1.Clear statement of the aims of the research (discontinue if ' No')	*2.Appropriate to use a qualitative methodology (discontinue if ' No')*	*3.Research design appropriate for addressing aims of the research*	*4.Recruitent strategy appropriate for aims of the research*	*5.Data collected in a way that addressed the research issue*	*6.Relationship between researcher and participants adequately considered*	*7.Ethical issues have been taken into consideration*	*8.Data analysis sufficiently rigorous*	*9.Clear statement of findings*	*10.The research has practical value*
68.Glasson NM et al (2017)	Yes	Yes	Yes	No	Yes	Not Reported	Yes	Yes	Yes	Yes
69.Hartnett ME et al (2005) (USA)	Yes	Yes	Yes	Yes	Yes	Yes	Not Reported	Yes	Yes	Yes
70.Hipwell AE et al (2014) (UK)	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
71.Katibeh M et al (2017) (Iran) First	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes

72.Lake AJ et al (2017) (Australia)	Yes	Yes	Yes	Yes	Yes	Not Reported	Yes	Yes	Yes	Yes
73.Lewis K et al (2007) (UK)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
74.Lindenmeyer A et al (2014) (UK)	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
75.Liu Y et al (2018) (USA)	Yes	Yes	Yes	Yes	Yes	Not Reported	Yes	Yes	Yes	Yes
53-b*. VanEijk KN et al (2012)	Yes	Yes	No	No	No	Not Reported	Yes	No	Yes	Yes

**VanEijk KN et al conducted using mixed methods. Two reviews articles were not included in quality analysis table as those were not complied with assessment criteria. (1-Burgess PI el al, 2013. 2-Khandekar R et al) 2012).*

5.4 - S4 Table. Participants' characteristics of included articles

Study ID	Country	Type of Study	Objective	Study Setting	Sampling Strategy / Participants' characteristics	Sample size (Response rate %)	Sample Numbers (Male: Female Ratio - %)	Mean age (SD) (95% CI) [Range] years	Mean duration of diabetes (Years) (SD) [Range]	Level of DR-Prevalence [or Number DR+ve]
1. Abdulsalam, S. et al. (2018)	Nigeria	Cross sectional study	To assess knowledge, attitude and practice of DR screening among physicians	Tertiary health hospitals	Participants were GPs, residents and consultants in family medicine.	Physicians N= 110 (Response rate 95%)	Female= 26 (24.8%)	21-30 yrs - 40% 31-40 yrs - 45%	N/A (experience - 76% less than 5 years)	N/A

								41 yrs and above - 14%		
2.Adriono, G. et al (2011)	Indonesia	Cross sectional	To assess the use of eye care and its predictors among diabetic patients	Tertiary clinic and 2 community clinics	Physician diagnosed diabetics	n=198 (99%)	Female 61.5%	58.4 (9.4)	5.58 (6.01)	[14/198]
3.Agrawal, S. et al (2005)	India	Cross sectional	To assess the rate of non-response who referred for eye examination	Rural screening camps	Physician diagnosed diabetics	N= 23,472 Known DM n=4111 (55%) New DM n=1076 (11.6%)	1.27:1	46.5 (13) [Range 20-58]	Not mentioned	Not mentioned
4.Anderson S. et al (2003)	United Kingdom	Cross sectional	To evaluate the Feasibility and cost of screening home bound diabetics	Private sector	GP diagnosed diabetes	80 (80%)	1:1.46	80 [Range 51-97 years]	Not mentioned	[46/80]
5.Bamashmus, M.A. et al (2009)	Yeman	Cohort study	Association of regularity of visit to diabetic clinic with presence of DR and visual disability	Eye clinic	Physician diagnosed diabetics	Group A-n=114 (Type 1-28.9%) Group B-n=114 (Type 1-28.1%)	Group A - (M-52.6%, F-47.4%) Group B - (M-43.9%, F-56.1%)	50.01 (11.995) [Range 17-85 years]	Not mentioned	51.1% (44.6-57.6%) [115]
6.Basch, C.E. et al (1999)	United States of America	RCT	Educational Interventions to increase ophthalmic examination rates	General medical clinics	Diagnosed diabetics from audit records	n=280 (Interventionn = 137, Control n=143)	Male 34.3% in intervention, 34.3% in control	Intervention-55.6 (12.9) Control-53.9 (12.8)	Intervention-8.1 (7.4) Control-7.8 (7.3)	Not mentioned

7.Baumeister, S.E. et al (2015)	Germany	Retrospective data analysis	To Study trends of barriers to receiving recommend eye care among subjects with diabetes	Population based samples	Physician diagnosed diabetics	1st group n= 4308 2nd group n=4402	Females in 1st group 2192 and 2nd group 2275	[Range 20 - 81 years]	Not mentioned	Not mentioned
8. Bennet GH, et al. (2018)	Ireland	Cross sectional	To determine the barriers to the uptake of diabetic retina screen	Tertiary hospital	Random sampling	Patients N=147 Practitioners N=72 (response rate 72/94, 76%)	Not mentioned	Not mentioned	Not mentioned	Not mentioned
9.Brechner, et al (1993)	United States of America	National survey	Factors associated with receiving recommended eye examinations for detection of DR	National level survey	Physician diagnosed diabetics	2829 (85%) (Type 1 n=124, Type 2 n=2268)	Male 41% - 53%	IDDM-34.1, NIDDM with insulin-60.6, NIDDM without insulin-62.6	IDDM-17.9, NIDDM with insulin-13.4, NIDDM without insulin-8.6	Ever told had DR 26.2%
10.Cetin, E.N. et al (2013)	Turkey	Cross sectional	To assess the awareness of DR and the utilisation of eye care services	University clinic and primary care clinic	Diagnosed diabetics on followed up	n=514 (85%) (Type 1-14.6%, Type not known-37.3%)	Male 211 (48.2%) Female 226 (51.8%)	55.2 (11.9)	9.4 (7.7)	Not mentioned
11.Creuzot, G.C. et al (2014)	France	Cross sectional	To evaluate the effectiveness of a mobile DR screening campaign with a non-mydriatic camera to encourage diabetics to undergo a subsequent ophthalmic follow-up.	Annual campaigns	Diabetics without having ophthalmic examination during last year	n=4699	Male 2757 (58.7%)	67.9 (10.7)	10.0 (9.0)	[805/4699]

12.Dervan, E. et al (2008)	Ireland	Cross sectional	To assess whether patients were receiving regular DR screening and to examine factors influencing screening uptake	Diabetes clinics	Diabetic patients were invited to two diabetic clinics	n=271 (77%) (Type1-13%)	Male 58%	61.6 (15)	7.7	28% (with history of DR and/or other eye disease)
13.Eiser, J.R. et al (2001)	United Kingdom	Cross sectional	To investigate patients' views of screening for DR and the effects of the screening process on health beliefs and behavioural intentions	GP clinic	Diabetic patients attending the retinal screening service	n=100 (Type 1- n=12)	53:47	67.0 (11.2) [Range 24-88 years]	9 (9.4) [Range 6 weeks-44 years]	[23/100]
14. Foreman, J et al. (2017)	Australia	Cross sectional	To determine the adherence of indigenous and non-indigenous Australians with diabetes, to NHMRC eye examination guidelines.	Thirty randomly selected geographic sites (National Eye Health Survey - National DR screening)	Self-reported diabetes	N=4836 Indigenous=1738 Non-indigenous=3098	Indigenous 41.1% male. Non-Indigenous 46.4% male.	Indigenous aged (40-92), mean - 55 - (SD = 10) Non indigenous aged (50-98), mean - 66.6, (SD = 9.7)	Indigenous median duration= 11y Non-indigenous median duration=10y	Not mentioned
15.Gillibrand, W.P. et al (2000)	United Kingdom	Cross sectional	To assess knowledge on eye complications	GP clinic	Diabetes not already attending an ophthalmologist	n=2386 (Insulin dependent- 17.1%)	Males 53.6% Females 46.4%	61 (14.9)	1-5 years (44.9%)	Not mentioned
16.Glasson, NM. et al. (2017)	Australia	Qualitative study	To assess the acceptability of a remote DR screening model	Remote Outreach DR Screening Modality	PwDM living in remote areas Stakeholders involved in the programme	N=14 PwDM N=9 Stake holders	PwDM 64% Female	Range (20-81) yrs	Range [<1 - 25] yrs	1/14 Moderate NPDR 1/14 Severe NPDR 2/14 Mild NPDR

17.Gulliford, M.C. et al (2010)	United Kingdom	Retrospective data analysis	To quantify socio-economic and ethnic inequalities in diabetes retinal screening	Teaching hospitals and one district hospital	GP-registered diagnosed diabetes	n=31484 (Type 1-n=1718, Other and not known-n=6728)	Male 16145, Female 15339	Not mentioned	Not mentioned	STDR 11.5% [2819]
18.Hartnett, M.E. et al (2005)	United States of America	Qualitative study	To address inadequate retinopathy screening at a largely indigent clinic and to explore perceived barriers using qualitative techniques	University health centre	Patients were recruited through a word of mouth and flyers in clinics	Diabetics n=17, n=12 staff members, n=10 residents, n=9 ophthalmologists, n=13 PDPs)	Male 4 Female 13	[Range 30 - 60 years]	>5 in 1/3	Not mentioned
19.Harvey, J.N. et al (2006)	United Kingdom	Retrospective data analysis	To examine population-based retinopathy screening, barriers to achieving comprehensive population coverage	Local health board areas	Diagnosed Diabetics	Under GP care n=3565 Optometrists Care n=8176	Not mentioned	Not mentioned	Not mentioned	STDR [78/305]
20.Hazavehei, S.M.M. et al (2010)	Iran	Comparison of groups	Determine the effect of educational program on eye care	Diabetes care centre	Patients with NIDDM at risk of ocular complications	100 (divided in to groups 50 each, from 250 invited)	Experimental group – male - 11, female – 39. Control group – male -13, female - 37	Experimental group-54.4 (7.52) Control group-54.24 (6.52) [Range 40-60 years]	>5yrs	Not mentioned

21.Hipwell, A.E. et al (2014)	United Kingdom	Qualitative study	Examine the experiences of patients, professionals and screeners ; their interactions with and understandings of DRS; and how these influence uptake	GP clinic	Diabetics from GP records	n=62 (DM patients n=38) Professionals=24)	Females 33 (53%)	Type 1 DM-49 Type 2 DM-60 Professionals-50	Not mentioned	Not mentioned
22.Huang, O.S. et al (2009)	Singapore	Cross sectional	To assess the awareness of diabetes and diabetic retinopathy in a Singaporean Malay population	Population based survey	Physician diagnosed diabetics	General population-n= 3280 (Including n=769 diabetics)	Females (50.5% to 64.4%)	[Range 40 - 80 years]	Not mentioned	35.7% [272/769]
23.Hwang, J. et al (2015)	Canada	National surveys	To examine the association between socioeconomic factors and ophthalmic care services/visual impairment	Community health survey	Self-reported diabetes	n=2323 (81.7% of 2933 of SLCDC responders)	Male 58.5%, Female 41.5%	Not mentioned	Not mentioned	Not mentioned
24.Islam FMA, et al. (2018)	Bangladesh	Cross sectional study	Factors associated with participation in a DR screening program in a rural district.	Rural community clinic	Participants selected from a cross-sectional study	N=213	Male 32%	>40 years	Not mentioned	Not mentioned
25.Katibeh M. et al (2017)	Iran	Qualitative study	To assess the national health system for management of DM, with particular focus on DR.	Work place of each stakeholder.	Identified at Ministry of Health and other professional bodies	N=15 stakeholders, 14 interviewed. 93.3% response rate.	Not mentioned	N/A	N/A	N/A

26.Katibeh et al (2017) (2nd Article)	Iran	Cross sectional	To determine diabetic individuals' level of awareness about the importance of regular eye examinations	Population based (Yazd Eye Study)	Random cluster sampling	Main sample N=2098, N=497/539 diabetics (92%)	Male: Female = 46:54	Not mentioned	6.71 [5.82-7.60]	[156/488]
27. Kreft D. et al. (2018)	Germany	Cohort study	To assess factors associated with DR screening uptake.	Ophthalmologist screening clinics.	Diagnosed PwDM identified in a public health insurance scheme	N= 26,560 type 2 DM	Men 12,861 48.4% Women 13,699 51.6%	(50-69) 55.3% (70-74) 17.2% (75-79) 12.6% (80-84) 8.4% (85-89) 4.1% (90+) 2.4%	Mean 5.2yrs Median 5.5yrs	Not mentioned
28.Khandekar, R. et al (2008)	Oman	Cross sectional	To determine the knowledge, attitudes practices regarding eye examination for DR among non-ophthalmologist physicians	Primary health care centres and policlinics	Physicians involved in care of diabetics	n=40 (14 family physicians, 9 hospital physicians, 1 diabetologis, 12 other doctors)	Not mentioned	Not applicable	Not applicable	Not applicable
29. Lake A.J. et al (2017)	Australia	Qualitative study	To explore screening barriers and facilitators compared to a comparator group.	Eye clinic in a community setting	Self-reported diabetes	N= 49 people with Type2 DM (n=14 young, 35 older)	Young adults 50% female. Older adults 50% female.	Young adults 32.6y (32.0–34.8) Older adults 62.5y (55.9–72.8)	Young adults 1.45y (0.3–4.5) Older adults 13y (2.8–15.3)	Young adults 0% Older adults 25%
30.Leese, G.P. et al (2008)	United Kingdom	Retrospective data analysis	To identify criteria that affect uptake of diabetes retinal screening in a community screening program using mobile retinal digital photography units	GP clinic	All diabetics	n=15150	Male 54%	63 (15) [Range 12-102 years]	7.34	Not mentioned

31.Lewis, K. et al (2007)	United Kingdom	Qualitative study	To determine what factors may influence diabetic patients' attendance at eye clinics	2ry eye clinic in rural district hospital and specialised eye clinic in a 3ry hospital	Diagnosed DR patients	Patients n=48 Service providers n= 25	Females N=14 (29.1%)	[Range 20-72 years]	Not mentioned	Not mentioned
32.Lian, J.X. et al (2013)	China	RCT	To examine whether inverse care law operates in DR screening based on fee for service	Primary care clinic	Self-reported diabetics	Free group - n=1316 (88.5%) Pay group- n=1277 (82.4%)	Females - Free group 721 (54.8%) Pay group 701 (54.9%)	Free group- 64.1 (10.8) Pay group 64 (11.2)	Free group- 7.7 (7.07) Pay group- 7.6 (6.99)	Free group 25.9% [302] Pay group 20.3% [214]
33. Lian, JX. Et al, (2018)	Hong-Kong	Cross sectional study	To assess the association between awareness of DR and actual attendance for DR screening	Two public general outpatient clinics	Diagnosed DM who participated in RCT in 2008	N= 2593 (screening attendance - 85% - 2217/2593)	Female = 1422 (54.8%)	Mean age 64 years	Mean 7.6 years	Not mentioned
34.Lindenmeyer, A. et al (2014)	United Kingdom	Qualitative case-based study	To identify factors contributing to high or low patient uptake of retinopathy screening	Hospital, high-street opticians and GP practice	Professionals and diagnosed diabetics	n=62 patients and professionals (38 Patients- and 9 GP practices)	Not mentioned	Not mentioned	Not mentioned	Not mentioned
35. Liu Y, et al. (2018)	United States of America	Qualitative study	To characterize contextual factors affecting rural patient adherence with diabetic eye screening guidelines.	Mile Bluff- rural- multi-payer health system	Physician diagnosed type 2 diabetics Providers	N= 20 N=9	Male 55%	67 years Range [46-86 years]	40% - <5years 30% - 5- 19 years 30%- 20+ years	Not mentioned

36.Maberley, D.A. et al (2002)	Canada	Cohort	To explore the factors that are associated with attendance in screening examinations for DR	General hospital	All diabetics	n=248	34.7:65.3	52.9 (15.1)	Not mentioned	Not mentioned
37.Moss, S.E. et al (1995)	United States of America	Cross sectional	To estimate the compliance with guidelines on ocular examination for diabetic persons, to examine factors that affect compliance, and to determine reasons for non-compliance.	Primary care clinic	Diagnosed diabetics	n=1298 (Younger onset <30 years n=765, Older onset >30 years n=533)	Younger onset- Males 375, Females 380 Older onset- Males 212, Females 296	Younger onset-37 [Range 14-76 years] Older onset-71 [Range 42-98 years]	Younger onset-23 Older onset-20 [Range - 10-40 years]	[718/1298]
38. Moreton R.B.R. et al (2017)	United Kingdom	Cross sectional study	To investigate variables at the demographic and primary care practice levels that influence the uptake of diabetic retinopathy screening.	79 general practices	GP diagnosed DM	N=21,789 invited, of which 82.4% attended.	Male 10,303 Female 7,633 [attended]	(12-39 yrs) n=940 (40-59 yrs) n=4727 (60-69 yrs) n=4763 (70-79 yrs) n=4727 >80 yrs N=2805	Not mentioned	82.4% of invited screened, but DR+ not mentioned

39.Muecke, J.S. et al (2008)	Myanmar	Cross sectional	Evaluate the awareness of diabetes-related eye disease among GPs and diabetic patients	GP clinics	Registered diabetics	GPs n=200 (50%) Patients n=480 Juvenile DM 1 (0.2%), Maturity 454 (94.6%), Missing 25 (5.2%)	GP - 49:49 Patients – Female 304 (63.5%)	GP - 47 (7.7) Patients-57.5 (11.0)	Not mentioned	Not mentioned
40.Mukamel, D.B. et al (1999)	United States of America	Cross sectional	To identify barriers to compliance with guidelines for DR screening	Database analysis	Diagnosed with diabetes	Patients-n=4410 Primary care physicians-n=408	Male - 55.8%	Patients 50.5 (8.7) [Range 31 - 64]	Not mentioned	Not mentioned
41.Mumba, M. et al (2007)	Tanzania	Prospective	To measure the current use of eye department by diabetics and improvement in usage after HE intervention	Urban specialised eye centre	Diabetics at KCMC	n=316 n=114 following referral	Male 147 (46.5%)	56.5 (13.3)	6.8 (5.5)	Of 225 - No DR 68 (64.1%) NPDR 17 (16%) PDR 1 (0.9%)
42.Munoz, B. et al (2008)	United States of America	Cross sectional	To determine gaps in knowledge and barriers to care for diabetic eye disease in Hispanic individuals	Not mentioned	Year 2000 census with and without diagnosed DM	Without Diabetes n=329 With Diabetes n=222	Female Without DM-43% With DM-46%	Without DM-35 (11) With DM-48 (12)	6.2 (SD 7)	Not mentioned

43.Murgatroyd, H. et al (2006)	United Kingdom	Cross sectional	To explore attitudes of patients towards mydriasis for DR screening	Diabetic clinics	Diabetics at clinics with and without experience on mydriasis	n=395 Group 1 (with mydriasis experience)-n=292 Group 2 (without mydriasis experience)-n=103	not mentioned	Group 1 - 63 [Range 20-94 years] Group 2 - 68 [Range 29-96 years]	Not mentioned	Not mentioned
44.Mwangi N. et al (2017)	Kenya	Clinic based Cross-sectional study	Identify the demand-side factors that influence uptake of eye examination	9 Diabetes clinics in 3 counties.	Diagnosed at county clinics	N=270 90 participants per county.	Men 127 (47%) Women 144 (53%)	52.3 years (SD 14.1, range 25–88 years).	7.3 Years (SD 5.5)	Not mentioned
45. Nam perumalsamy, P. et al 2004	India	Cross sectional	To determine current levels of knowledge, attitudes and practices regarding retinopathy in the community to aid development of appropriate health education materials	Community project	Paramedical personnel and general public (including self-reported diabetics)	Paramedics n=99 (99.5%) Members of the community n=204 including 69 (33.8%) diabetics	Paramedics 153 (77.3%) females Community 138 (67.6%) males	Paramedics 42.4 [Range 24-58 years] Community 44.5 [Range 20-75 years]	Not mentioned	Not mentioned
46.Newcomb, P.A. et al 1990	United States of America	Cross section	To evaluate the factors associated with compliance following Diabetic eye screening	Mobile examination van	Diabetics	n=1878 Further care recommended n=819 Younger-onset n=445	49:51 Males - Younger-onset 227 (74.9%) Older onset insulin	Not mentioned	Not mentioned	Not mentioned

						Older onset insulin taking n=260 Older onset non-insulin taking n=114	taking 128 (75.8%) Older onset non-insulin taking 47 (66%)			
47.Newcomb, P.A. et al 1992	United States of America	Population based survey	To evaluate the incidence and associated risk factors for DR (provided the opportunity to evaluate an intervention to increase ophthalmologic care)	Mobile examination van	Diabetics	WESDR Intervention n=619 Control n=241	WESDR Male – 289 (47%) Control Male – 105 (44%)	Not mentioned	Not mentioned	WESDR 26% [161/616] Control 24% [55/233]
48.Kurji, K. et al 2013	Kenya	Cross sectional	To assess the patient preference for DR screening with teleophthalmology or face to face ophthalmologist evaluation	Diabetic clinic	Diagnosed diabetics in a diabetic clinic - data base	n=57 (26 responded)	Male 15(58%) Female 11(42%)	Male-52.4 Female-46.5	Not mentioned	Not mentioned
49.Lane, M. et al 2015	United Kingdom	Case-control	To determine whether social deprivation is a risk factor for late presentation of PDR and whether it affects their access to urgent laser treatment.	DR screening program	Known diabetics at UK national DR screening program	n=102 (n=34 cases and n=68 controls)	M:F Case 23:11, Control 35:31	Case-57 (12.3) Control-64 (18.1)	Not mentioned	R3 level in cases, R1-2 levels in controls
50.Lee, P.P. et al 1998	United States of America	Cross sectional	To access the association between structural factors in the health care delivery system and self -reported utilization of ophthalmic services	Non-profit, staff model HMOs	Patients in the MOS had medical conditions that were clarified by physicians and reports	Diabetics N=522	Male 44%	59	Not mentioned	Not mentioned

51.Onakpoya, O.H. et al 2010	Nigeria	Cross sectional	To assess the prevalence and factors influencing previous dilated eye examination in screening for retinopathy among type II diabetics.	Teaching hospital clinic	Diabetic patients receiving treatment at a University Teaching Hospital	n=83	Female 51 (61.4%)	57.5 (10.8)	6.6	DR 21.6% No DR 62 (74.8%) NPDR 17 (20.4%) PDR 1 (1.2%)
52.Orton, E. et al 2013	United Kingdom	Mixed methods health equity audit	To assess equity of access to DR screening in a geographically and ethnically diverse population and determine predictors for poor uptake	Postal survey	Diagnosed diabetics invited for DR screening	n=1000 (n=809 type 2 and n=148 type 1, n=43 not known) (43%, 435 postal response)	Returned questionnaire Female 202 Male 232	Men - 64 (14.1) Women - 66.6 (15.2)	Not mentioned	Not mentioned
53.Paksin Hall, A. et al 2013	United States of America	Retrospective data analysis	To examine the variables that contribute to diabetes patients not receiving annual dilated eye examinations	System data analysis	Diabetics registered in the National survey Diagnosis of diabetes	System data n= 52,386	Male - 21,348 (weighted 50.8%) Female - 31,038 (weighted 49.2%)	Not mentioned	Not mentioned	Not mentioned
54.Pasagian, M.A. et al 1997	United States of America	Cross sectional	To study the relationship between patients' socio demographic characteristics and their knowledge and beliefs of diabetes	Telephone interviews	Diagnosed diabetics in a clinic	n=150	100% Female	59.1 (11.3)	Mean age at diagnosis 47.1 (14)	Not mentioned

55.Paz, S.H. et al 2006	United States of America	Cross sectional	To determine the prevalence of and personal factors associated with non-compliance with American Diabetes Association (ADA) guidelines for vision care	In home and local eye centre	Self-reported diabetics from the Los Angeles Latino Eye Study	Type 2 diabetes n=821	Females 56%	59.8 (10.1)	Not mentioned	Not mentioned
56.Puent, B.D. et al 2004	United States of America	Telephone interview	To determine the reasons some diabetics not receiving a dilated eye exam at least every year	Optometry practice	Chart review at optometrists - diabetes diagnosis by ICD 9 codes (Diabetes - 250)	Total n=100 n=43 completed the interview	Females 52%	56.2 (13.6-85.2)	13.7 (1.20-37.9)	No DR 48% NPDR 45% PDR 4% Unknown 3.0%
57.Rim, T.H. et al 2013	Korea	Cross sectional	Identify and determine the socio-demographic and health related factors associated with DR screening	Survey data	Diabetic patients	n=2660	Male 1285 (48.3%)	62.6 (10.4)	Not mentioned	Not mentioned
58.Saadine, J.B. et al 2008	United States of America	Retrospective (medical records)	To study the process of diabetes eye care by assessing follow-up eye examinations in patients with diagnosed diabetes in a managed care organization.	Tri-Central medical service area	Diabetic patients from a database	n= 2412 (Divided into who had a follow-up examination within 1 year and > 1 year)	Female ≤1 Year sample - 327 (48.6%) >1 Year sample – 849 (51.2%)	≤1 Year sample - 63.7 (11.5) >1 Year sample - 60.4 (12.5)	≤1 Year sample -10.3 (9.6) >1 Year sample - 6.9 (8.0)	11 – 50%
59.Scanlon, P.H. et al 2008	United Kingdom	Cross sectional	To investigate socioeconomic variations in diabetes prevalence, uptake of screening for DR, and prevalence of DR.	GP clinic	Diabetics from GDESS database	n = 13304 from data set 1 n = 10,312 from data set 2	Not mentioned	Data set 1-64.7 (15.3) Data set 2-66.5	Not mentioned	Data set 2 STDR 1386 (13.4%) Background DR 2150 (20.8%)

										No DR 6776 (65.7%)
60.Scanlon, P.H. et al 2016	United Kingdom	Cross sectional	To report relationship between age at diagnosis of DM, time from registration with the screening program to first DR screening and severity of DR	National screening program	Retrospective anonymised data of diabetics	n=689025 (9.4% of 620281 - Type 1)	54.9% : 43.1%	Not mentioned	Type 1 - 22 (IQR 12-34) Type 2 - 59 (IQR 50-68)	Average 33%
61.Schmid, K.L. et al 2003	Australia	Cross sectional	To determine the level of awareness of diabetes and its ocular complications within the community and among the members of Diabetes Australia	Regional survey	Two samples – One with diabetics from members of Diabetes Australia and other without diabetics from the current electoral roll	n= 500 diabetics (response rate-33.5%) N=1000 random people (response rate-58.6%) 23.2 % type I diabetes	From 1000 sample 46% males and 54% females. From 500 sample 53% males and 47% females	Not mentioned	9.4 (9.7)	Not mentioned Patient reported DR From 1000 sample 1%, From 500 sample 16.1%.
62.Schoenfeld, E.R. et al 2001	United States of America	Cross sectional prospective + RCT	To describe the baseline patterns of adherence to vision care guidelines and to evaluate the factors associated with non-adherence, RCT - to evaluate the effect of an educational intervention	Community wide campaign	Physician diagnosed diabetics	n=2308 (both type 1 and 2)	Total Male 45%	54.1 (14.3) Median 55 [Range 18-91]	9.6 (9.5) Median 6 [Range 0.5-70]	17% had DR

63.Shep-pler, C.R. et al 2014	United States of America	Cross sectional	To identify variables that predict adherence with annual eye examination	GP clinic	Adult diabetics already diag-nosed for an on-going trial (cri-teria not speci-fied)	n=316	Male 45.9% Female 54.1%	55.7 (11.6)	12.8 (8.1)	Not mentioned
64.Shih, H.C. et al 2007	Taiwan	Commu-nity based study	To explore the willing-ness to pay values for screening for DR	Community based screening	Community based screening program - diabe-tes diagnosis based on WHO - 1985 criteria	Adult, Type 2 diabetics in a community n=406 (56% of 725) partic-ipated	Male 156 Female 250	Not mentioned	Not men-tioned	No DR 289 (71.2%), NPDR 87 (21.4%), PDR 21 (3%), Blind 9 (2.2%)
65.Sirini-vasan NK, et al (2017)	India	Cross sectional	To document Knowledge, Attitude and Practice (KAP) patterns of diabetic patients regarding diabetes and diabetic retinopathy, and to identify barriers.	Tertiary hospital	Random sam-pling	N=288	Male: Fe-male= 160:128	Not mentioned	Not men-tioned	[108/288]
66. Storey, P.P. et al 2016	United States of America	Retro-spective cohort study	To evaluate the effect of written communication between an ophthalmolo-gist and a PCP on patient adherence to diabetic eye examination recommen-dations	Urban eye centre	Diabetics fol-lowed up – (us-ing a data base)	n=1968	Female 1077 (54.75%) Male 890 (45.25%)	>40 years (40-64 years) - 1369 (69.56%) ≥65 years- 599 (30.44%)	Not men-tioned	Mild DR 1468 (74.59%) Moderate DR 107 (5.44%) Severe DR 393 (16.65%)

67.Thapa, R 2012	Nepal	Cross sectional	To investigate the demographic characteristics and awareness of DR among new cases of DM	Tertiary eye clinic	New diabetics attending to VR clinic	New cases of DM at a VR clinic n=210	1.38:1	57 (10.2) [Range 30-81 years]	Not mentioned	DR 77.6%, PDR 16.67% CSME (36.7% - 40.5%), Non-CSME 3.3%
68.Trento, M. et al 2002	United Kingdom and Italy	Cross sectional	To assess how diabetic patients perceive retinopathy, screening for sight-threatening lesions and their own role in preventing blindness	GP clinics and diabetic clinics	Diabetics on follow up (screening for STDR)	Diabetic patients n=258 (Turin 130, Wales 128)	Males in 3 groups – W- 64 (50%) T1- 39 (56%) T2- 33 (55%)	Median age (25^{th}-75^{th} percentile) W- 66 (59-74) T1 - 63 (58-69) T2-63 (57-70)	Median (25^{th}-75^{th} percentile) W- 7 (3-14) T1- 12 (9-16) T2-11 (7-16)	Not mentioned
69.VanEjik, K.N. et al 2012	Netherland	Cross sectional	To examine incentives and barriers to attend DR screening	Primary care clinic	Diagnosed diabetics on follow up	Quantitative- n=2363 (73.1% of 3236) Qualitative – G 1 n=5 G 2 n=8 G 3 n=9 G 4 n=8	Total n=1891 DRS attendees- M-49.3% F-50.7% DRS non attendees- M-49.4% F-50.6%	Not mentioned	Not mentioned	Not mentioned
70.Walker, E.A. et al 1997	United States of America	Cross sectional	To assess the knowledge and health beliefs related to preventing diabetic eye complications	County medical centre	Diagnosed diabetics receiving care in a county medical centre	African American Diabetics n=67 (64% of 104)	Female 54 (80.5%)	58 (12)	12 (10)	Not mentioned

71.Wang, D. et al 2010	China	Cross sectional	To assess the use of eye care and its predictors among diabetic patients	Endocrinology clinic (urban 3ry), Medical (urban community) and a rural hospital clinic	Patients with physician-diagnosed diabete	n=824 (92.7% of 889) Type 1 - 6%	Female 58.8%	62.6 (12.9)	77.9 (89.6) months	Not mentioned
72.Xiong, Y. et al 2015	China	Cross sectional	To investigate prevalence and awareness of DR and its influential factors	Community	Diabetics in a community	n=1120	M : F - 508:612	58.2 [Range 36-72) years]	Not mentioned	DR 23.6% Mild DR 17.1% Moderate DR 5.1% Severe DR 1.4%
73.Yeo, S.T. et al 2012	United Kingdom	Cross sectional	To determine the preferences for diabetic retinopathy screening and examine the trade-offs between frequency of screening and other service attributes	DR screening clinics	Diagnosed diabetics registered in Wales DR screening program	n=160 (86.4% of 198)	Female n=65 (40.6%)	Not mentioned	Not mentioned	Not mentioned
74.Yeo, S.T. et al 2012	United Kingdom	Cross sectional	To obtain the views about the provision of DR screening services and interval of screening	DR screening clinics	Diabetics already on a National Level Screening program	n=621 (40% of 1550)	Female 244 (40.7%)	Not mentioned	8.5 (7.8)	Not mentioned

75.Zhang, X. et al 2009 *	United States of America	Data from Project DIRECT (Population based)	To examine diabetic retinopathy, dilated eye examination, and eye care education among African Americans before and after a community-level public health intervention	Community based health promotion program	Self-reported a health care provider's diagnosis of diabetes who participated in Project DIRECT	n=1289 (617 in 1996-1997 672 in 2003-2004)	Female 63.6 % to 66.5% in different groups	Not mentioned	Not mentioned	Crude DR 41.1% - 48.4% in different groups

**Two articles are reviews (75/77)*

5.5 - S5 Tables. Themes tables by country income setting

S5 Table 1 – LIC

Study 1st Author Name, Year and Setting	Modality of screening	Consumer Barriers	Consumer Enablers	Provider Barriers	Provider Enablers	System Barriers
1.Burgess, P.I. et al (2013) (Africa) [LIC]	Not mentioned	Poor patient attendance	Not mentioned	Lack of skilled human resources and training, Lack of access to imaging and DR treatment infrastructure, Lack of a systematic monitoring system for complications of diabetes, Non-existence of a referral system, Non-existence of diabetes multidisciplinary healthcare teams	Increase human resources (ophthalmologists) and sub-specialisation, Provision of imaging and treatment infrastructure, Provision of tertiary retinal care and training, Development of retinal research networks, Prioritization of sub-specialty development in post-graduate training programs and facilitate	Competing disease priorities, Lack of a national policy, Non-existence of a systematic screening program, Poor record keeping and lack of infrastructure to support services, Provision of retinal fellowships tailored to developing world trainees in retinal centres in developed countries

					knowledge and skills sharing	
2.Mumba, M. et al (2007) (Tanzania) [LIC]	Dilated fundus examination by ophthalmologist	Lack of knowledge on eye complications (OR), Lack of awareness about important of eye exam, Lack of knowledge on availability of eye clinics	Knowledge on eye complications (OR)	Not mentioned	Counselling	Distance to the institution
3.Thapa, R. (2012) (Nepal) [LIC]	Detailed fundus evaluation after dilation in a vitreo retinal clinic	Lack of awareness of diabetes ocular complications	Awareness and literacy (OR), Having a family member with diabetes (OR), Prior fundus evaluation elsewhere (OR)	Not mentioned	Not mentioned	Place of living (in a geographically diverse setting) (OR), Short time duration with patients due to lower doctor-patient ratio

S5 Table 2 – LMIC

Study 1st Author Name, Year and Setting	Modality of screening	Consumer Barriers	Consumer Enablers	Provider Barriers	Provider Enablers	System Barriers
4.Abdulsalam S. et al, 2018, (North-Western Nigeria) [LMIC]	Fundoscopy	Not mentioned	Not mentioned	Lack of knowledge on DR among the physicians Lack of functional ophthalmoscopes Lack of dilating eye drops	Training physicians on DR screening Conduct the eye examination by the physicians rather than referring	Lack of human resources for DR screening

				Lack of skills in identifying DR signs Poor attitude on dilating pupils, and taking responsibility of DR screening	Variable duration of refresher training, essential to improve DR screening skills.	
5.Adriono, G. et al (2011) (Indonesia) [LMIC]	Dilated eye examination by an eye care professional	Lack of knowledge, attitude, awareness on DR (OR), Financial barriers, Feeling of no need if vision is good, Lack of understanding of the role of eye examination	Knowledge, attitude, awareness on DR (OR), More severe diabetes and comorbidities (OR)	Financial barriers (cost of services), Lack of diabetic health education	Information given by the service provider (OR), Having told of the need of regular eye examination, Educational strategies aimed both patients and physicians	Financial implications in having an insurance coverage
6.Agarwal, S. et al (2005) (India) [LMIC]	Dilated fundus examination by binocular indirect ophthalmoscopy (screening camp setting)	Unawareness of diabetes eye complications, Poor motivation, Other priorities, Fear, Spirituality (faith and hope)	Not mentioned	Not mentioned	Awareness campaign with integrated team, Educational programs by meetings, distribution of information leaflets and through media	Economic and logistic reasons
7.Bamashmus, M.A. et al (2009) (Yemen) [LMIC]	Dilated bio microscopic examination by ophthalmologist	Lack of knowledge, Disadvantaged health habits,	Regular clinic visits (OR)	Challenges faced by ophthalmologists in dealing with blindness, Lack of resources/facilities,	Not mentioned	Cost of investigations in private labs, Lack of health programs

		Disability, being handicapped		Need of frequent and costly investigations		
8.Islam FMA et al, 2018, (Bangladesh) [LMIC]	Digital imaging in a rural community clinic	Poor health literacy on DR and poor general education No felt need of DR screening, when asymptomatic Lack of time Fear of complications. Longer time to recover after pupil dilation	Increase health literacy of the users	Lack of skill of confidence upon skills of ophthalmic assistants Lack of availability of DR treatment facilities	Make people aware of the detrimental effects of DM.	Shortage of number of ophthalmologists overall and maldistribution in rural areas
9.Kurji, K. et al (2013) (Kenya) [LMIC]	Tele-ophthalmology by dilated digital fundus imaging	Low literacy	Patient satisfaction over the modality Time saving and convenient method, Ability to see the fundus images by patients	Low number and inadequate distribution of medical specialists, Low availability of diagnostic and treatment equipments and medications	Convenience, Reduced examination time, Ability to visualize own retina, and less cost (tele-ophthalmology) Utilization of more convenient avenues for communication (in sending reports through registered mail / secure electronic mail)	Low medical insurance coverage, Challenges in transport and communication
10.Muecke, J.S. et al (2008) (Myanmar) [LMIC]	Not mentioned	Lack of understanding of the nature and treatment of DR, Lack of schooling (OR),	Development of visual symptoms related to DR	Lack of resources (ophthalmoscopy equipment), Time constraints (for fundus examination in busy urban practice),	A reminder of the serious consequences of the failure to examine fundi of diabetic patients,	Lack of training for GPs and increased work load, Lack of epidemiological studies

		Inconvenience or a fear of visiting a specialist, Thought of examination needed only if there are problems, Inability to pay for private health care		Lack of awareness among GPs, (technique and signs of DR) Poor opinion of the quality of service available in the public eye centres, Lack of action by GP in examining the fundus	Repeated reminder from GP, Information pamphlets, posters and medical education seminars for GPs, Public health education by media	Lack of optometrists for primary screening, Accessibility to eye centres.
11. Mwangi N. et al 2017 (Kenya) [LMIC]	Eye examination at an eye clinic after referral or opportunistic	Lack of knowledge about DM and DR. Misconceptions about diabetes related eye disease. Not following up on referrals.	Written communication from the patient's ophthalmologist to the primary care provider	Not mentioned	Having a referral letter	Not mentioned
12.Namperumalsamy, P. et al (2004) (India) [LMIC]	Not mentioned	Lack of knowledge and awareness on DR, Gaps between attitude knowledge and actual practice	Better understanding of risk factors	Lack of knowledge and awareness on DR	Health education	Not mentioned
13.Onakpoya, O.H. et al (2010) (Nigeria) [LMIC]	Mydriatic direct ophthalmoscopy	Lack of knowledge on DR, Not having eye problems or symptoms	Presence of visual impairment or blindness and non-diabetic vision threatening eye diseases	Low referral rates, Lack of adequate knowledge on DR among PCPs	Trained non-ophthalmologist physicians screen diabetics for DR regularly at endocrinology clinic, Availability of fundus camera,	Not mentioned

					Periodic review with ophthalmologists, Health education on DR and DR screening	
14. Sirinivasan NK et al 2017 (India) [LMIC]	Dilated fundus examination using slit lamp binocular indirect ophthalmoscopy.	Lack of knowledge on DM, Lack of awareness of DR, Lack of awareness of importance Affordability, Poor family support, did not find time, physically unwell.	Good Knowledge on DM	Not mentioned	Health education by the doctor	Long distance to the hospitals

S5 Table 3 – UMIC

Study Author Name and Year	Modality of screening	Consumer Barriers	Consumer Enablers	Provider Barriers	Provider Enablers	System Barriers
15.Cetin, E.N. et al (2013) Turkey [UMIC]	Not mentioned	Lack of knowledge, attitude and awareness on DR	Knowledge, attitude, awareness on DR, Higher education level attainment Attending endocrinology department for medical care (tertiary level), DM education (OR),	Changing awareness among physicians Less referrals from state hospital	Physician's recommendation, Awareness among physicians regarding eye complications of diabetes, Establishment of referral guidelines, Targeted education programs	Not mentioned

			Knowing need of annual examination			
16.Hazavehei, S.M.M. et al (2010) (Iran) [UMIC]	Examination by ophthalmologist	Lack of knowledge, awareness and attitude (Mean scores)	Not mentioned	Not mentioned	Educational intervention	Availability of health educational interventions
17.Katibeh et al 2017 (2nd Article) (Iran) [UMIC]	Masked grading of stereoscopic fundus photographs	Low literacy level associated with poor awareness on DR	Higher secondary level education, properly controlled HbA1c	Lack of source of awareness	Having educational strategies Physicians as a source of information	Disparity in services between rural and urban settings.
18.Katibeh M. et al 2017. (Iran) [UMIC]	Not specified	Not mentioned	Not mentioned	Provider unawareness on guidelines. Poor usage of available DM and DR prevalence data. Poor referral systems Lack of retinal imaging technology at lower levels of service delivery Lack of systematic recall system	Availability of continuous medical education	Strengthened clinical guidelines on DR. Coverage of whole country in a national plan. Poor transport systems. Cost of services Lack of health information systems Poor auditing systems
19.Khandekar, R. et al (2012) (Meditarranean) [UMIC]	Not mentioned	Inertia to change life style	Not mentioned	Scarce human resources and material, Weak health systems, Cost of technology and resources, Palliative nature of DR management	Training human resources, Health education on DR, Involvement of community and patient groups	Limitations in public health approach, Civil unrest and poverty related health issues

20.Wang, D. et al (2010) (China) [UMIC]	Not mentioned	Lack of awareness and knowledge of DR, Poor language fluency, Less well educated, Lower monthly income, Misconceptions- as DR having early symptoms and screening unnecessary without symptoms	More concern about vision loss (OR), Knowledge on DR (OR)	Lack of training, Lack of programs to raise awareness, Poor physician–patient communication (Not telling the importance of regular eye examinations), Inability to cope with the large number of diabetes patients,	Recommendation and education of importance of eye examination (OR), Attendance to the urban tertiary and community hospitals	Disparity in services between rural and urban settings (OR)
21.Xiong, Y. et al (2015) (China) [UMIC]	Non-mydriatic digital retinal imaging	Poor health education Lack of awareness and income, Lack of understanding of early treatment as the key to prevent blindness	More educational level (OR), Severe DR stage (OR), Vision loss	Lack of communication between the patients and doctors, Unclear explanations of disease (DR) and treatment, Medical costs	Community health management network coverage, Community based health education, Effectively locate DR patients who unaware of the disease	Medical insurance (OR), Transportation

S5 Table 4 – HIC

Study Author Name and Year	Modality of screening	Consumer Barriers	Consumer Enablers	Provider Barriers	Provider Enablers	System Barriers
22.Anderson, S. et al (2003) (UK) [HIC]	Slit lamp examination following dilatation and 6feild fundus	Poor cooperation and problems in mobility, Refusal of screening, Medically unfit to attend screening	Not mentioned	Level of experience of the screener, Lack of effective way for screening of confused or immobile patients	Not mentioned	Home bound diabetics

	photography (hand held)					
23.Basch, C.E. et al (1999) (USA) HIC	Dilated retinal examination	Lack of knowledge, Low Literacy and awareness	Not mentioned	Lack of Health education	Educational intervention (OR), Focusing on high risk group, Intervention on broad scale	Not mentioned
24.Baumeister, S.E. et al (2015) (Germany) HIC	Not mentioned	Lower socio-economic status (OR), Living alone (OR), Lower educational attainment (OR), Lower income (OR), Poorly controlled diabetes (OR), Diabetes related co-morbidities (OR), Employed and unemployed individuals (OR), Patients visits GPs or Internists for care (OR)	Poor self-reported health (OR), Lower physical and mental health-related quality of life (OR), Adherence to best practice guidelines, Having DR (OR)	Lack of attention by GPs, Non-adherence to guidelines	Better screening, detection and management, Adherence to best practice guidelines, Screening services, preventive services, self-management education and counselling integrated within primary care, Focused screening (Patients with poor DM control, complications and co-morbidities)	Lack of proper referral and reminding system, Lack of insurance coverage (OR), Lower socio-economic position
25.Bennet GH et al 2018 (Ireland) [HIC]	Not mentioned	Difficulties in getting appointments	Having non-ocular complications	Inconveniences in referral mechanisms	Online registration and appointment systems	Not mentioned
26.Brechner, R.J. et al (1993) (USA)	A dilated eye examination	Lower income (OR), Level of education (OR),	Higher socioeconomic status,	Not inform the patients about having DR (OR),	Having told to have DR	Health insurance

HIC		Less frequency of physician visits for DM	Having diabetes education class (OR)	Not having education class		
27.Creuzot, G.C. et al (2014) (France) **HIC**	3F digital photography with or without dilatation	Lack of awareness of eye care, Problems in access to GP, Cost effectiveness of the treatments, Not feeling the symptoms, Not feeling concerned about it (asymptomatic nature)	Declared frequency of ophthalmic visit every 2 years Awareness of eye care (OR)	No adequate patient education system, Lack of information provided to patients Problems in access to GP or ophthalmologist	Mobile DR screening, Patient education and information, Recommendation	Low GP density,
28.Dervan, E. et al (2008) (Ireland) **HIC**	A dilated eye examination	Lack of knowledge regarding eye examination (OR), Lack of awareness, Effect of mydriasis prohibiting driving, Lack of concern about the vision, Wrong expectation of screening as a routine	Think eye examination is needed every 6 months (OR), Expect eye examination as part of routine, Worrying about vision, Aware of developing an eye disease and having symptoms, History of DR or another eye disease (OR)	Lack of physician recommendation, Lack of appointments, Requirement of mydriasis, Unaware of importance of mydriatic funduscopy by examining physician	Having told by physician to have regular eye examinations (OR), Reinforcing the importance of eye examination by health care providers	Not mentioned
29.Eiser, J.R. et al (2001) (UK) **HIC**	Dilated polaroid photography	Lack of knowledge,	Having diabetes related eye problems	Not mentioned	Retinal screening services organized in primary care settings,	Not mentioned

	followed by direct ophthalmoscopy	Lack of flexibility in adjusting attitude and behaviour, Reluctance to change self-management, Reluctant to make behavioural changes			Showing image of retina to patients (irrespective of their understanding), Information to patients which easy to understand	
30.Foreman, J. et al. (2017) (Australia) [HIC]	National level DR screening	Lack of awareness of the NHMRC eye examination guidelines. Unaware of the need for regular eye examinations. Being indigenous status. Lack of time.	Longer duration of diabetes. Living in an inner regional locality	Missed appointments.	Integrated DR screening services especially in remote areas. Improved referral pathways. Health education	Unavailability of services in remote areas.
31.Gillibrand, W.P. et al (2000) (UK) [HIC]	Dilated 3 field fundus photography	Lack of knowledge of DM (can cause eye complications)	Knowledge on diabetes control, Self-perceived importance of good control of DM	Limited knowledge in health care professional	Health education strategies (as required by individual)	Local health promotion services for all groups
32.Glasson, NM. et al. (2017) (Australia) [HIC]	Remote outreach DR Screening modality	Difficulty in getting leave from the employment to attend screening. Financial constrains in travelling long distances Dislike pupil dilation and camera flash light	Not mentioned	Lack of infrastructure (clinic space). Lack of training and education (at nurse screener and GP grader level)	Improved, efficient access through outreach screening Acceptability of remote screening	Long travel distances and lack of transportation Governance and operational elements (identification of people with DM at community level) in service delivery Financial implications

				Lack of communication, coordination and information sharing.		Sustainability Quality and safety Coordination and integration of services
33.Gulliford, M.C. et al (2010) (UK) HIC	2 field digital photography	Socio economic inequalities with regard to ethnicity (OR), Socio economic deprivation (OR)	Not mentioned	Not mentioned	Not mentioned	Socio economic inequalities
34.Hartnett, M.E. et al (2005) (USA) [HIC]	Dilated fundus imaging	Lack of insight, education, knowledge on diabetes and blindness, Multiple appointments at one time, Lack of understanding the rationale of annual exams and about DR, Burden of diabetes and treatment overshadowing eye disease, Personal issues (child care concerns, transportation difficulty, work, and forgetting appointments), Not remembering physician's names,	Fear of blindness, Attending DM education classes	Cost of services, Poor physician-patient communication, Poor access to care-long wait for appointment, long clinic waiting time, large number of patients per doctor, Frequent change of staff, Lack of understanding needs in-between specialities, Medical records not always available	Electronic medical records or email	Transportation, Unavailability of medical records on time

		Gap between patient education and their understanding, Financial burden				
35.Harvey, J.N. et al (2006) (UK) [HIC]	Mydriatic imaging by optometrists and direct ophthalmoscopy by ophthalmologists	Failure to attend (Move away or died), Failure to keep appointments, Not appreciate the importance of eye screening, Cost incurred by screening	Not mentioned	Unavailability of (digital retinal) screening, Failure to refer by GP	Identifying and targeting non-attendees	Diabetes register, complete records and communication system
36.Hipwell, A.E. et al (2014) (UK) [HIC]	Mydriatic fundus photography	Denial of having diabetes, Understanding of the importance of screening, Dislike the method of screening - proximity, Side effects and adverse effects of mydriatics (unable to drive), Confusions about DR screening vs routine eye check, Work commitments, Postoperative recuperation,	Protecting the eye as priority, Proximity of screening clinic to patient's homes, Knowledge about DR and screening	Perception of making appointments, Length of appointment and duration of food abstinence, Absence of appointments, Failure to deliver the right message, Side effects and adverse effects of mydriatics (significant pain and visual disturbances), Unable to drive after mydriasis	Integrating DR screening with diabetic care, Efficient GP practice appointments, Short and efficient appointments, Convenience and transport safety	Transport, Temporary accommodation, Lack of media attention, Appointment booking system issues

		Residential changes, Problems of making appointments, Forgetfulness especially working people, Psychological, pragmatic and social factors,				
37.Huang, O.S. et al (2009) (Singapore) [HIC]	Dilated retinal photography by digital retinal camera	Awareness of DR/DM status, Less educational level (OR), Apathy, Patient denial	Severity of DR	Poor patient-doctor communication	Emphasise the need for regular examination, Patient education and their initiatives	Lack of health education
38.Hwang, J. et al (2015) (Canada) [HIC]	A dilated eye examination	Low income (OR), Lack of private health insurance (OR), Poor self-rated health status (visual impairment) (OR)	Having visual impairment (symptomatic) (OR), Discussion of DM complication with a health care professional (OR), Having private health insurance, Highest income	Not discuss about diabetes complications	Educating the importance of DR screening by PCPs	Private health insurance (OR)
39.Khandekar, R. et al (2008) (Oman) [HIC]	Not mentioned	Not mentioned	Not mentioned	Limited knowledge, attitude and practice of physicians, Limited experience of using the ophthalmoscope	Training of primary staff by regional ophthalmologists	Availability of training programs

				during undergraduate training and professional practice, Lack of attention to diabetic eye care (in eye care workshops).		
40.Kreft D. et al 2018. (Germany) [HIC]	DR screening by an ophthalmologist - National screening	Multiple comorbidities and high level of disability.	Low severity of diabetes Participation in a educational program	Not mentioned	Educational programs	Not mentioned
41.Lane, M. et al (2015) (UK) [HIC]	Annual digital mydriatic fundus photography	Poor language skills, Knowledge gap, Socioeconomic status	Not mentioned	Long waiting time for treatment	Not mentioned	Social deprivation and ethnicity
42.Lake A.J. et al 2017 (Australia) [HIC]	Australian national DR screening programme (dilated biomicroscopy - community setting)	Social influences. Anticipated regret and perceived vulnerability Concern on impact of the family unit Lack of financial resources Misconceptions on DR knowledge Absence of planning	Beliefs about the consequences of missed screening Positive reinforcement through negative screening results Positive intentions and emotions to check eyes Intention to commence or maintain screening	Lack of clinician's recommendations Clinical inertia Reluctance to acknowledge about DR by providers (on young patients)	Influences from professionals (GP).	Cost of the procedures

43.Lee, P.P. et al (1998) (USA) [HIC]	Dilated fundus examination	Lack of knowledge on eye care, Cost, Healthcare related behaviour, Age	Not mentioned	Lower use of specialists' care, Low rate of diabetic eye screening	Not mentioned	Better managed care plans, Geographic and demographic factors
44.Leese, G.P. et al (2008) (UK) [HIC]	Digital retinal photography by mobile retinal cameras	Social deprivation (OR)	Having visual symptoms	Invited to eye vans rather than static unit (OR)	Mobile retinal cameras, Structural and patient-system evaluation, Constant screening location (OR)	Social deprivation (OR), Travel time
45.Lewis, K. et al (2007) (UK) [HIC]	Regular eye examination by digital fundus camera	Lack of awareness (DR could lead to blindness and could be asymptomatic), Fear, guilt and family attitude, Problems in career, Limited knowledge of DR and misunderstanding of risk factors, Not appreciate the long-term follow-up,	Fear of losing vision	Waiting time at eye clinic, Reluctant to ask questions and difficulties in accompanying patients, Awareness on DR among the providers, Reluctant to discuss the possibility of blindness, Little education provided by eye clinic, Underestimate the difficulties faced by patients in obtaining time off work to attend,	Using screening images as educational material, Education on asymptomatic disease and risk of blindness, Reinforce the importance of eye care, Avoid giving impression that DR is due to carelessness and poor control, Evening clinics, Early involvement of social workers, Reorganization of clinic bookings	Transport

				Reluctance of diabetic educators to dwell on negative consequence of DM, Reluctant to mention blindness, Fear of laser, Eye clinics tend to run late, and patients compete for early appointments		
46.Lian, J.X. et al (2013) (Hong Kong) [HIC]	Non-mydriatic fundus camera	Cost of the services (Affordability), Socio economic factors, Being in a pay group (OR)	Higher family income (OR), Currently not working (OR) Welfare of recipients (OR),	Fee for services (Cost of services), Co-payment for screening	Not mentioned	Not mentioned
47.Lian J et al, 2018, (Hong Kong) [HIC]	Not mentioned	Specific deficits in knowledge that early DR can be asymptomatic and availability of treatment Having specific knowledge (as assumed by the patient) on how often screening should be performed	Lack of knowledge on frequency of screening Worry about vision loss Awareness on importance of eye examination	Not mentioned	Increasing patient awareness of DR screening. Recommendation of screening by the health care provider	Not mentioned
48.Lindenmeyer, A. et al (2014) (UK) [HIC]	Mydriatic digital retinal photographs	Poor English fluency, Perception of non-attenders	Experience symptoms	Less space for screening, Lack of communication between screening services and practices	Contacting and motivating patients, Integrating screening with routine care,	Transport and access, Social deprivation, Diversity of ethnicities and languages

					Integrating/Focusing the newly Diagnosed, Communication between screening services and practices	
49.Liu Y, et al, 2018, (United States of America) [HIC]	Not specified	Multiple health conditions Poverty and financial trade-offs Limited health literacy Infrequent use of health care Burden of DM management Negative self-perception Anxiety related to DM complications Experiences with family members struggles with DM complications - led to fear of receiving bad news.	Surveillance and judgment from family, friends and providers Trust in health care provider Motivation due to anxiety related to diabetes complications	Not specified	Recommendations of health care provider Teleophthalmology may complement patient education by addressing the environment barriers Teleophthalmology present in primary care clinics in rural areas Trust on the providers	Long travel distances to obtain health services (lengthy travel time and transportation barriers) Limited access to health care Policies to improve reimbursements for teleophthalmology
50.Maberley, D.A. et al (2002) (Canada) [HIC]	Not mentioned	Lack of awareness and knowledge, Reluctant to seek medical care	More advanced DM, Likely to have DR	Lack of human resources - Physicians, Lack of availability of educational programs,	Reserve-based diabetes education programs	Inadequacy of clinics and hospitals in the region, Distance to the service provider (Residence) (OR),

				Less advice given to younger patients, Less opportunity and less education for younger patients, Less aggressive in encouraging younger patients		Inadequate physician resources
51.Moss, S.E. et al (1995) (USA) [HIC]	Dilated ophthalmoscopy followed by 7F stereoscopic colour fundus photos	Perception of no problem with eyes when asymptomatic, Not liking the pupil dilatation, Behaviours (smoking and drinking), Years of education, Family income, Thought of no problems in eyes means no need to examine, Could not afford an examination, Being working people (busy), Fear of prognosis or needing treatment	Higher education, Currently not working, Thought of at least every12 month exam is needed (OR), More severe retinopathy (OR), History of cataract or glaucoma (OR), Higher income, Health insurance that covered eye examination (OR), Visually impaired, Having eyes examined by PCPs	Lack of provision of information, Difficulties in getting an appointment, Not having been told eye examination is needed	Having told annual examination in needed (OR), Recommendation to continue seeing the eye physician, Impress on importance of annual examination, Flexible office hours on the part of ophthalmologists and optometrists including evenings and weekends, Education on need for eye exam and treatable nature of DR, PCPs familiarize with guidelines of eye exam, Attending to internists	Geographical accessibility, Financial barriers, Far to the optometrists or ophthalmologists or difficult to get a ride

52.Moreton R.B.R. et al 2017. (United Kingdom) [HIC]	Oxfordshire DR screening program	Socio-economic deprivation Younger age	Older age	Screening by high street optometrists	Higher uptakes for those invited for screening by mobile units	Not mentioned
53.Mukamel, D.B. et al (1999) (USA) [HIC]	Dilated fundus examinations by an ophthalmologist or an optometrist	Socio demographic and economic characteristics	Contact with the PCPs	Less visiting frequency (OR), Lack of correlation between PCPs and screening	Higher referrals by GP, Under care of PCPs, High patient expenditure (OR), Increased interaction and increased chance to educate patients, Interventions addressing both patients and physicians (All PCPs and targeted patents with certain ethnicity and limited education), Higher visiting frequency to PCP (OR)	Lack of correlation between PCP specialty and screening services, Living in lower educational and income areas (OR)
54.Munoz, B. et al (2008) (USA) [HIC]	Dilated eye examination	The lack of correct information and awareness, Poor educational level (OR), Poor language fluency, Financial constraints,	Long-time residing in place (OR), Having insurance (OR), Higher education (OR)	Less options and access for eye care professionals, Incomplete explanation of the diseases to patients, Providers' poor language fluency	Increase awareness using health educational materials (in local language and according to educational level of target population), Personalised strategies such as phone calls and door to door visits, Flexible schedules on screening	Having insurance (OR)

		Poor level of knowledge on diabetic eye complications				
55.Murgatroyd, H. et al (2006) (UK) [HIC]	Mydriatic and non-mydriatic photography	Discomfort and effects following mydriasis (driving, working outside home), Unacceptability of mydriasis specially by patients who had previous non-mydriatic examination technique	Non-mydriasis	Not mentioned	Education on mydriatic drops, Targeted use of mydriasis and age relate strategies	Not mentioned
56.Newcomb, P.A. et al (1990) (USA) [HIC]	7F Stereoscopic fundus photographs	Lack of awareness, Financial constrains	Experiencing vision loss, More educational levels, Had been seen previously by ophthalmologist, More frequent insulin reaction, Previous diagnosis of eye disease, Better DM control, More severe DR, Knowledge of pre-existing diabetic eye disease,	Poor physician availability	Telling patients that they have affected eyes, Screening recommendations	Being in a rural area, Metropolitan residence

			Perceptions of personal susceptibility, Severity of the consequences of retinopathy,			
57.Newcomb, P.A. et al (1992) (USA) [HIC]	7F Stereoscopic fundus photographs	Attitudinal issues (possess awareness but lacks compliance), Less degree of knowledge	Not mentioned	Not mentioned	Not mentioned	Not mentioned
58.Orton, E. et al (2013) (UK) [HIC]	An eye screening	Patients' understanding about screening, Other health issues as higher priority, Forget to make appointments, Lack of awareness and knowledge, Preference of booking appointments, Perceiving no eye problems as not necessary to screen again	Not mentioned	Comprehensiveness of the Information given by the service provider	Talking about screening by GP / Nurse, Written information leaflets, Primary care level changes - Simplify the screening invitation letters, Use the term diabetic eye disease rather than retinopathy, contact by post rather than waiting for the next visit, Establishing a direct line between practices to the screening booking team, Online patient access booking and text reminder service, Maintaining the availability of out of hours	Increasing deprivation (city vs county) (OR), No nationally specified screening programmes

					screening provision and agreement, Working with the practices to minimise the exclusion of patients from screening, Reconciling practice and screening patient listings	
59.Paksin Hall, A. et al (2013) (USA) [HIC]	Dilated eye examination	Lack of awareness and knowledge	Being married (OR), DM education class (OR), Had feet checked within the last year by a health professional (OR), Higher income (OR), More education (OR), Fewer days of unhealthy mental status (OR)	Not mentioned	Diabetes education	Availability of health insurance (OR)
60.Pasagian, M.A. et al (1997) (USA) [HIC]	Dilated annual eye examination	Lack of knowledge and awareness, Financial constraints, Transportation, traveling alone after having their eyes dilated,	Being concerned about eye complication, Higher level of education	Lack of Human resources, Long waiting time in the clinic or doctor's office, Lack of individually scheduled appointments, Length of getting an appointment	Educate patients and counselling	Lack of SPs, Transportation problems

		Difficulty getting someone to accompany, Cost of the examination, Difficulty getting to clinic				
61.Paz, S.H. et al (2006) (USA) [HIC]	Dilated 7F stereoscopic fundus photography	Less education level (OR), Knowledge on DR, Less annual income (OR), Lack of routine medical care, Lack of annual physical exam (OR)	Having eye disease (glaucoma or DR)	Lack of provision of health education	Educational programs	Lack of health insurance schemes
62.Puent, B.D. et al (2004) (USA) [HIC]	Annual dilated eye examination	Limited personal mobility due to poor overall health, Low socio-economic status, Misunderstanding of benefits of health insurance, Lack of understanding in periodic eye examination, Not accept diagnosis of DM and periodic care,	Not mentioned	Transferring of eye care to another doctor, Pupil dilatation, Last examination at a homeless clinic, Discontinuity of eye care	Chief symptom of need for diabetic examination, Maintain recall system, Educating patient on how to use insurance for eye care	Lack of health insurance

		Forgetfulness, Extended vacation, Other illness (reason cancer treatment), Self-reported apathy				
63.Rim, T.H. et al (2013) (Korea) [HIC]	Fundus photography	Financial constraints, Lack of education on diabetes and reluctant to undergo re-examination, Lack of time	Higher level of education (OR), Self-reported unhealthy health status (OR), Having other comorbidities (OR)	Lack of ophthalmologists and primary physicians in rural areas	Not mentioned	Socio-economic discrepancies (urban vs rural) (OR), Difference in health systems
64.Saadine, J.B. et al (2008) (USA) [HIC]	A dilated eye examination	Chronic diseases	Worse acuity and DR level (OR)	Not mentioned	Not mentioned	Not mentioned
65.Scanlon, P.H. et al (2008) (UK) [HIC]	Mobile camera - digital photography	Lack of financial support	Not mentioned	Not mentioned	Not mentioned	Socio-economic deprivation (OR)
66.Scanlon, P.H. et al (2016) (UK) [HIC]	Eye screening programme-Mydriatic digital imaging	Socio-economic deprivation	Not mentioned	Factors related to primary care practices and screening team	Not mentioned	Socio-economic deprivation
67.Schmid, K.L. et al (2003) (Australia) [HIC]	Not mentioned	Lack of awareness and knowledge among the less educated, Financial issues,	Awareness and Knowledge,	Optometrists - lack of adequately trained and not having correct equipment	Educating patients	Being in a rural area

		Poor English fluency, Thought of already under care of a specialist	Being a member of Diabetes organisation (Diabetes Australia)			
68.Schoenfeld, E.R. et al (2001) (USA) [HIC]	Dilated eye examination	Knowledge of DM and frequency of eye examination (OR), Non-attendance at a diabetes education class (OR), Not having heart disease or neuropathy, Believe of no treatment currently available, Lack of concern vision loss	Not mentioned	Type of the eye care provider performed last eye examination (ophthalmologist vs other) (OR), Availability of health education programs	Physicians' recommendation, Focused care on high-risk group for developing DR	Availability of insurance schemes
69.Sheppler, C.R. et al (2014) (USA) [HIC]	Telemedicine with non-mydriatic camera	Lack of insurance, Believes about health insurance covering eye health care, Cost, Time, Felt no need, Unaware of importance, Other commitments, Not care, Forgetfulness, Afraid, Lazy, No vision problems, Procrastination,	Having an insurance, Making eye examination as top priority	Cost, Provider availability, Accessibility	Clinicians address potential barriers and misconceptions	Transportation, Insurance (OR)

		Health issues, Dislike the examination				
70.Shih, H.C. et al (2007) (Taiwan) [HIC]	On site indirect ophthalmoscopy after dilatation followed by single field polaroid fundus imaging	No DR, Educational level-Illiteracy, Income	Willingness to Pay (Mean scores), Increased number of chronic illnesses, Severe stage of DR, Patients with impaired quality of life to avoid blindness, Higher educational level, Patient satisfaction	Cost	Not mentioned	Not mentioned
71.Storey, P.P. et al (2016) (USA) [HIC]	Dilated fundus examination	Severity of DR (OR), Ethnicity	Severe DR (OR)	Communication among the ophthalmologist and primary care physician (OR)	Showing the fundus photographs and teaching, Identifying interventions to improve DR care, Intervention to improve doctor-doctor communication, Electronic medical record system, Written communication among the ophthalmologist	Insurance

					and primary care physician (OR)	
72.Trento, M. et al (2002) (UK and Italy) [HIC]	2F mydriatic colour photographs by digital fundus camera	Knowledge and attitude on DR, Awareness	Spontaneous health perceptions and beliefs	Wrong assumption on patients' level of knowledge	Group care approach, More structured way of involving the patients, Structured education approach than simple information during consultation	Not mentioned
73.VanEjik, K.N. et al (2012) (Netherland) [HIC]	Fundoscopy and mydriatic fundus photography	Lack of awareness, Physical disability, No one to accompany, Thought of not useful at old age, No interest or no time, Lower level of education	Fear of impaired vision (OR), Feeling obliged to attend screening-Sense of duty, More frequent visit to health care providers and more contact, Knowledge of detrimental effects of DR on visual acuity (OR), Awareness of possibility of treating DR (OR)	No recommendation, No confidence over the service provider, Long waiting time (>30 min)	Eye screening recommendation by care provider (OR), Trained technicians	Underserved inner city areas, Language and financial constraints, Active education and encouragements,
74.Walker, E.A. et al (1997) (USA) [HIC]	Dilated fundus examination	Fear of denial, Priority of the other work, Knowledge and attitude (Waiting for symptoms), Spirituality (faith and hope),	Internal and external motivation, Acute situation (acute loss of vision), Having eye problems,	Lack of Health Education, Cost, Wrong interpretation of doctor not let them to go or doctor said eyes are fine, Dilation uncomfortable,	Doctors recommendation, Recommendation by the service provider, Health promotion materials emphasizing yearly DFE in absence of symptoms	Economic (insurance affordability) Logistic reasons

		False believes (Early symptoms to alert them),	Thought to keep good eye sight and find problems early	Difficult to get an appointment		
75.Yeo, S.T. et al (2012) (UK) [HIC]	Dilated fundus photography	Discrete choice over attributes	Not mentioned	Waiting time for results (OR), Limited health care resources	Ability of the DR screening modality to detect other changes, Explanation of results (OR), Frequency of screening-shorter screening intervals, Less waiting time for results, Care as user's preference and reassurance, Detail information about the process (OR)	Travel time (OR)
76.Yeo, S.T. et al (2012) (UK) [HIC]	Mydriatic photography	Discomfort of mydriasis, Awareness of patients	Concerned about maintaining eye health	Time taken to give results, Fixed appointment date, Cost of attending screening, Waiting time in clinic, Discomfort from eye drops, Inability to drive after screening,	Detailed information on screening process, Explanation of results, Reassurance of screening intervals (longer intervals), Able to change the appointments	Travel time, Screening location (Near home or work)

				Attitude of staffs, Awareness of staff		
77.Zhang, X. et al (2009) (USA) [HIC]	Dilated eye examination	Low income	Having DR (OR)	Not mentioned	Provision of eye care education (OR) and screening interventions	Health insurance (OR), Rural area, Ethnicity

5.6 - S6 Table. Quantitative Data Synthesis - Factors associated with DR screening uptake and regular follow up

S6 Table 1. [LIC]

Study Author Name and Year	Participants' characteristics	Variables in General	Results	Results - Further Analysis
1.Mumba M et al 2007 (Tanzania) LIC	Diabetics Consecutive sample N=316 N=114 following referral	Factors associated with ever having had a dilated fundus examination	187 (59.1%) reported that they had undergone dilated fundus exam at some point since their diagnosis.	Factors associated with ever having had a dilated fundus examination- -Knowledge that diabetes damages the eye [OR 7.34 (95%CI 4.66-11.57)] -Age [OR 1.02 (95%CI 1.01-1.03)] -Duration of diabetes [OR 1.00 (95%CI 1.00-1.01)]
2.Mumba M et al 2007 (Tanzania) LIC	Diabetics Consecutive sample N=316 N=114 following referral	Factors associated with having had a dilated fundus examination in the past year	Only 29% had eye examination in previous year, this increased up to 47% after the 'counselling intervention'.	Factors associated with having had a dilated fundus examination in the past year- -Knowledge that diabetes damages the eye [OR 19.67 (95%CI 7.01-55.20)] -Age [OR 1.03 (95%CI 1.02-1.04)]

3.Thapa R 2012 (Nepal) LIC	Diabetics N=210	Awareness on DR	Only 63 % of the subjects were aware that diabetes mellitus can affect the eye and result in blindness.	Awareness of diabetic retinopathy- -Literate patients [OR 2.74 (95%CI 1.33 - 5.63 p=0.006)] -Living in the Kathmandu valley [OR 2.24 (95%CI 1.08 - 4.64 P=0.030)] -Having DM in the family [OR 2.34 (95%CI 1.07 - 5.13 p=0.034)] -Having a history of prior fundus evaluation elsewhere [OR 11.94 (95%CI 5.66 - 25.18) p<0.001)]

S6 Table 2. [LMIC]

Study Author Name and Year	Participants' characteristics	Variables in General	Results	Results - Further Analysis
4.Abdulsalam et al, 2018, (Nigeria) LMIC	Service providers comprised of physicians from 4 tertiary level institutions	Knowledge among the providers	Lack of knowledge on gold standard of DR screening (knew only 4.8%) Lack of knowledge in complications of DM (92% were wrong)	Relation-ship of KAP of physicians on DR Knowledge and attitude [Correlation coefficient - r = 0.13, p=0.166] Attitude and practice (negative relation) [r= - 0.13, p= 0.144] Practice and knowledge- [r= 0.086, p= 0.385] shows no correlation

5.Adriono G et al 2011 (Indonesia) LMIC	Diabetics N=196	Knowledge about diabetic retinopathy (score)	Mean knowledge score 4.7 (those who had eye examination) vs score 3.6 (without eye examination) [p <0.001]	Factors associated with having an eye examination – -Higher with high knowledge score [OR 1.52 - 95%CI 1.09 - 2.11, p = 0.01] -Years since being diagnosed as having diabetes [OR 1.56 (95% CI 1.09-2.78 p=0.04)] for second vs first tertile; [OR 1.7 (95% CI 1.49-4.78 p=0.02)] for third vs first tertile
6.Bamashmus MA et al 2009 (Yeman) LMIC	Patients with DM Group A (Regular attendance) N=114 Group B (Irregular attendance) N=114	Relative risk of having DR	DR was found in 47 (41.2%) and 68 (61.4%) patients, respectively. The risk of DR, bilateral blindness and low vision disability were higher in group B. The severity of DR was positively associated with irregularity in clinic visits (X^2=33.56, degrees of freedom = 5, P = 0.000003).	-Relative risk of having DR [RR - 1.51, 95% CI 1.23-2.18] -Bilateral blindness [RR=4.0, 95% CI 1.38-11.6] -Low vision disability [RR=2.53, 95% CI 1.84-3.47]
7.Bamashmus MA et al 2009 (Yeman) LMIC	Patients with DM Group A (Regular attendance) N=114 Group B (Irregular attendance) N=114	Not having DR	The duration of diabetes and the regularity in clinic visits were the predictors of DR.	Not having DR in patients with DM associated with- -Less duration of DM <5 Years [Adjusted OR 0.04 (95%CI 0.01–0.10 p=0.0000000001)] 5–9 Years [Adjusted OR 0.12 (95%CI 0.05–0.30 p=0.000010)] 10–14 Years [Adjusted OR 0.31 (95%CI 0.12–0.79 p=0.01)] -Regular clinic visits [Adjusted OR 0.41 (95%CI 0.2–0.77 p=0.01)]

8.Islam FMA, et al 2018 (Bangladesh) LMIC	N = 213 Patients identified with diabetes N= 68 Patients participated in the screening program	Awareness DR related vision loss	68 (32%) patients participated in the DR screening program. Diabetes related health literacy is the major factor associated with participation in DR screening.	Awareness related DM causes eye disease and uptake of screening [OR 8.47(95% CI 3.95-18.18)] Awareness of DR and uptake [OR 5.15 (95% CI 1.89-14.01)] Awareness of possibility to prevent DR related vision loss [OR 3.15 (95% CI 1.53- 6.51)] Having secondary or higher education associated with screening uptake [OR 11.8 (95% CI 4.02-34.7)]
9.Mwangi N. et al 2017. (Kenya) LMIC	9 Diabetes clinics in 3 counties. N=270 90 participants per county.	Factors that affect uptake of eye examination	Only 25.6% of participants had ever had an eye examination in their lifetime. 24.4% had been referred from the diabetes clinic for a retinal examination. 13.3% had taken a funduscopic examination in the last 12 months.	The main predictors for having ever had funduscopic examination Referral for eye examination [OR 20.5, 95% CI 10.2–40.9, p < 0.001). Knowledge of diabetes eye complications [OR 2.7, 95% CI 1.5–4.8, p < 0.001] Comorbid hypertension [OR 1.8 95% CI 1.0–3.1 p = 0.02]
10.Muecke JS et al 2008 (Myanmar) LMIC	Diabetics N=100 (50%) (Total N=200)	Likely to visit an ophthalmologist	Although 99% of GPs were aware that diabetes could result in loss of vision, 49% never examined the fundi. Although 92% realized they should visit an ophthalmologist regularly, only 57% had seen an ophthalmologist.	Less likely to visit an ophthalmologist -Never attended school [OR 0.24 (95%CI 0.09-0.66)] -Diabetes for less than 2 years [OR 0.21 (95%CI 0.9-0.44)]
11.Sirinivasan NK et al 2017 (India) [LMIC]	Diabetic patients N=288	Association of knowledge of diabetes with the practice regarding DR	Out of the 288, 42% had good knowledge about diabetes, but only 4.5% had good knowledge about DR.	Good knowledge of DM was associated with good practice of DR [OR 3.95, 95% CI 1.97-7.94 p<0.01]

		Association of awareness of DR with the practice of DR	A total of 61.1% of patients did not have periodic eye examination; most common barrier identified was lack of awareness about the necessity for this (38.5%).	Awareness of DR with practice of DR [OR 3.58, 95% CI 1.67-7.69, p<0.01]

S6 Table 3. [UMIC]

Study Author Name and Year	Participants' characteristics	Variables in General	Results	Results - Further Analysis
12.Cetin EN et al 2013 (Turkey) UMIC	Diabetic patients, N=514	Awareness of diabetic retinopathy	88.1 % aware that DM could affect eyes, 94.2% aware that DM could affect vision, only 38.8% on regular ophthalmologists follow up, awareness on laser treatment 43.8%.	Independent factors affecting visiting an ophthalmologist on regular basis – - No DM education – [OR 0.39 (95% CI 0.24 - 0.65)], - duration of diabetes < 5years [OR 0.45 (95%CI 0.26 - 0.77)]
13.Hazavehei SMM et al 2010 (Iran) UMIC	Diabetics at risk of ocular complications N = 250	Mean scores of patient knowledge	The knowledge and all BASNEF model components were significantly increased in experimental group after intervention.	Factors affecting the means scores of patient knowledge- -Knowledge [Mean 73.45 (SD 17.79) P<0.001] -Evaluation of behavioural outcomes [Mean 77.42 (SD 10.56) P<0.001] -Attitude towards the behaviour [Mean 82.00 (SD 8.32) P<0.001] -Enabling factors [Mean 77.66 (SD 12.19) P<0.001] -Normative believes [Mean 72.08 (SD 11.70) P<0.001] -Subjective norms [Mean 60.90 (SD 18.80) P<0.001] -Intention towards the behaviour [Mean 85.40 (SD 13.36) P<0.001]

				-Patients' behaviour [Mean 78.00 (SD 17.31) P<0.001]
14.Katibeh et al 2017 (2nd Article) (Iran) [UMIC]	Diabetics	patient awareness	364 (73.4%, 95% CI: 68.6, 78.2) were unaware of the necessity of regular eye examinations.	Awareness associated with level of education [p=0.004] Secondary or higher education [OR 1.88, 95% Ci 1.23-2.88] Controlled HbA1c [OR 2.66, 95% CI 0.80-8.82, p=0.1] Those who had DR more likely be aware of necessity of eye examination [OR 2.61, 95% CI 1.75-3.88, p<0.001]
15.Wang D et al 2010 (China) UMIC	Patients with diabetes N=824 (92.7%) (Total N=889)	Predictors for ever had an eye examination	356 (43.2%) had never been examined the eye.	Potential Predictors for ever had an eye examination- -Attendance at urban hospitals Tertiary hospital- [OR 6.92 (95%CI 4.16–11.53 P<0.001)] Community hospital- [OR 2.23 (95%CI 1.40–3.56 P=0.001)] -Recommendation of regular eye examinations by caregivers [OR 2.22 (95% CI 1.49 –3.31 P<0.001)] -Having a higher DR knowledge score [OR 1.31 (95%CI 1.14–1.51 P<0.001)] -More concern about vision loss from diabetes [OR 1.26 (95%CI 1.08–1.48)] P=0.004)] -Wearing glasses regularly [OR 2.06 (95%CI 1.19–3.57 P=0.010)] Positive history of hypercholesterolemia [OR 1.58 (95%CI 1.07–2.33 P=0.021)]

16.Wang D et al 2010 (China) UMIC	Patients with diabetes N=824 (92.7%) (Total N=889)	Predictors for having an eye examination in the last 12 months	550 (66.7%) had not been examined the eye in the last year as recommended	Potential Predictors for having an eye examination in the last 12 months- -Attendance at urban hospitals Tertiary hospital- [OR 3.46 (95%CI 2.13–5.64 p<0.001)] Community hospital- [OR 1.76 (95%CI 1.09–2.86 p= 0.021)] -Recommendation of regular eye examinations by caregivers [OR 2.36 (95%CI 1.29–3.59 P=0.011)] -Having a higher DR knowledge score [OR 1.24 (95%CI 1.09–1.42 p=0.001)] -More concern about vision loss from diabetes [OR 1.22 (95%CI 1.06–1.41p= 0.007)] -Wearing glasses regularly [OR 1.64 (95%CI 1.06–2.53 P=0.025)] -Positive history of hypercholesterolemia [OR 1.70 (95%CI 1.20–2.41 p=0.003)]

17.Xiong Y et al 2015 (China) UMIC	Diabetics in a community N=1120	Awareness of diabetic retinopathy	The average score of the awareness question-naires was 61.1.	Higher Awareness regarding DR- -Younger patients [OR 0.9292 (95% CI 0. 6554 - 1. 3173 p=0.0000)] -More education [OR 1.8396 (95% CI 0. 9825 - 3. 4442 p=0.0000)] -Lower medical insurance reimbursement rates [OR 1.5964 (95%CI 0.9244-2.7570 p=0.0056)] -Longer diabetes durations [OR 1.7500 (95%CI 1.2321-2.4856 p=0.0000)] -On diet control [OR 2.1485 (95%CI 1.4756-3.1284 p=0.0000)] -More frequent exercise [OR 1.0894 (95%CI 0.4372-2.7149 p=0.0058)] -More severe DR stages [OR 1.7966 (95% CI 1. 2302 - 2. 6237 p=0. 0255)]

S6 Table 4. [HIC]

Study Author Name and Year	Participants' characteristics	Variables in General	Results	Results - Further Analysis
18.Basch CE et al 1999 (USA) HIC	Diabetics N=280	Effectiveness of a health educational intervention	DF with 6 months after randomisation, rate of examination - 54.7% in intervention vs 27.3% in the control	Higher odds for eye examination status associated with- receiving intervention – [OR 4.3 (95% CI 2.4 - 7.8)] Odds ratio associated with being male – [OR 0.3 (95% CI 0. 1 - 0.9)]

19.Baumeister SE et al 2015 (Germany) HIC	Self-reported diabetics N=4308 and N=4402	Patient characteristics related to eye care utilisation		Past-year eye care use decrease- -Male [OR 0.50 (95%CI 0.29-0.84 p<0.01)] -Age 20-39 years [OR 0.09 (95% CI 0.01-0.70 p<0.05)] 40-64 years [OR 0.45 (95% CI 0.28-0.75 p<0.01)] -Marital status Never married [OR 0.14 (95% CI 0.03-0.76 p<0.05)] Married/current partnership [OR 0.53 (95% CI 0.35-0.82 p<0.01)] -Educational attainment <10 years [OR 0.37 (95%CI 0.16-0.88 p<0.05)] 10 to 13 years [OR 0.49 (95%CI 0.31-0.77 p<0.01)] -Employment situation Currently employed [OR 0.28 (95% CI 0.13-0.63 p<0.01)] Unemployed [OR 0.26 (95% CI 0.09-0.79 p<0.05)] -Income 1st tertile [OR 0.34 (95%CI 0.18-0.63 p<0.01)] -Statutory health plan [OR 0.52 (95%CI 0.36-0.75 p<0.01)]
20.Baumeister SE et al 2015 (Germany) HIC	Self-reported diabetics N=4308 and N=4402	Past year eye care use by disease characteristics		More likely to visit an ophthalmologist- -Time since diagnosis of diabetes >5years [OR 0.49 (95%CI 0.31-0.80 p<0.01)] -Treatment of diabetes with oral antidiabetic drugs and insulin [OR 0.17 (95%CI 0.08-0.36 p<0.01)] -High HbA1c >7%

				[OR 0.44 (95%CI 0.25-0.78 p<0.01)] -High blood pressure [OR 0.52 (95%CI 0.35-0.78 p<0.01)] -Dyslipidaemia [OR 0.48 (95%CI 0.27-0.85 p<0.05)] -Poor self-reported health [OR 0.48 (95%CI 0.28-0.85 p<0.05)] -Lower physical health-related quality of life 0.48 (0.29e0.78 p<0.01)] -Lower mental health-related quality of life [OR 0.36 (95%CI 0.20-0.68 p<0.01)] -Number of comorbid conditions >3 [OR 0.30 (95%CI 0.17-0.53)] -Obese >30 [OR 0.41 (95%CI 0.24-0.68 p<0.01)] -Physical inactivity [OR 0.43 (95%CI 0.27-0.68 p<0.01)] -Moderate alcohol consumption [OR 0.48 (95%CI 0.33-0.71 p<0.01)] -Last visit to general practitioners longer than 12 months [OR 0.55 (95%CI 0.36-0.83 p<0.01)] -Last visit to internists longer than 12 months [OR 0.69 (95%CI 0.39-1.24)]
21.Baumeister SE et al 2015 (Germany) HIC	Self-reported diabetics N=4308 and N=4402	Predicting past year eye-care utilization		(during 1997-2001) Factors positively correlates with eye-care use- -Time since diagnosis of diabetes 20 years [OR 2.66 (95%CI 1.18-5.98 p=0.041)] -Treatment with oral anti diabetics insulin [OR 2.83 (95%CI 1.09-7.35 p=0.957)] -Past-year visits to general practitioners and internists [OR 1.55 (95%CI 0.84-2.87 p=0.161)] Factors inversely associated with eye-care use-

				-Heavy alcohol consumption [OR 0.33 (95%CI 0.16-0.69 p=0.003) -Mental health-related quality of life-25th percentile [OR 1.81 (95%CI 0.98-3.34 p=0.041)] (2008-2012) Predictors of eye-care services use- -Time since diagnosis of diabetes >20 years [OR 1.44 (95%CI 0.63-3.32 p<0.001)] -Diabetic retinopathy [OR 3.09 (95%CI 1.26-7.56 p=0.009)] -Diabetic nephropathy [OR 2.71 (95%CI 0.57-12.99 p=0.197)] -Past year visits to general practitioners or internists [OR 2.73 (95%CI 1.47-5.05 p=0.001)] Predictors of less likely of eye-care services use- -Unemployment [OR 0.47 (95%CI 0.19-1.13 p=0.091)] -Diabetic foot [OR 0.44 (95%CI 0.21-0.94 p=0.035)] -HbA1c levels [OR 0.34 (95%CI 0.15-0.77 p=0.022)]
22.Bennet GH, et al 2018 (Ireland) [HIC]	GP from Cork N=72, Patients N=147	Referral systems	The most popular referral method was online registration (53%, 38/72), followed by a phone call (18%, 13/72), e-mail (17%, 12/72), and a letter (14%, 10/72). 11% (8/72) of general practitioners proposed that patients refer themselves to the service.	Factors that increase attendance Older age [OR 1.023, 95% CI 1.001 to 1.046] Non-ocular complications of diabetes [OR 2.741, 95% CI 1.158 to 6.489]

23.Brechner RJ et al 1993 (USA) HIC	Diabetics N=2405	Factors associated with who received a dilated eye examination in the past year	The proportion with a dilated eye examination was 61% among diabetics at high risk of vision loss and 57% those who had diabetes for longer duration	The odds of having had a dilated eye examination in the last one year- -Women (vs men) [OR 1.20 (95% CI 0.95 – 1.21] -Diabetics >70 yrs (vs 40 yrs) [OR 1.95 (95% CI 1.47 – 2.58)] -Family income > $50,000 [OR 1.94 (95% CI 1.29 – 2.92)] -More than high school education [OR 1.47 (95% CI 1.03-2.09)] -Having attended a diabetes education class [OR 1.54 (95% CI 1.22 – 1.94)] -Not treated with insulin, told to have retinopathy [OR 1.63 (95% CI 1.13-2.37)] -Treated with insulin, never told to have retinopathy [OR 2.57 (95% CI 1.83 - 3.61)]
24.Creuzot GC et al 2014 (France) HIC	Diabetic patients, N=4699	Attendance at subsequent ophthalmic follow up	1,241 (79%) of recommended ophthalmic examinations were conducted.	Factors influencing good compliance with the recommended ophthalmic visit- -Duration of diabetes <5 years [OR 1.70 (95%CI 1.24–2.34 p<0.01)] Factors influencing poor compliance with the recommended ophthalmic visit= -Frequency of ophthalmic visit Less than every 2 years [OR 0.61 (95%CI 0.42–0.87 p<0.01)]
25.Dervan E et al 2008 Ireland HIC	Diabetic patients N=209 (77%) (Total N=271)	DF with in last one year	12 (30%) of unscreened had not been examined within the last 12 months. 6 (15%) of unscreened had never had their eyes examined.	Predictors of patient uptake of diabetic retinopathy screening -Physician recommendation to have regular eye examination [OR 1.32 (95%CI 1.11–1.58)]

			21 (55%) of unscreened had screened inappropriately.	-History of diabetic retinopathy or other eye disease [OR 1.2 (95%CI 1.07–1.35)] -Think eye examinations are needed every 6 months [OR 1.25 (95%CI 1.12–1.40)]
26.Foreman J et al 2017. (Australia) HIC	Thirty randomly selected geographic sites N=4836 Indigenous=1738 Non-indigenous=3098	Adherence to screening recommendations	Adherence to screening Non-indigenous - biennial - 77.5% Indigenous - annual - 52.7% (p<0.001)	Greater adherence by non-indigenous Australians was associated with longer duration of diabetes [adjusted odds ratio aOR - 1.19 per 5 years; p= 0.018] Increasing age was associated with poorer adherence in non-Indigenous Australians [aOR, 0.70 per decade; P=0.011] Indigenous Australians - factors positively associated with adherence Residing in inner regional areas [aOR,1.66; p=0.007] and Being male [aOR, 1.46; p=0.018]
27.Gulliford MC et al 2010 (UK) HIC	Diabetics N=31,484	Non-attendance at screening	7026 (22%) subjects were not screened in the period.	Factors associated with non-attendance at screening after invitation- -Male gender [OR 1.16 (95%CI 1.05–1.27 p=0.002)] -Age 18–34 Years of age [Adjusted OR 1.40 (95%CI 1.14–1.73 p=0.002)] 35–44 Years of age [Adjusted OR 1.44 (95%CI 1.24–1.68 p<0.001)] >85 Years of age [Adjusted OR 0.97 (95%CI 0.77–1.24 p=0.830)] -Deprivation quintile

				Most deprived [Adjusted OR 1.37 (95%CI 1.15–1.62 p<0.001)] -Ethnicity Black other [Adjusted OR 1.72 (95%CI 1.38–2.15 p<0.001)] Mixed [Adjusted OR 3.97 (95%CI 3.33–4.75 p<0.001)] Not known [Adjusted OR 15.8 (95%CI 14.0–17.9 p<0.001)] -Diabetes type Other and not known [Adjusted OR 3.53 (95%CI 3.01–4.14 p<0.001)] -Longer diabetes duration (years) 5–9Years [Adjusted OR 1.90 (95%CI 1.65–2.19 p<0.001)] 10–14Years [Adjusted OR 2.13 (95%CI 1.78–2.54 p<0.001)] 15–19Years [Adjusted OR 3.11 (95%CI 2.55–3.80 p<0.001)] >20Years [Adjusted OR 3.40 (95%CI 2.73–4.24 p<0.001)] Not known [Adjusted OR 8.01 (95%CI 6.70–9.58 p<0.001)]
28.Gulliford MC et al 2010 (UK) HIC	Diabetics N=31,484	Good attendance at screening	24458 (78%) having one or more screening episodes.	Factors associated with good-attendance at screening after invitation- -Ethnicity African [Adjusted OR 0.26 (95%CI 0.18–0.37 p<0.001)] Caribbean [Adjusted OR 0.22 (95%CI 0.14–0.34 p<0.001)] Other ethnicity [Adjusted OR 0.32 (95%CI 0.20–0.50 p<0.001)] -Age <18 Years [Adjusted OR 0.27 (95%CI 0.11–0.68 p=0.006)] 75–84 Years

				[Adjusted OR 0.74 (95%CI 0.64–0.87 p<0.001)]
29.Huang OS et al 2009 (Singapore) HIC	General population N=3280 and n=768 diabetics	Awareness of diabetes + diabetic retinopathy and associated factors	13.2% unaware of diabetes, 84.4% were unaware of having DR, 59.2% were unaware of vision threatening retinopathy.	Lack of awareness (regarding diabetes) associated with- -Older age [(60-69) years OR (Multivariable-adjusted) 10.45 (95% CI 0.22 - 0.91 p=0.03) -Poorly controlled HbA1c [OR (Multivariable-adjusted) 4.91 (95% CI 2.51 - 9.62) p=<0.001] -Male gender [OR (Multivariable-adjusted) 1.18 (95% CI 0.75 - 1.85 p=0.47)] Lack of awareness (regarding diabetic retinopathy) associated with- -Older age [(70-80) years [OR (Multivariable-adjusted) 4.63 (95% CI 1.08-19.93 p=0.04)]
30.Huang OS et al 2013 (Singapore) HIC	Participants with at least one of five eye conditions N=2112	Awareness of eye condition	1757 (83.2%) were unaware of at least one of their eye conditions.	Factors related to unawareness of eye condition – -older age [Multivariable adjusted OR 1.03 (95%CI 1.02–1.04 p<0.0001)] -Lower education (Primary or less) [Multivariable adjusted OR 1.89 (95%CI 1.40–2.55 p<0.0001)] -lower income (Singapore$ <2000) [Multivariable adjusted OR 1.73 (95%CI 1.20–2.50 p=0.003)] -Poorer literacy (Unable to write) [Multivariable adjusted OR 1.44 (95%CI 1.02–2.05 p=0.03)]

				-Higher serum glucose [Multivariable adjusted OR 1.08 (95%CI 1.04–1.12 p<0.0001)] Serum LDL [Multivariable adjusted OR 1.20 (95%CI 1.06–1.36 p=0.003)] Wears glasses of any kind no [Multivariable adjusted OR 2.90 (95%CI 2.10–3.98 p<0.0001)] -Had better visual acuity [Multivariable adjusted OR 1.32 (95%CI 1.01–1.73 p=0.04)] -Lower annual eye examination attendance [Multivariable adjusted OR 2.08 (95%CI 1.48–2.92 p<0.0001)]
31.Hwang J et al 2015 (Canada) HIC	Self-reported diabetics N=2323	Factors associated with increased eye screening	72% reported receiving a dilated eye examination within 2 years.	Increased eye screening associated with- -Discussion of diabetic complications with health professionals [OR 2.02 (95% CI 1.28–3.19 p=0.00)] -Having private insurance [OR 3.23 (95% CI 2.21–4.73 p=0.00)] -Duration of diabetes longer than 10 years [OR 1.53 (95% CI 1.04–2.25 p=0.03)] -Having visual impairment [OR 2.60 (95% CI 1.73–3.91 p=0.00)]
32.Jones HL et al 2010 (USA) HIC	Adults with diabetes N=305	Factors associated with increased screening after a telephone intervention	Nearly all participants who obtained a DFE did so after 4 or fewer phone calls, all did so by the fifth phone call.	Factors associated with having a dilated eye exam within the intervention 6 months -Higher baseline level of worry regarding complications [OR 3.47 (95%CI 1.78–6.77)]

33.Kreft D. et al 2018. (Germany) HIC	Germany's largest public insurance provider records of patients with type 2 DM. N= 26,560 type 2 DM	To assess factors associated with DR screening uptake.	More than half of the incident cases had not seen an ophthalmologist - > 2 years (2.25 yrs).	Factors associated with a lower likelihood of DR screening Older age (compared to 50-69 yrs) [Hazard ratio - HR (70 - 74 yrs) = 0.93, 95% CI 0.89 - 0.97] [HR (90+ yrs) = 0.50, 95% CI 0.42 - 0.60] Higher disability level [HR (disability level 3) = 0.30, 95% CI 0.25-0.36] Factors associated with a higher likelihood of DR screening Female sex [HR = 1.12, 95% CI 1.08-1.15] Six or more comorbidities [HR = 1.26, 95% CI 1.15-1.37] Type of DM Moderate [HR = 1.51, 95% CI 1.46-1.56] Severe [HR = 1.53, 95% CI 1.45-1.61] Being enrolled in a type 2 diabetes disease management program [HR = 1.78, 95% CI 1.69-1.87]
34.Leese GP et al 2008 (UK) HIC	All patients with diabetes Diabetes patients N=15150	Risk factors for non-attendance	12% of the invitations to attend eye screening were missed.	*Model 1 – (All patients invited to both the mobile units and the static, hospital-based unit)* Factors associated with failure to attend eye screening – -Deprived areas Most deprived areas [OR 2.32 (95%CI 1.92–2.81)] Second most deprived areas were [OR 1.5 (95%CI 1.24–1.82)]

				-Patients who were invited to eye vans [OR 2.92 (95%CI 2.48–3.44)] -Longer Duration of Diabetes [OR 1.019 (95%CI 1.012–1.027)] -Poor AIC control [OR 1.253 (95%CI 1.079–1.455)] -Poor blood pressure control [OR 1.012 (95%CI 1.007–1.018)] -Smoker [OR 2.516 (95%CI 2.186–2.895)] Factors associated with attending to eye screening- -Constant Screening location [OR 0.016 (95%CI 0.013–0.021)] -Older age [OR 0.968 (95%CI 0.965–0.972)] *Model 2 - Only those patients invited to the mobile units)* Factors associated with failure to attend eye screening- -Deprived areas Most deprived areas [OR 1.981 (95%CI 1.573–2.495)] Second most deprived areas were [OR 1.414 (95%CI 1.14–1.753)] -Longer Duration of Diabetes [OR 1.024 (95%CI 1.015–1.033)] -Poor AIC control [OR 1.426 (95%CI 1.190–1.709)] Poor blood pressure control [OR 1.007 (95%CI 1.001–1.014)] -Smoker [OR 2.265 (95%CI 1.904–2.694)]

				Factors associated with attending to eye screening- -Constant Screening location [OR 0.061 (95%CI 0.047–0.078)] -Older age [OR 0.964 (95%CI 0.959–0.969)]
35.Legorreta AP et al 1997 (USA) HIC	Patients with diabetes N=19,397	Increase in screening	25% and 27% increases in patients who received DR examinations in 1995compared with 1993 and 1994, respectively.	The increase in diabetic retinal examinations- -After the health educational intervention [OR 1.4 (McNemars x2 = 102.7; P < 0.0001)]
36.Lian JX et al 2013 Hong Kong) HIC	Self-reported diabetics N=1165 Free group N=1052 Pay group	Factors associated with uptake of screening	Being in the pay group was negatively associated with uptake of screening (OR 0.59, 95% CI 0.47 to 0.74)	Higher uptake of screening associated with- -Occupation Retired [Adjusted OR 1.53 (95% CI 1.08–2.16 p=0.016)] Homemaker [Adjusted OR 1.76 (95% CI 1.18–2.60 p=0.005)] -Family income $10,000–19,999 [Adjusted OR 1.46 (95% CI 1.02–2.09 p=0.040)] >$20,000 [Adjusted OR 1.66 (95%CI 1.04–2.67 p=0.034)] Low uptake of screening associated with- -Being in the pay group [Adjusted OR 0.59 (95% CI 0.47–0.74 p<0.001)]
37.Lian J, et al, 2018, (Hong Kong) [HIC]	Diagnosed PwDM who participated in a previous RCT Sample size= 2593	Knowledge, awareness and perceptions of vision loss due to DR, importance of screening and frequency.	Perception of vision loss (42.9% - 1113/2593 - worry about vision loss) Knowledge on DM causes vision loss (79.6% - 2063/2593)	Adjusted awareness and screening attendance Worry about vision loss [OR=1.72, 95% CI 1.31-22.26, p<0.001]

			Availability of DR treatment (17.5%, 453/2593) Asymptomatic nature of early DR (11.5%, 297/2593)	Awareness of the importance of regular eye examination [OR=1.83, 95% CI 1.24-2.70, p=0.002] Awareness of the frequency of eye examinations Every year - [OR=2.64, 95% CI 1.65-4.22, P<0.001] Every 6/12 [OR=3.27, 95% CI 1.92-5.56, P<0.001] Did not know [OR 2.11, 95% CI 1.38-3.25, p=0.001]
38.Maberley DA et al 2002 Canada HIC	Diabetics N=248	Status of a retinal examination	85% (241) - attended a DR examination within the preceding 2 years, 42 had not.	Factors associated with good attendance of a retinal examination (Univariate) -Older age (>60 years) [OR 0.09 (95%CI 0.02-0.41)] -Longer duration of DM 5-10 years [OR 0.25 (95%CI 0.08-0.74)] >10 years [OR 0.22 (95%CI 0.07-0.70)] (Multivariate) -Older age (>60 years) [OR 0.10 (95%CI 0.02-0.50)] -Longer duration of DM 5-10 years [OR 0.24 (95%CI 0.08-0.76)] -Community of residence-moose factory (not from Moosonee) [OR 0.48 (95%CI 0.18-1.27)]
39.Moss SE et al 1995 (USA) HIC	Diabetics at primary care clinics N=2990	Factors associated with previous eye examination	64% percent of the younger-onset group and 62% of the older-onset group had had a dilated eye examination in the previous year.	Factors associated with having a previous eye examination Younger onset

				-Cataract history [OR 3.57 (95%CI 1.90 – 6.71 p<0.0001)] -Proliferative Retinopathy [OR 2.61 (95%CI 1.77 – 3.86 p<0.0001)] -having told that an eye examination is needed [OR 1.92 (95%CI 1.29 – 2.87 p<0.005)] -Health insurance with eye examination covered [OR 3.17 (95%CI 2.22 – 4.54 p<0.0001)] -Thought of person with DM should have eye examination every 12 months [OR 2.28 (95%CI 1.47 – 3.54 p<0.0005)] Older onset -Cataract history [OR 2.91 (95%CI 1.91 – 4.45 p<0.0001)] -Moderate to proliferative Retinopathy [OR 1.91 (95%CI 1.21 – 3.01 p<0.01)] -Health insurance with eye examination covered [OR 3.35 (95%CI 2.19 – 5.13 p<0.0001)] -Thought of person with DM should have eye examination every 12 months [OR 2.62 (95%CI 1.68 – 4.08 p<0.0001)]
40.Moreton R.B.R. et al 2017. (UK) [HIC]	79 general practices N=21,789 invited, of which 82.4% attended. Oxfordshire DR screening programme	Factors that affect DR screening uptake	Uptake was 82.4% during the study period and was higher for men (83.2%) than for women (81.5%) (P = 0.001) Uptake varied by age group (P < 0.001), being lowest in those aged 12–39 years (67%). Uptake was higher for people invited to a general practice for screening by a mobile unit (83.5%) than for those invited for screening by a high-street optometrist (82%) (P = 0.006).	Those with GP based screening and most deprived areas are least likely to attend Deprivation Group 1 [OR - 0.75, 95% CI 0.58-0.96] Deprivation Group 2 [OR 0.66, 95% CI 0.53-0.96]

41.Mukamel DB et al 1999 (USA) HIC	Patients with diabetes N=4410 Primary care physicians N=408	Probability of screening in a 12-month period	34% of patients were screened in 1993.	Factors affecting the probability of screening in a 12-month period- Increase in screening odds- -Older patients [OR 1.02 ($p<0.001$)] -Patients who visit their PCPs more often [OR 1.28 ($0.001<p<0.01$)] -Living in areas of higher average education and lower percentage of blacks. Decrease in screening odds- -Male [OR 0.87 ($0.01<p<0.05$)] -Living in areas of higher percentage of blacks. [OR 0.94 ($0.01<p<0.05$)]
42.Mukamel DB et al 1999 (USA) HIC	Patients with diabetes N=4410 Primary care physicians N=408	Probability of an annual screen in two successive years	Only 16% of diabetic patients received a true annual screening.	Factors affecting the probability of an annual screen in two successive years- Increase in screening odds- -High patient expenditures per month. [OR 1.04 ($0.001<p<0.01$)] Reduce screening odds- -Male gender [OR 0.74 ($0.01<p<0.05$)]

43.Munoz B et al 2008 (USA) HIC	Persons Without Diabetes (N=329) Persons with Diabetes (N=222)	Knowledge about diabetic eye disease	The level of knowledge of the adverse consequences of uncontrolled diabetes was low. .	Predictors of knowledge that uncontrolled diabetes could cause eye disease- -Educated up to high school or more [OR 2.48 (95%CI 1.50-4.01 P<0.05)] -With diabetes >1 years [OR 4.03 (95%CI 2.41-6.76 P<0.05)] -No diabetes, having family history [OR 3.66 (95%CI 1.94-6.89 P<0.05)]
44.Munoz B et al 2008 (USA) HIC	Diabetics Consecutive sample N=316 N=114 following referral	Having a dilated eye examination	A total of 30% of diabetic participants had had an eye examination in the previous year	Predictors of having a dilated eye examination in the past 2 years in persons with diabetes- -Older age [OR 1.06 (95%CI 1.02-1.09 P<0.05)] -Length of stay in the United States >5 years [OR 4.14 (95%CI 1.48-11.57 P<0.05)] -Having health insurance [OR 3.11 (95%CI 1.41-6.89 P<0.05)] Predictors of less likely to have a dilated eye examination in the past 2 years in persons with diabetes- -Newly diagnosed with diabetes [OR 0.21 (95%CI 0.06-0.85 P<0.05)]

45.Orton E et al 2013 (UK) HIC	Persons Without Diabetes (N=329) Persons with Diabetes (N=222)	Reasons for not up taking DR screening	Of those invited, 26.1% did not make an appointment. (54.9% men).	More likely to be non-responders – -People lived in most deprived areas [OR 1.23 (95% CI 1.18 - 1.35, univariate)] -Younger age (<40, male - compared to 80+ years, multivariate) [OR 3.13 (95% CI 2.70 - 3.64)]
46.Paksin Hall A et al 2013 (USA) HIC	Diabetics N= 52,386	Receipt of annual DF	24,198 (69.8%) reported that they had had a diabetic eye examination within the last year.	Unadjusted OR- Increased odds of undergoing a dilated eye examination within the past year -65 and older [adjusted OR 3.11 (95%CI 1.46–6.62)] -Higher income $35,000–$49,999 [adjusted OR 1.48 (95%CI 1.27–1.72)] >$75,000 [adjusted OR 1.55 (95%CI 1.29–1.86)] -College graduate or higher [adjusted OR 1.79 (95%CI 1.53–2.09)] -Have health insurance [adjusted OR 2.97 (95% CI 2.47–3.57)] -Had fewer than 14 mentally unhealthy days within the past month [adjusted OR 1.49 (95% CI 1.32–1.69)] -Taking insulin [adjusted OR 1.55 (95% CI 1.39–1.73)]

				-Participating in diabetes management classes [adjusted OR 1.67 (95% CI 1.51–1.84)] -Had their feet checked within the last year by a health professional [adjusted OR 2.34 (95% CI 2.07–2.64)] Adjusted OR- Increased odds of undergoing a dilated eye examination within the past year -65 and older [adjusted OR 2.51 (95%CI 1.15–5.47)] -Higher income $35,000–$49,999 [adjusted OR 1.30 (95%CI 1.09–1.55)] >$75,000 [adjusted OR 1.30 (95%CI 1.07–1.57)] -College graduate or higher [adjusted OR 1.55 (95%CI 1.26–1.91)] -Have health insurance [adjusted OR 1.75 (95% CI 1.42–2.16)] -Had fewer than 14 mentally unhealthy days within the past month [adjusted OR 1.22 (95% CI 1.04–1.41)] -Taking insulin [adjusted OR 1.44 (95% CI 1.27–1.63)] -Participating in diabetes management classes [adjusted OR 1.40 (95% CI 1.24–1.57)] -Had their feet checked within the last year by a health professional [adjusted OR 1.89 (95% CI 1.67–2.13)]

47.Paz SH et al 2006 (USA) HIC	Self-reported diabetics N=821	Factors associated with compliance with ADA guidelines for vision care.	55% not complied with the ADA vision guidelines. DF more than 12 months ago - 64%, never had DF - 36%.	Noncompliance associated with- -Less educated [OR 1.5 (95%CI 1.1–2.2 p=0.0185)] -Lack of health insurance [OR 2.5 (95% CI 1.7–3.7 p<0.0001)] -Have had no routine physical examination in the last 12 months [OR 1.8 (95% CI 1.3–2.5 p=0.0003)] -Have a glycosylated hemoglobin level ≥9.0% [OR 1.7 (95% CI 1.1–2.6 p=0.0088)]
48.Rim TH et al 2013 (Korea) HIC	Diabetic N=2660	Factors associated with screening	998 (37%) had received a diabetic retinopathy screening within one year.	Factors associated with screening for diabetes complications- Multivariate analysis -65 Years or older [aOR 1.6 (95% CI 1.1-2.4 p=0.01)] -Living in urban areas [aOR 1.7 (95% CI 1.3-2.1 p<0.01)] -Graduated from Middle school [aOR 1.5 (95% CI 1.1-2.1 p=0.01)] High school [aOR 1.5 (95% CI 1.1-2.1 p<0.01)] Higher education institute [aOR 2.8 (95% CI 1.9-4.2 p<0.01)] -Self- reported “unhealthy” health status [aOR 1.7 (95% CI 1.3-2.3 p<0.01)] Univariate analysis -Living in urban areas [OR 1.5 (95%CI 1.2-1.8 p< 0.01)]

				-Monthly house income in highest quintile [OR 1.4 (95%CI 1.1-1.8 p< 0.01)] -University or higher Education [OR 1.7 (95%CI 1.3-2.2 p< 0.01)] -Self- reported "unhealthy" health status [OR 1.6 (95% CI 1.3-2.0 p<0.01)] -Having co-morbidities 1-2 co-morbidities [OR 1.3 (95%CI 1.1-1.6 p< 0.01)] 3 or more co-morbidities [OR 1.5 (95%CI 1.2-2.0 p< 0.01)
49.Saadine JB et al 2008 (USA) HIC	Diabetic patients N= 2412	Systemic factors associated with follow up	Only 2412 of 5000 (48%) had an eye examination during the baseline study enrolment period.	Systemic factors independently associated with follow-up examination within 1 year- -Older age [OR 1.023 (95%CI 1.012-1.034 p<0.0001)] -Longer duration of diabetes (>15Years) [OR 1.894 (95%CI 1.379-2.603 p<0.0001)] -Used insulin [OR 1.322 (95%CI 1.004-1.740 p=0.0466)]

50.Saadine JB et al 2008 (USA) HIC	Diabetic patients N= 2412	Ocular and systemic factors associated with follow up		Ocular and systemic factors independently associated with follow-up examination within 1 year- -Slightly worse visual acuity (<20/40) [OR 1.402 (95%CI 1.125-1.748 p=0.0026)] -Slightly worse retinopathy level - Moderate retinopathy or worse [OR 2.172 (95%CI 1.594-2.960 p<0.0001)]
51.Scanlon PH et al 2008 (UK) HIC	Diabetics N = 13304 from data set 1 N = 10,312 from data set 2	Uptake of screening	The least deprived quintile showed a screening uptake of 76.7%, decreasing down to 67.4% in the most deprived quintile.	Probability of having been screened for diabetic retinopathy- -Socioeconomic deprivation (Each increasing quintile of socioeconomic deprivation probability decreased) [OR 1.11 (95%CI 1.08–1.15 P<0.001)]
52.Schoenfeld ER et al 2001 (USA) HIC	Diabetics N=2308	Adherence to vision care guideline - factors associated with adherence	69% had no DF eye examination in the year preceding	Factors related to non-adherence – -last eye examination by optometrist [OR 5.32 (95% CI 4.21 - 6.72)] - last eye examination non-ophthalmologist [OR 4.29 (95% CI 2.30 - 6.16)] - less practical knowledge about diabetes [OR 1.57 (95% CI 1.18 - 2.08)] - No prior formal diabetes education [OR 1.30 (95% CI 1.06 - 1.61)]

53.Sheppler CR et al 2014 (USA) HIC	Diabetic adults N=316	Associations with self-reported adherence to annual eye examination	Reasons for adherence – -associated with longer duration of diabetes, -having insurance coverage and -better glucose control	Compliance with annual eye examination- -Insurance coverage [OR 2.23 (95% CI 1.15 - 4.33 p =0.02)] - Years diagnosed with diabetes [OR 1.06 (95% CI 1.01 - 1.12 p=0.01)] -HbA1c [OR 0.81 (95% CI 0.68 - 0.96 p=0.01)]
54.Shih HC et al 2007 (Taiwan) HIC	Type 2 diabetics in the community - N=406	Mean Willingness to pay for DR screening	Mean amount willingness to pay (Mean + SD) - No DR (Taiwan dollars - NTD 468.9 ± 327.7) vs Blindness (NTD 822.2 ± 192.2), [p = 0.0005]	Highest proportion of not willing to pay in the No DR group - 40.8%. 100% willing to pay in legal blindness
55.Storey PP et al 2016 (USA) HIC	Diabetics N=1968	Factors associated with examination adherence	Increased adherence associated with - written communication, severity of DR, >65 years of age, smoking status, insulin use, HbA1c / blood glucose listed in chart, insurance status. Multi-variate analysis - communication, severity of DR, >65 years, insulin use and HbA1c/blood glucose.	Factors associated with examination adherence- -Written communication from ophthalmologist to PCP [OR 1.47 (95%CI 1.11-1.94 P=0.0071)] -Written communication from PCP to ophthalmol-ogist [OR 1.53 (95%CI 1.03-2.29 P=0.036)] -Severe DR [OR 3.56 (95%CI 2.70-4.69 P<0.0001)] -Age older than 65 [OR 1.33 (95%CI 1.03-1.72 P=0.027)] -Insulin use [OR 1.40(95%CI 1.10-1.78 P=0.0061)] -Haemoglobin AIC listed in chart [OR 1.57 (95%CI 1.23-1.99 P=0.0002)] -Blood glucose listed in chart

				[OR 1.72 (95%CI 1.37-2.16 p<0.0001)] Factors associated with examination non-adherence- -Smoking [OR 0.54 (95%CI 0.41-0.70 P<0.0001)]
56.VanEjik KN et al 2012 (Netherland) HIC	N=3236, (respondents n=1891)	Individual barriers to DR screening	81% of the diabetics attended DR screening.	Individual incentives to DR screening – Knowledge and instructions – -Recommendation by the care provider [OR 341 (95% CI 164 - 715)], -Knowledge of effects of DR on vision [OR 3.3 (95% CI 2.0 - 5.5)], -Awareness of possibility of treat DR [OR 1.6 (95% CI 0.9 - 3.0)], -Fear of impaired visual acuity- [OR 1.9 (95% CI 1.5 - 2.5)]

57.Yeo ST et al 2012 (UK) HIC	Diabetics N=198	Perspectives of diabetics on DR screening		Proportions that responded the factors as extremely important – -Travel time to screening venue [23.5% (chi 2.930 (p=0.402)], - Length of time to receive results - [31.3% (Chi 4.785 p=0.188)], - Detail information about the processes – [40% (Chi - 0.619 p=-.892)], - Explanation of the results – [53.5% (Chi 0.898 p=0.826)]
58.Zhang X et al 2009 (USA) HIC	Self-reported diabetes N=617 and N=672	Receipt of dilated eye examination	Receipt of eye care education was independently associated with receipt of dilated eye examination	Factors associated with receipt of dilated eye examination- -Eye care education [OR 1.59 (95% CI 1.19-2.13)] -Aged 65 years and older [OR 2.60 (95% CI 1.65-4.09)] -Females [OR 1.62 (95% CI 1.18-2.22)] -Individuals with DR [OR 1.89 (95% CI 1.41-2.54)]. Factors associated with no receipt of dilated eye examination- -Without health insurance coverage [OR 0.51 (95% CI 0.35-0.76)]

Appendix 6

6.1 - Additional File 1 - Topic guide of the focus group discussions

Topic Guide Version 1.2_Oct_2016

1. Topic Guide for Conducting the Focus Group Discussions (Service Users)-

Date and Time of the FGD:

Names of the investigators:

Place of the discussion:

Details of the group-(participants' characteristics data were collected using a questionnaire schedule)

Introduction

Background information

"Burden of the diabetic retinopathy in the Western province of Sri Lanka - about one fourth (26%) of the total population live with in the Western province of Sri Lanka (5.8 million). The prevalence or the percentage of people having diabetes is high as 18.6% in this province. Available literature / publications show about one third (33%) of the people wit diabetes have any form of retinopathy and about 4% of them are blind due to the same. Diabetes is an emerging public health problem / epidemic in Sri Lanka and it has a significant impact on the health system.

A situation analysis done in this province in the year 2014 showed that there was no systematic diabetic retinopathy screening program. It is only an opportunistic screening method. Most of the developed countries have well established screening programs in diabetic retinopathy in order to identify the people who need treatment early. In the Western province, there is a huge gap in the service delivery. Clinicians have experienced that many people present with blindness due to diabetic retinopathy leading to costly surgeries such as pars plana viterctomy and long waiting time for surgeries in the public sector. Therefore it would be a public health concern to identify the reasons for not taking up available services and development of a screening program in the Western province of Sri Lanka. This discussion would be based on this background information and you are allowed to express your views regarding development of a screening program for your province".

1) General health care (accessibility and behaviour)

Topic - Where do you usually go for seeking medical care when you fall ill?

Probe - When do you decide to seek medical advice?

2) Specific disease condition (current knowledge, attitude and practice of diabetes)

Topic - Tell me about your condition (diabetes)?

Topic - How did you get to know that you have this condition?

Topic - How do you get treatment for your condition (diabetes)?

3) Perceptions regarding the service providers (medical care)

Topic - What is your opinion on receiving the services and treatment from your health care provider for diabetes?

Prompts - How do you rate the staff members providing the services?

4) Current knowledge regarding the complications of diabetes and medium of receiving information

Topic - What do you know about conditions (complications) that may be associated with long standing diabetes?

Probe - How do you acquire any information or knowledge about those conditions?

5) Patients view about current health educational interventions

Topic - Tell me about the things you have seen, heard or read about the complications of diabetes?
Probe - How would you like to acquire this type of information (? through a poster displays at clinics / leaflets/ through newspaper / radio / television / video / from your doctor)

6) Diabetic retinopathy blindness and visual impairment (Current knowledge) –

Topic - Tell me about the things that you know about your condition and associations with your eyes / sight?

7) Diabetic retinopathy - Current attitude and practice

Topic - Tell me about the things that you do about the diabetic eye conditions?

Probe - Have you seen an eye doctor / optician regarding this last few years?

8) Behaviour regarding diabetic retinopathy screening)

Topic - Tell me about the things which may have prevented you from seeing an eye doctor with regard to undergoing an eye examination due to diabetes?

Probe - Was it due to you were not told? You did not have time? Did not have money to go?

Did not like the hospital staff?

(Following questions are specifically for group 3 and 4)

9) Diabetic retinopathy Screening - perceptions regarding the modality of screening -

Topic - What is your opinion about need for checking your eyes as you have diabetes?

Probe - Can you tell me how would you like to check your eyes (method of screening)?

If you have done so, how was the experience at that eye care facility?

10) Follow up

Topic - What is your opinion about check your eyes (for diabetic eye problems) if a doctor suggests it to do regularly?

Topic - How frequent would you like to visit your eye doctor?

11) Barriers in accessing DR treatment services

Topic - What is your opinion about the treatment that you are getting for your eyes for diabetic eye condition?

Topic - Tell me about your experience in undergoing diabetic laser treatment / injections / eye surgery?

(If they have not attended for treatment when required)

Topic - In your opinion what is the main reason for you not undergoing diabetic eye treatments?

(Probes if necessary - Assumptions - was it because you were not aware / expenses / travelling / waiting time / communication problems with the health staff / was it due to you did not like the method of treatment / was it due to the thought that it is not useful since you do not have any eye complains?)

12) Additional

Can you tell me anything that you would like to add to this discussion or any questions that you have regarding checking your eyes (or treating) due to diabetes?

Appendix 7

7.1 - Additional File 1 - Semi structured interviews topic guide

A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

Formative Research (Qualitative Study - Topic Guide Version 1.2_Oct_2016)

Topic Guide for Semi Structured Interviews (Service Providers)

Date and Time of the FGD-……..

Names of the investigator-…….

Place of the discussion-……

Details of the participant-…….

Background information

"Burden of the diabetic retinopathy in the Western province of Sri Lanka - about 26% of the total population live with in the Western province of Sri Lanka (5.8 million). The prevalence of diabetes is as 18.6% in this province. Available literature shows about 33% of the diabetics have any form of retinopathy and about 4% of them are blind due to the same. Diabetes is an emerging epidemic in Sri Lanka and it has a significant impact on the health system.

A situation analysis done in this province in the year 2014 showed that there was no systematic DR screening program. It is only an opportunistic screening method. There is huge gap in service delivery. Clinicians have experienced that many people present with blindness due to DR leading to costly TPPV surgeries and long waiting time for surgeries in the public sector".

Section 1

A) Views regarding the barriers / challenges faced by the service providers –

Back Ground

Question – Could you tell me about the burden of diabetes in the region (Western province) at present?

Probes – Any prevalence data?

Current knowledge about the burden of DR by the decision makers -

Question - Could you please tell me about the burden of diabetic retinopathy in the Western province of Sri Lanka at present?

Probe – How many diabetic patients are being screened in this region / district per year?

Current situation on DR screening

Question - What are the modes of DR screening and treatment facilities available in this region?

Question – What are the challenges you faced when screening diabetics?

B) Specific question in order to develop a new DR screening modality – (non-mydriatic retinal imaging - decision makers views - SSI topic guide) –

Leadership

Question – In your opinion, who do you think the best person to lead a DR screening program?

Prompts – NCD / Community physicians / Vision2020 coordinators / Ophthalmologists / General physicians.

Question - Whom do you think has the capacity to make decisions on such a program – leading to effective implementation?

Question – Could you please tell me about the challenges in developing a screening program in this region with regard to leadership?

Financing

Question - How do you think that a DR screening program can be funded?

Question - What is the possibility of allocation of finances for training of HR and purchasing of screening instruments?

What are barriers for that?

Medical supplies and Infrastructure

Question - In your opinion what would be the most suitable / feasible DR screening modality for the Western province of Sri Lanka (eg; digital retinal camera, direct ophthalmoscope, indirect ophthalmoscope, mobile retinal camera, slit lamp examination)?

Question – What are the problems you have faced or foresee in each method?

Probe – How do you think about the suitability of each methods to the local context?

Question - What is your opinion on suitability of digital retinal imaging (Non-mydriatic) for DR screening in the Western province of Sri Lanka?

Questions - What are the suitable institutions to establish a DR screening program after supplying the relevant instruments (medical units or the eye units)?

Management Information Systems

Question – Could you please tell me about the current method of HMIS under the MOH for diabetic patients?

Probe - Is there a register of diabetic patients?

Question - What the systems available for tracking follow up of a patient? Do we have a call-recall system?

Question - How would you do a referral of a diabetic patient among institutions?

Questions – What are the challenges in development of a HMIS for DM patients in DR screening?

Human Resources

Question – Could you please tell me about the staff / cadres who perform DR screening at present?

Questions - What could be the most suitable category to employ as DR screeners?

Question - What are mechanisms available to train them (competency-based training)?

Probe - What is your opinion on training a separate cadre as “DR Screeners” in Sri Lanka (as in English Screening Program - UK). Do you think it is feasible in Sri Lanka?

Question - What are the current problems in eye care human resources in the Western province with regard to DR screening?

Service Delivery

Question - What could be the most suitable place (eye clinic / medical clinic) to start DR screening?

Probe – What are the challenges / What are your thoughts in provision of screening at each clinic / place?

DR Screening – Program development

Question - In your opinion what would be the best way to establish a DR screening unit in this institution / province? What is the most suitable modality (ie; Mydriatic camera, Non-mydriatic camera, indirect ophthalmoscopy?)

Question - Who would be the best person to be trained in DR screening and grading? (Physician, ophthalmologist, optometrists, new cadre)?

Question - In your opinion what is the best place to conduct a DR screening program, (medical clinic, eye clinic, mobile clinic, community)?

Question - What could be the reasons for non-attendance in DR screening in your institution? How can we improve the uptake of the services by the diabetic patients?

Question - What are your suggestions to develop a comprehensive DR screening program for the Western province Sri Lanka?

Question - In overall - What are the current problems do you encounter in doing DR screening on a patient?

Question – Could you please tell me anything that you would like to add for this discussion with regard to development of a DR screening program in Sri Lanka?

Section 2

C) Topic guide for the clinical staff – involve in DM / DR screening and management (Target participants – General physicians, general ophthalmologists and vitreo-retinal surgeons)

(*Adopted from-Influence of primary care practices on patients’ uptake of DR screening-a qualitative study: Reference: Lindenmeyer A et al-Kings College-London).

Background -

Question - How do you identify a diabetic patient when you see patients in a busy clinic?

DR screening – current practice

Question - How do you a received a patient for DR screening? What do you think influence in this?

Question - In your opinion what is happening when the DM patient attends for the clinics? Do they accept to undergo DR screening or not?

Question - What is your role in screening and grading DR when you see a diabetic patient at your clinic?

Question - What is the mode of screening?

Question - What is the level of acceptance by the diabetic patients when you offer DR screening? Do they happy to undergo screening?

Question - What are your views regarding the current method of DR screening?

Probe – What are challenges you face?

DR Screening Health Education

Question – Could you please tell me about the method of health education provided on DR screening at present?

Probe – What could be the most feasible method of doing it?

Question - Who is responsible for giving these pieces of information?

Question – What are the main problems

7.2 - Additional File 2-Table 1. Main domains and themes of barriers identified by the providers

Main Domain	Sub domains	Themes	Subthemes	Quotations of Providers
Perceptions about the current DRS situation	Levels of provider awareness	Adequate awareness on diabetes is an emerging epidemic in Sri Lanka	An emerging health issue A multi-dimensional health issue	*"It is a burden. So exactly I don't have the figures, but I am getting lots of patients…about 50% of the new referrals I receive per clinic is due to diabetic complications. Not only that, I receive referrals from all over the country and about 50% are from the Western province" (Retinologist, 3ry level)*
		Unaware of current situation of DRS	Unaware of DRS No systematic DRSP	*"We do not know what is happening and about the screening as well regarding the diabetic retinopathy in this province." (Planning staff)*
	Poor DRS equipment and technology	Negative perceptions on current technology of DRS at medical clinics and the referral system	Examining patients using direct ophthalmoscope Creating difficulties for patients on current referral system	*"Current practice is all the diabetics are referred to an ophthalmologist's clinic. Mostly referred by medical clinics. The challenges I have seen from patients' side are such as debilitated patients with walking difficulties, some need a by stander to ac-company, some say they do not have money for transport etc." (Medical officer, 3ry level)*
	Lack of health education	Lack of knowledge and awareness on importance of DRS and treatment among the PwDM	Lack of awareness on DR Lack of knowledge of patients on DR Lack of health education on DR	*"Lack of awareness among the diabetics is the main problem". (Physician, 3ry level)* *"We do not have proper methods on health education especially for diabetic retinopathy". (Medical officer, 2ry level)*
Barriers	Health work force	Lack of training for mid-level HR	Examining patients by several doctors due to lack of skills	*"The problem is we are not trained and not experienced in looking at the fundus". (Medical officer, 2ry level)*
	Equipment	Lack of skilled personnel and DRS instruments	Lack of skills and knowledge Lack of trained staff	*"The problem we have in Sri Lanka with regard to human resources is lack of a trained staff in DR screening". (Medical officer, 3ry level)*
	Referral systems	The practical barriers with regard to referral system at present	No proper referral system	*"Current practice is all the diabetics are referred to an ophthalmologist's clinic. Mostly referred by medical clinics. The challenges I have seen from patients' side are such as debilitated patients with walking difficulties, some need a by stander to accompany, some say they do not have money for transport etc. I think it is actually not the transport cost since we have a cheaper public transport system. (Medical officer, 3ry level)*

7.2 - Additional File 2-Table 2. Main domains and the themes of enablers identified in the local context and suggestions from providers point of view

Main Domain	Sub domains	Themes	Quotations of Providers
Enablers	Leadership	Capacity of personnel	*"Since this is a health issue, so it has to be taken up by the Ministry of Health, under the leadership. You know it should be done by personnel from top level, it has to be led by a person who has enough knowledge, enough experiences and the interest". (Institutional administrator, 2ry level)*
	Human resources	Suitable non-ophthalmic personnel	*"General medical clinics, it should be the medical officer, you know they are the one who screen these patients for diabetes, so at the same time I think if they have the capability, I think, they should be the screeners." (Institutional administrator, 3ry level)*
		Medical clinic as the suitable place of service delivery in DRS	*"The best unit to start the screening would be the medical unit". (Program planner, national level)*
	Finance	Financing a DRS program	*"It should be from the main health budget. Whatever the country's economic status there are lot of money flowing through the Ministry each year. We do not have proper evidence to convince the decision makers to use this money". (Program planner)*
Suggestions	Screening modality	Fundus photography as a suitable DRS modality	*"Ideal would be something like fundus photography where you send someone to take photographs and send the photographs electronically or soft copies (DVD or CDs). Fundus photography will be a very good idea because given the high patients numbers. photography will probably help in this". (Retinologist, 3ry level)*

Appendix 8

8.1 - Additional file 1 - PRISMA check list

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	3-4
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5-6
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	8
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	8,33

Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7,8,9
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	8,9
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	9
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	10
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	10

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	9
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	9,10
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	10
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	10,11 and additional file 3
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	12 Table 2

Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	13
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	13,14,15
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	12
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	16,17
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	17,18
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	19,20
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	21
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	23

8.2 - Additional file 2 – Table 1 – Study setting, reasons for exclusion and DTA reported in studies excluded from current review

Study Source	Type of Study	Setting	Screening Strategy	Sample Size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
1.Al Sabti, K. et al 2003 (Kuwait)	Cross sectional	Retina clinic	Digital fundus photography (Mydriatic, 30^0 and 60^0)	51	Not a study assessing sensitivity/specificity	Examiners	Dilated slit lamp examination by retina specialist	Kappa = 0.93	Not mentioned
2.Andonegui, J. et al 2008 (Spain)	Interventional	Primary Care	Digital fundus photography	4 primary care	Full article not in English	Primary care physicians	Same images graded by ophthalmologists	Kappa = 0.8 to 0.95	Not mentioned

Study Source	Type of Study	Setting	Screening Strategy	Sample Size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
				physicians					
3.Andonegui, J. et al 2012 (Spain)	Audit	Primary Care	Digital fundus photography (Mydriatic and Non-mydriatic)	2750	An audit. Does not involve a proper reference standard	General practitioners	Same images graded by ophthalmologists	False positive = 55%	False negative = 7%
4.Anonymous 1986	Not relevant	Not relevant	Not relevant	Not relevant	A letter to the editor	Not relevant	Not relevant	Not relevant	Not relevant
5.Anonymous 1988	Not relevant	Not relevant	Not relevant		No such article available	Not relevant	Not relevant	Not relevant	Not relevant
6.Awan, A. M. et al 1974 (Kenya)	Cross sectional	National Hospital	Colour fundus photography (Mydriatic, 5F)	115	Not a study on DRS DTA	Not mentioned	Not mentioned	Not mentioned	Not mentioned
7.Backlund, L. B. et al 1998 (Sweden)	Cross sectional	Primary Care	Film fundus photography (Mydriatic and non-mydriatic, 4F, 45^0)	5490	Not a study on DRS DTA	Registered ophthalmic nurses and a GP	Not relevant	Not relevant	Not relevant
8.Baeza Diaz, M. et al 2004 (Spain)	Cross sectional	Primary Care	Digital fundus photography	188	Full article not in English	Not mentioned	Not mentioned	>75%	>95%
9.Barrie, T. et al 1986	Not relevant	Not relevant	Not relevant	Not relevant	A letter to the editor	Not relevant	Not relevant	Not relevant	Not relevant
10.Benbassat, J. et al 2009	Literature review	Not relevant	Not relevant	Not relevant	A literature review	Not relevant	Not relevant	Not relevant	Not relevant
11.Bragge, P. et al 2011	Meta-analysis	Not relevant	Not relevant		A meta-analysis	Not relevant	Not relevant	Not relevant	Not relevant
12.Burns-Cox, C. J. et al 1985 (UK)	Cross sectional	GP, clinic and in-ward	Ophthalmic optician examination	844	Does not involve digital retinal imaging	Ophthalmic opticians	Ophthalmologist examination or retinal photography	Not mentioned	Not mentioned

Study Source	Type of Study	Setting	Screening Strategy	Sample Size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
13.Buxton, M. J. et al 1991 (UK)	Cross sectional	Medical centres	Polaroid fundus photography (Non-mydriatic, 45^0)	3318	Does not involve digital retinal imaging	Ophthalmologists	ophthalmoscopic examination by ophthalmological clinical assistant	35% - 67%	95% - 98%
14.Bursell, S.E. 2000 (USA)	Cross sectional	Eye care centre	Digital fundus photography (Non-mydriatic, 45^0, 3F, stereoscopic)	54	Digital video imaging. Not relevant to the review question	Two independent readers	7SF ETDRS	59%	80%
15.Carmichael, T. R. et al 2005 (South Africa)	Cross sectional	Diabetic clinic	Film fundus photography (Mydriatic, 60^0, 1F)	1595	Does not involve digital retinal imaging	Endocrinologists	Photographs graded by ophthalmologists	83%	99%
16.Cavallerano, J. D. et al 2005 (USA)	Prospective cohort	Eye care centre	Digital fundus photography (Non-mydriatic, 45^0, 3F, stereoscopic)	52	Not a study on DRS DTA	Certified readers	Dilated retinal examination by retinal Specialist and 7SF ETDRS	Not mentioned	Not mentioned
17.Chalam, K. V. et al 2009 (USA)	Not relevant	Not relevant	Not relevant	Not relevant	A short communication on a new retinal imaging technique	Not relevant	Not relevant	Not relevant	Not relevant
18.Chantelau, E. et al 1989 (Germany)	Cross sectional	Not mentioned	Polaroid fundus photography (Non-mydriatic, 45^0)	473	Does not involve digital retinal imaging	Not mentioned	Not mentioned	82%	100%
19.Christopher, M. et al 2012 (USA)	Pilot study	Tertiary care	Images graded using a tablet computer	1200	Not a study on DRS. Uses images from a database.	Retinal specialists	Same images graded using a desktop PC	84.8%	98.7%
20.Chun, D. W. et al 2007 (USA)	Cross sectional	Primary care	Digital fundus photography (Non-mydriatic, 45^0, 1F)	137	Does not involve onsite grading of images	Ophthalmologist	Dilated retinal examination	60%	100%

Study Source	Type of Study	Setting	Screening Strategy	Sample Size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
							by retina specialist		
21.Clements, C. et al 2002	Not relevant	Not relevant	Not relevant	Not relevant	A letter to the editor	Not relevant	Not relevant	Not relevant	Not relevant
22.de Los Terreros, A. S. et al 2010 (Spain)	Cross sectional	Tertiary care	Digital fundus photography (Non-mydriatic and mydriatic, 30^0 and 45^0, 1F, stereoscopic)	53	Not a study on DRS DTA. A study on diabetic macular oedema	Endocrinologists	Same images graded by a second endocrinologist	Not relevant	Not relevant
23.de Sonnaville, J. J. et al 1996 (Netherlands)	Cross sectional	Primary care	Film fundus photography (Mydriatic, 60^0, 2F, black and white)	323	Does not involve digital retinal imaging	Not mentioned	Dilated fundoscopy	97%	97%
24.Deb-Joardar, N. et al 2005 (France)	Cross sectional	Diabetic care	Digital fundus photography (Non-mydriatic and mydriatic, 45^0, 5F)	150	Not a study on DTA	Endocrinologists	Mydriatic retinal images graded by consensus of ophthalmologists	Not mentioned	Not mentioned
25.Deb-Joardar, N. et al 2007 (France)	Cross sectional	Diabetic care	Digital fundus photography (Mydriatic, 45^0, 3F)	1157	Not a study on DTA	Ophthalmologists	Not relevant	Not relevant	Not relevant
26.Diamond, J. P. et al 1998 (Australia)	Cross sectional	Primary care	Polaroid fundus photography (Non-mydriatic and mydriatic, 45^0)	164	Does not involve digital retinal imaging	Ophthalmologists	Dilated Indirect fundoscopy by ophthalmologist	Kappa = 0.41	Not mentioned
27.Emanuele, N. et al 2009 (USA)	Cross sectional	Diabetic care	Dilated fundus examination	340	Does not involve digital retinal imaging	Ophthalmologists and optometrists	7SF ETDRS	51%	91%

Study Source	Type of Study	Setting	Screening Strategy	Sample Size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
28.Evans, P. M. et al 1997 (UK)	Cross sectional	Primary care	Polaroid fundus photography (mydriatic)	1010	Does not involve digital retinal imaging	Ophthalmologist	Ophthalmoscopy by Ophthalmologist	Not mentioned	Not mentioned
29.Farley, TF et al 2008 (USA)	Cross sectional	Community health centre	Polaroid imaging (Mydriatic, 45, 1F)	1040	Does not involve digital retinal imaging	Family physicians	Same images graded by a retina specialist	85%	94%
30.Feman, S. S. et al 1995 (USA)	Cross sectional	Medical centres	7SF ETDRS	2329	Does not involve digital retinal imaging	Trained non-ophthalmologist research personnel	Same images graded by a different grader or same grader at a later time	Not mentioned	Not mentioned
31.Forrest, R. D. et al 1987 (UK)	Cross sectional	Primary care	Ophthalmoscopy by a trained nurse and diabetologist	282	Does not involve digital retinal imaging	Independent assessor at the Retinal Photography Unit	Film fundus photography (Mydriatic, 5F)	Nurse - 50.0%, Doctor - 51.3%	Nurse -99.2%, Doctor – 98.7%
32.George, L. D. et al 1998 (UK)	Cross sectional	Diabetic and ophthalmology care	Digital fundus photography (Mydriatic, 45^0, 2F)	40	Does not involve a proper reference standard. Not a study assessing sensitivity/specificity	Research physician	Film fundus photography (Mydriatic, 45^0, 2F) graded by a research physician	Kappa = 0.92	Not mentioned
33.Germain, N. et al 2011 (France)	Cross sectional	Diabetic care	Digital fundus photography (Mydriatic, 45^0, 3F)	500	Does not involve a proper reference standard	Endocrinologists and ophthalmology residents	Same images graded by retina specialists	Endocrinologists -89.7%, ophthalmology residents 96.4%	Endocrinologists - NPV = 91.9, ophthalmology residents NPV = 96.7
34.Gonzalez, M. E. et al 1995 (Mexico)	Cross sectional	Diabetic care	7SF ETDRS	15	Does not involve digital retinal imaging	Retinal specialists	Same images graded by certified graders	Kappa = 0.53	Not mentioned

Study Source	Type of Study	Setting	Screening Strategy	Sample Size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
35.Guigui, S. et al 2012	Literature review	Not relevant	Not relevant	Not relevant	A literature review	Not relevant	Not relevant	Not relevant	Not relevant
36.Harding, S. P. et al 1995 (UK)	Cross sectional	Primary care	Film fundus photography (Mydriatic, 45^0, 3F)	395	Does not involve digital retinal imaging	Ophthalmic clinical assistant	Dilated slit lamp examination by a consultant specialist in medical retinal disease	89%	86%
37.Harper, C. A. et al 1998 (Australia)	Cross sectional	Community based	Polaroid fundus photography (Non-mydriatic, 45^0)	1177	Does not involve digital retinal imaging and not a study on DTA	Ophthalmologist	Not relevant	Not relevant	Not relevant
38.Healy, R. et al 2014 (UK)	Cross sectional	DR screening program	Digital fundus photography (Mydriatic, 2F)	1501	Not a proper study on DTA as only screening positives were considered in analysis	Nonmedical graders	Dilated slit lamp examination by ophthalmologist	Not relevant	Not relevant
39.Higgs, E. R. et al 1991 (UK)	Cross sectional	Community based	Film fundus photography (Non-mydriatic)	405	Does not involve digital retinal imaging and not a study on DTA	Ophthalmologist	Not relevant	Not mentioned	Not mentioned
40.Jackson, C. L. et al 2002 (Australia)	Interventional	General Practices	Fundal examination	17	Does not involve digital retinal imaging	General practitioners	Clinical assessment by ophthalmologists	Post-test – all GPs achieved 50-100% sensitivity	Post-test – 77% of GPs achieved 50-100% specificity
41.Jacob, J. et al 1995 (UK)	Cross sectional	Primary care	Direct and indirect ophthalmoscopy and Polaroid fundus photography (Mydriatic and non-mydriatic, 45^0)	1050	Does not involve digital retinal imaging	Trained non-medically qualified technician	Same images graded by ophthalmologist	Not mentioned	Not mentioned

Study Source	Type of Study	Setting	Screening Strategy	Sample Size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
42.Joannou, J. et al 1996 (South Africa)	Cross sectional	Diabetic care	Film fundus photography (Mydriatic, 60^0, 1F)	663	Does not involve digital retinal imaging	Diabetic clinic doctors	Dilated clinical assessment by an ophthalmologist	93%	89%
43.Johansen, M. A. et al 2008 (Norway)	Cross sectional	Diabetic care	Digital fundus photography (Mydriatic, 50^0, 3F, red-free monochrome)	20	Does not involve a proper reference standard	Ophthalmologists	Film fundus photography (Mydriatic, 50^0, 3F, colour) graded by ophthalmologists	Not mentioned	Not mentioned
44.Kalm, H. et al 1989 (Sweden)	Cross sectional	Primary care	Film fundus photography (Mydriatic, 45^0, 2F)	154	Does not involve digital retinal imaging	ophthalmologist	Dilated slit lamp examination by ophthalmologist	R eye = 87%, L eye = 97%	Not mentioned
45.Kernt, M. et al 2012 (Germany)	Cross sectional	Eye care	Digital fundus photography (Non-mydriatic, 200^0, 1F, scanning laser)	141	Does not involve onsite grading of images, not a study assessing sensitivity/specificity	Independent graders	7SF ETDRS and dilated slit lamp examination	7SF – Kappa = 0.79, Slit lamp – Kappa = 0.93	Not mentioned
46.Kinyoun, J. L. et al 1992 (USA)	Cross sectional	Community based	7SF ETDRS	124	Does not involve digital retinal imaging	Retina Specialist (S) or a Trained Grader (G)	Same images graded by a retina specialist or dilated ophthalmoscopy by a retina specialist (O)	O vs S Kappa = 0.68, O vs G Kappa = 0.49, S vs G Kappa = 0.79	Not mentioned

Study Source	Type of Study	Setting	Screening Strategy	Sample Size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
47.Klais, C. M. et al 2004 (New Zealand)	Cross sectional	DR screening centre	Digital fundus photography (Mydriatic, 45^0, 2F)	1946	Not a study on DTA. A study on image quality	Retina specialist	Film fundus photography (Mydriatic, 45^0, 2F)	Not relevant	Not relevant
48.Klein, R. et al 1985 (USA)	Cross sectional	Not mentioned	Film fundus photography (Mydriatic and non-mydriatic, 45^0, 1F)	99	Does not involve digital retinal imaging	Trained graders	Film fundus photography (Mydriatic and non-mydriatic, 30^0, 3F, stereoscopic)	Not mentioned	Not mentioned
49.Larizza, M. F. et al 2013 (Australia)	Cross sectional	Pathology collection centre	Digital fundus photography (Non-mydriatic, 45^0, 2F)	93	Not a study on DTA. A feasibility study	Trained graders	Not relevant	Not relevant	Not relevant
50.Lau, H. C. et al 1995 (Singapore)	Cross sectional	Primary care	Polaroid fundus photography (Mydriatic, 45^0)	13296	Does not involve digital retinal imaging. Not a study on DTA.	Ophthalmologists	Not relevant	Not relevant	Not relevant
51.Lee, V. S. et al 1993 (USA)	Cross sectional	Not mentioned	Film fundus photography (Mydriatic, 45^0, 1F)	410	Does not involve digital retinal imaging	Reading centre	Dilated indirect ophthalmoscopy by retina specialists	Kappa = 0.74	Not mentioned
52.Leese, G. P. et al 2002 (UK)	Cross sectional	Not mentioned	Polaroid fundus photography (Non-mydriatic)	408	Does not involve digital retinal imaging	Diabetologists	Slit lamp examination by ophthalmologists	Kappa = 0.47	Not mentioned
53.Liegl, R. et al 2014 (Germany)	Cross sectional	Eye care	Digital fundus photography (Non-mydriatic, 200^0, 1F, scanning laser)	143 eyes	Does not involve a proper reference standard	Ophthalmologist	Digital fundus photography (Mydriatic, 45^0, 2F, stereoscopic)	Kappa = 0.54	Not mentioned
54.Li, H. K et al 2010 (USA)	Cross sectional	Tertiary level eye clinic	Stereoscopic imaging	85	Inadequate data for DTA calculations	Image readers	7F stereoscopic	90 – 100%	90 – 99%

Study Source	Type of Study	Setting	Screening Strategy	Sample Size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
			(Mydriatic, 35, 7F, 35mm)				mydriatic 35-degree 35 mm colour slides read by readers		
55.Lin, D. Y. et al 1999	Literature review	Not relevant	Not relevant	Not relevant	A review article	Not relevant	Not relevant	Not relevant	Not relevant
56.Lin, D. Y. et al 2002 (USA)	Cross sectional	Diabetic care	Digital fundus photography (Non-mydriatic, 45^0, 1F, monochromatic)	197	Does not involve onsite grading of images	Certified reader	7SF ETDRS and dilated ophthalmoscopy by an ophthalmologist	78%	86%
57.Lim, J.L et al 2000 (USA)	Comparative observational case series	University based retina referral practice	Photography with a digital back (N0n-mydriatic, 3F, 45)	22	Inadequate data for DTA calculations	Retina specialist	3F mydriatic 35mm colour slides read by retina specialist	25 – 100% (Described based on signs)	90 – 100% (Described based on signs)
58.Liu, F. H. et al 1998 (Taiwan)	Cross sectional	Diabetic care	? Film fundus photography (Non-mydriatic, 45^0)	694	Does not involve digital retinal imaging	Endocrinologists and ophthalmologist	Not mentioned	84%	77%
59.Maberley, D. et al 2004 (Canada)	Cross sectional	Eye care	Digital fundus photography (Mydriatic and non-mydriatic, 45^0, 1F)	33	Not a study on DTA. A study on image quality.	Retina specialist	Same images taken by an experienced professional ophthalmic photographer	Not relevant	Not relevant
60.Marks, J. B. et al 1992	Review	Not relevant	Not relevant	Not relevant	A review article	Not relevant	Not relevant	Not relevant	Not relevant
61.Martinez, J. et al 2011 (Costa Rica)	Cross sectional	Eye care	Digital fundus photography (Mydriatic and non-mydriatic, 45^0, 1F)	1327	Not a study on DTA. A feasibility study.	Ophthalmologist	Not relevant	Not relevant	Not relevant

Study Source	Type of Study	Setting	Screening Strategy	Sample Size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
62.Milton, R. C. et al 1977 (USA)	Pilot study	Not mentioned	7SF ETDRS	148 photos of 22 persons	Does not involve digital retinal imaging. Not a study on DTA.	Ophthalmologist, physician and 2 lay readers	Not relevant	Not relevant	Not relevant
63.Mizrachi, Y. et al 2014 (Israel)	Cross sectional	Primary care	Digital fundus photography (Non-mydriatic, 45^0, 2F)	362	Does not involve onsite grading of images ???	Retina specialist	Dilated examination by an ophthalmologist	99.3%	88.3%
64.Mohan, R. et al 1988 (UK)	Cross sectional	Diabetic care	Polaroid fundus photography (Non-mydriatic, 45^0, 1F)	85	Does not involve digital retinal imaging.	Ophthalmologist	Dilated direct ophthalmoscopy by an ophthalmologist	Not mentioned	Not mentioned
65.Mollentze, W. F. et al 1990 (South Africa)	Cross sectional	Diabetic care	Polaroid fundus photography (Mydriatic and non-mydriatic, 45^0, 1F)	86	Does not involve digital retinal imaging.	Ophthalmologist	Dilated direct ophthalmoscopy	Not mentioned	Not mentioned
66.Moller, F. et al 2001 (Denmark)	Cross sectional	DR screening clinic	Film fundus photography (60^0, 1F)	23	Does not involve digital retinal imaging.	Ophthalmologist	7SF ETDRS and fluorescein angiography	88.9%	Not mentioned
67.Moss, S. E. et al 1985 (USA)	Cross sectional	Community based	Direct and indirect ophthalmoscopy	1949	Does not involve digital retinal imaging	Ophthalmologist, optometrist and an ophthalmic technician	7SF ETDRS and 1F red reflex photograph	Kappa = 0.75	Not mentioned
68.Moss, S. E. et al 1989 (USA)	Cross sectional	Community based	Film fundus photography (Mydriatic, 2F, 3F, and 4F)	2694	Does not involve digital retinal imaging	Reading Centre	7SF ETDRS	2F – 87%, 3F – 92%, 4F – 95%	Not mentioned
69.Neubauer, A. S. et al 2008 (Germany)	Randomised	Eye care	Digital 7SF ETDRS using	64	Not a study on DTA for DR screening. A	Reading Centre	Digital 7SF ETDRS using	99%	92%

Study Source	Type of Study	Setting	Screening Strategy	Sample Size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
	controlled trial		Zeiss Visucam PRO NM		study comparing two cameras.		Zeiss FF450plus		
70.O'Hare, J. P. et al 1996 (UK)	Cross sectional	Primary care	Dilated ophthalmoscopy with and without film fundus photography (Mydriatic, 45^0, 1F)	1010	Does not involve digital retinal imaging	General practitioners or opticians	Dilated ophthalmoscopy and same images graded by an ophthalmologist	Without photo – 70%, With photo – 79%	Without photo – 96%, With photo – 99%
71.Okoli, U. et al 2002 (UK)	Retrospective review	Primary care	Indirect ophthalmoscopy and/or fundus photography	2230	Not a study on DTA. Review comparing 3 DR screening models.	General practitioner, orthoptist and optometrists	Not relevant	Not relevant	Not relevant
72.Paton, R. C. et al 1988	Not relevant	Not relevant	Not relevant	Not relevant	A letter to the editor	Not relevant	Not relevant	Not relevant	Not relevant
73.Penman, A. D. et al 1998 (Egypt)	Cross sectional	Community based	Film fundus photography (Mydriatic, 45^0, 1F)	456	Probably does not involve digital retinal imaging (as study was from 1991-94). Not a study assessing sensitivity/specificity	Reading Centre	Indirect ophthalmoscopy	Kappa = 0.33	Not mentioned
74.Perez-de-Arcelus, M. et al 2013	Literature review	Not relevant	Not relevant	Not relevant	A review article	Not relevant	Not relevant	Not relevant	Not relevant
75.Pugh, J. A. et al 1993 (USA)	Cross sectional	Primary care	Film fundus photography (Non-mydriatic 45^0 1F monoscopic, and mydriatic 45^0 3F mono & stereoscopic) and dilated ophthalmoscopy	352	Does not involve digital retinal imaging	Reading centre (RC) & trained internists (TI) for photos, and ophthalmologist (OP) and physician's assistant (PA) for	7SF ETDRS	1F RC – 61%, 1F TI – 54%, 3F RC – 81%, 3F TI – 64%, OP – 33%, PA – 14%	1F RC – 85%, 1F TI – 87%, 3F RC – 96%, 3F TI – 90%, OP – 99%, PA – 99%

Study Source	Type of Study	Setting	Screening Strategy	Sample Size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
						ophthalmoscopy			
76.Rodriguez Garcia, L. C. et al 2013 (Spain)	Prospective longitudinal descriptive	Primary care	Digital fundus photography	In 2009 – 2850, in 2011 - 3357	Full article not in English. Not a study on DTA.	ophthalmologist	Not relevant	Not relevant	Not relevant
77.Rogers, D. et al 1990 (UK)	Cross sectional	Primary care	Polaroid fundus photography (Non-mydriatic, 45^0, 1F)	84	Does not involve digital retinal imaging. Not a study on DTA.	General practitioners	Not relevant	Not relevant	Not relevant
78.Romero, P. et al 2010 (Spain)	Audit	Primary care	Digital fundus photography (Mydriatic, 45^0, 2F)	879	An audit. Does not involve a proper reference standard.	Family physicians	Same images graded by an ophthalmologist	95.2%	98.6%
79.Ruamviboonsuk, P. et al 2005 (Thailand)	Cross sectional	Diabetic care	Digital fundus photography (Non-mydriatic, 45^0, 1F)	150	Does not involve onsite grading of images	Retina specialist	Dilated fundus examination by retina specialist	80%	96%
80.Ruamviboonsuk, P. et al 2006 (Thailand)	Inter-observer reliability study	Various healthcare centres	Digital fundus photography (Mydriatic and non-mydriatic, 45^0, 1F)	400	Does not involve a proper reference standard. A study on inter-observer agreement using images from a database.	Retina specialists (R), ophthalmologists (O), ophthalmic nurses (N) and ophthalmic photographer (P)	Same images graded in consensus by the retina specialists	Median of the 3 values given: R – 93%, O – 86%, N – 89%, P - 86%	Median of the 3 values given: R – 96%, O – 62%, N – 73%, P – 77%
81.Ryder, R. E. et al 1985 (UK)	Cross sectional	Diabetic care	Polaroid fundus photography (Non-mydriatic, 45^0, 1F) and, dilated & un-dilated ophthalmoscopy	227 eyes	Does not involve digital retinal imaging. Not a study on DTA.	Not relevant	Not relevant	Not relevant	Not relevant

Study Source	Type of Study	Setting	Screening Strategy	Sample Size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
82.Saari, J. M. et al 2004 (Finland)	Cross sectional	Eye care	Digital fundus photography (Mydriatic, 20^0 45^0, & 50^0, 2F, colour and 50^0 1F red free)	70	Does not involve onsite grading of images	Ophthalmologists and a Bachelor of Medicine with special training	Dilated fundus examination by an ophthalmologist in combination with digital colour and red free images	20^0 - 6.9%, 45^0 – 88.9%, 50^0 colour – 94.0%, 50^0 red free – 97.7%	20^0 – 50.0%, 45^0 – 100.0%, 50^0 colour – 99.0%, 50^0 red free – 98.9%
83.Schwartz, S. et al 2015 (USA)	Cross sectional	DR screening clinics	Digital fundus photography (Non-mydriatic, 45^0, 1F)	513	Not a study on DTA. An evaluation of a DR screening program.	Retina specialists	Not relevant	Not relevant	Not relevant
84.Silva, P. S. et al 2012 (USA)	Instrument validation study	Eye care	Digital fundus photography (Non-mydriatic, 100^0 and 200^0, 1F, stereoscopic)	103	Does not involve onsite grading of images	Trained optometrist	7SF ETDRS	99%	100%
85.Soto-Pedre, E. et al 2008 (Spain)	Cross sectional	Diabetic care	Digital fundus photography (Non-mydriatic, 45^0, 3F) in the eye with the poorer visual acuity	183	Does not involve a proper reference standard.	Retina specialist	Same images graded in both eyes	Kappa = 0.75	Not mentioned
86.Sridhar, G. R. et al 1993 (India)	Cross sectional	Diabetic care	Film fundus photography (Non-mydriatic, 45^0, 1F)	42	Does not involve digital retinal imaging. Not a study on DTA	Not mentioned	Not relevant	Not relevant	Not relevant
87.Tapp, R. J. et al 2015	Literature review	Not relevant	Not relevant	Not relevant	A review article	Not relevant	Not relevant	Not relevant	Not relevant
88.Taylor, R. et al 1990 (UK)	Cross sectional	Diabetic care	Polaroid fundus photography (Non-mydriatic, 45^0) and dilated ophthalmoscopy	2159	Does not involve digital retinal imaging. Does not involve a proper reference standard.	Photos - consultant physicians, ophthalmosco	Findings by both methods in combination	Photo – 65.0% , Ophthalmoscopy – 77.5%	Photo - 60.3% , Ophthalmoscopy – 39.7%

Study Source	Type of Study	Setting	Screening Strategy	Sample Size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
						py - diabetic clinic doctor			

Study source	Type of Study	Setting	Screening Strategy	Sample size	Reason for Exclusion	Index Test Grader	Reference Standard	DTA Values (Sensitivity)	DTA Values (Specificity)
89.Van de Kar, W. et al 1990 (Netherlands)	Cross sectional	Primary care	Polaroid fundus photography (1F)	62	Does not involve digital retinal imaging. Does not involve a proper reference standard.	General practitioners and hospital physician	Same imaged graded by ophthalmologists	99%	55%
90.Von Wendt, G. et al 2000 (Finland)	Cross sectional	Eye care	Film fundus photography (Mydriatic, 60^0, 1F, colour and red-free black & white)	74	Does not involve digital retinal imaging. Does not involve a proper reference standard.	Ophthalmologists	Film fundus photography (Mydriatic, 60^0, 2F, colour and red-free black & white)	Kappa = 0.84–0.86	Not mentioned
91.Vujesevic, S. et al 2009 (Italy)	Prospective masked comparative case series	Tertiary level diabetic clinic	Mydriatic retinagraphy device ? (3F, 45 degree)	55	Inadequate data for DTA analysis	Retinal specialists	ETDRS 7F 35 mm color slides	99%	100%
91.Wareham, N. et al 1991	Not relevant	Not relevant	Not relevant	Not relevant	An editorial	Not relevant	Not relevant	Not relevant	Not relevant
92.Williams, G. A. et al 2004	Literature review	Not relevant	Not relevant	Not relevant	A review article	Not relevant	Not relevant	Not relevant	Not relevant
93.Williams, R. et al 1986 (UK)	Cross sectional	Diabetic care	Film or polaroid fundus photography (Non-mydriatic, 45^0, 1F)	62	Does not involve digital retinal imaging.	Ophthalmologists	Dilated fundus examination by an ophthalmologist	96%	98%
94.Zafar, A. et al 2008	Systematic Review	Not relevant	Not relevant	Not relevant	A review article	Not relevant	Not relevant	Not relevant	Not relevant

95.Zhang, X. et al 2007	Systematic Review	Not relevant	Not relevant	Not relevant	A review article	Not relevant	Not relevant	Not relevant	Not relevant

8.3 - Additional files 3

Table 1 - Participants' characteristics of the included studies in the current review

Nonmydriatic digital imaging using a single retinal field

Study	Country	Study Setting	Sample Size	Mean (SD) Age in Years	Percentage of Males	Mean (SD) Duration of Diabetes in Years
1.Aptel, F. et al 2008	France	Not mentioned	79	52.4 (Min:16, Max:89)	47.1%	13.6
2.Baeza, M. et al 2009	Spain	Primary care	216	68.5 (10.5)	43.7%	12.8 (8.9)
3.Ding, J. et al 2012	China	Primary care	531	Min:35, Max:84	37.7%	Duration ≤5 in 48.9%
4.Kuo, H. K. et al 2005	Taiwan	Retinal care	100	59 (Min:31, Max:88)	61%	Not mentioned
5.Murgatroyd H. et al 2004	UK	Medical and ophthalmology care	398	Median: 63 (Min:17, Max:88)	57%	9.3 (8.1)
6.Neubauer, A. S. et al 2008	Germany	Ophthalmology care	51	60 (12.1)	Not mentioned	11 (10.1)
7.Phiri, R. et al 2006	Australia	Retinal and ophthalmology care	196	68.8 (10.1)	57%	12.3 (7.7)
Scanlon, P. H. et al 2003 (2nd article)	UK	Primary care	1549	65	Not mentioned	Not mentioned

Nonmydriatic digital imaging using two retinal fields

Study	Country	Study Setting	Sample Size	Mean (SD) Age in Years	Percentage of Males	Mean (SD) Duration of Diabetes in Years
1.Baeza, M. et al 2009	Spain	Primary care	216	68.5 (10.5)	43.7%	12.8 (8.9)
2.Boucher, M. C. et al 2003	Canada	Retinal care	98	59.9 (12.2)	46.9%	Not mentioned
3.Ding, J. et al 2012	China	Primary care	531	Min:35, Max:84	37.7%	Duration ≤5 in 48.9%
4.Lopez-Bastida, J. et al 2007	Spain	Primary care	773	Median: 50.8	48%	9.8 (7.1)

Nonmydriatic digital imaging using >2 fields

Study	Country	Study Setting	Sample Size	Mean (SD) Age in Years	Percentage of Males	Mean (SD) Duration of Diabetes in Years
1.Ahmed, J. et al 2006	USA	Diabetes care	243	60 (11.3)	54.5%	8.9 (6.4)
2.Aptel, F. et al 2008	France	Not mentioned	79	52.4 (Min:16, Max:89)	47.1%	13.6
3.Baeza, M. et al 2009	Spain	Primary care	216	68.5 (10.5)	43.7%	12.8 (8.9)
4.Hansen, A. B. et al 2004	Denmark	Diabetes care	83	47 (11.2)	60.2%	22 (11.8)
5.Hansen, A. B. et al 2004	Denmark	Diabetes care	59	47 (11.2)	60.2%	22 (11.8)
6.Massin, P. et al 2003	France	Retinal care	74	52 (Min:25, Max:74)	62.2%	8 (Min:0, Max:23)

Mydriatic digital imaging using a single retinal field

Study	Country	Study Setting	Sample Size	Mean (SD) Age in Years	Percentage of Males	Mean (SD) Duration of Diabetes in Years
1.Aptel, F. et al 2008	France	Not mentioned	79	52.4 (Min:16, Max:89)	47.1%	13.6
2.Baeza, M. et al 2009	Spain	Primary care	216	68.5 (10.5)	43.7%	12.8 (8.9)
3.Ding, J. et al 2012	China	Primary care	531	Min:35, Max:84	37.7%	Duration ≤5 in 48.9%
4.Herbert, H. M. et al 2003	UK	Diabetic retinopathy screening program	145	Not mentioned	Not mentioned	Not mentioned
5.Ku, J. J. et al 2013	Australia	Primary care	396	48 (13)	36%	Not mentioned
6.Maberley, D. et al 2002	Canada	Diabetic retinopathy screening program	100	54.6 (13.7)	31%	Not mentioned
7.Murgatroyd H. et al 2004	UK	Medical and ophthalmology care	398	Median: 63 (Min:17, Max:88)	57%	9.3 (8.1)

Mydriatic digital imaging using two retinal fields

Study	Country	Study Setting	Sample Size	Mean (SD) Age in Years	Percentage of Males	Mean (SD) Duration of Diabetes in Years
1.Baeza, M. et al 2009	Spain	Primary care	216	68.5 (10.5)	43.7%	12.8 (8.9)
2.Ding, J. et al 2012	China	Primary care	531	Min:35, Max:84	37.7%	Duration ≤5 in 48.9%
3.Olson, J. A. et al 2003	UK	Diabetes care	586	56.5 (Min:15.9, Max: 85.4)	65%	Not mentioned

4.Scanlon, P. H. et al 2003 (1st article)	UK	Retinal care	239	Not mentioned	Not mentioned	Not mentioned
5.Scanlon, P. H. et al 2003 (2nd article)	UK	Primary care	1549	65	Not mentioned	Not mentioned

Mydriatic digital imaging using >2 retinal fields

Study	Country	Study Setting	Sample Size	Mean (SD) Age in Years	Percentage of Males	Mean (SD) Duration of Diabetes in Years
1.Aptel, F. et al 2008	France	Not mentioned	79	52.4 (Min:16, Max:89)	47.1%	13.6
2.Baeza, M. et al 2009	Spain	Primary care	216	68.5 (10.5)	43.7%	12.8 (8.9)
3.Hansen, A. B. et al 2004	Denmark	Diabetes care	83	47 (11.2)	60.2%	22 (11.8)
4.Murgatroyd H. et al 2004	UK	Medical and ophthalmology care	398	Median: 63 (Min:17, Max:88)	57%	9.3 (8.1)

DR grading (using digital imaging) by Non-Ophthalmologist HR

Study	Country	Study Setting	Sample Size	Mean (SD) Age in Years	Percentage of Males	Mean (SD) Duration of Diabetes in Years
1.Kuo, H. K. et al 2005	Taiwan	Retinal care	100	59 (Min:31, Max:88)	61%	Not mentioned
2.Henricsson, M. et al 2000	Sweden	Diabetic retinopathy screening program	283	Median: 59 (Min:10, Max:84)	60%	Not mentioned
3.Sundling, V. et al 2013	Norway	Norwegian Association of	Not mentioned (No of images – DR+ 518, DR- 518)	Not mentioned	Not mentioned	Not mentioned

		Optometry working in private practice				
4.Suansilpong	Thailand	Diabetes care	248	61.1 (10.4) (Min: 30 Max: 83)	31.9%	(60.5% - <10 years)

Table 2 – Participants Characteristics of studies eligible but not included in meta-analysis

Study	Country	Study Setting	Sample Size	Mean (SD) Age in Years	Percentage of Males	Mean (SD) Duration of Diabetes in Years
1.Bhargava, M. et al 2012	Singapore	Poly clinics	397	62.9 (11) DR- 65.5(14.9) DR+	44%	No DR – 7.3 DR present – 9.9
2.Mizrachi, Y. et al 2014	Israel	Community health clinic	362	63.2	46.7%	Not mentioned
3. Perrier, M, et al 2003	Canada	3ry Retinal clinic	98	59.9 (Range 26 – 92)	46.9%	Not mentioned
4.Schiffman, R.M. et al 2005	USA	Retinal Clinic (private sector)	111	57 (14)	41%	19 (12)
5.Tu, K.L. et al 2004	UK	DR screening clinic (Audit)	126	61.2	52.1%	Not mentioned

8.4 - Additional File 4 - DTA of different strategies and ungradable image proportions as reported by study authors

Table 1 – Diagnostic test accuracies of identification of any level of diabetic retinopathy using different field strategies, gradability of the images in each study and method of analysis (primary data)

Study	Imaging Method	Sensitivity (95% CI)	Specificity (95% CI)	Kappa Statistic for Agreement (95%CI)	Grader of Index Test images	Reference Test	Ungradable Percentage of Tests	How ungradable Images were treated by each study authors	If analysis was for number of Eyes or Persons
1.Ahmed, J. et al 2006	Nonmydriatic 3 field	98%	100%	N/a	Retina specialist	Dilated funduscopic examination by ophthalmologists (87%) or optometrists (13%)	35%	Excluded	Eyes
2.Aptel, F. et al 2008	Nonmydriatic 1 field	76.92%	99.16%	0.82	Ophthalmologist	Dilated slit lamp examination by ophthalmologist	11.4%	Test positive	Eyes
	Nonmydriatic 3 field	92.31%	97.48%	0.90			13.3%		
	Mydriatic 1 field	89.74%	98.32%	0.90			2.5%		
	Mydriatic 3 field	97.44%	98.32%	0.95			3.8%		
3.Baeza, M. et al 2009	Nonmydriatic 1 field	68 (60-75)%	98 (96–100)%	0.679	Ophthalmologist	7SF ETDRS	15.3%	Not specified (probably test positive)	Not specified (probably persons)
	Nonmydriatic 2 field	76 (70-83)%	97 (94-95)%	0.771			17.1%		
	Nonmydriatic 3 field	79 (73-86)%	96 (93-99)%	0.771			17.6%		
	Mydriatic 1 field	77 (71-83)%	98 (96-99)%	0.767			1.4%		
	Mydriatic 2 field	86 (81-91)%	95 (92-98)%	0.815			1.6		
	Mydriatic 3 field	85 (80-90)%	94 (91-97)%	0.805			2.1		
4.Boucher, M. C. et al 2003	Nonmydriatic 2 field	95.4 (88.8-98.2)%	86.4 (77.3- 92.2)%	0.821 (0.734 -0.907)	Retina specialist	7SF ETDRS	12.2%	Excluded	Eyes
5.Ding, J. et al 2012	Nonmydriatic 1 field	76.1 (64.4-83.8)%	80.3 (75.3-84.6)%	N/a	Ophthalmologist	Dilated slit lamp examination by ophthalmologist	27.1%	Excluded	Persons
	Nonmydriatic 2 field	90.7 (67.8-84.4)%	90.7 (67.8-84.4)%	N/a			28.2%		

	Mydriatic 1 field	77.7 (80.8-95.5)%	76.5 (71.9-80.7)%	N/a			8.3%		
	Nonmydriatic 1 field	85.6 (77.6-91.5)%	75.6 (70.9-79.9)%	N/a			8.9%		
6.Hansen, A. B. et al 2004	Nonmydriatic 5 field	96.8%	85.7%	0.84 (0.76-0.92)	Retinal Readers	7SF ETDRS	7%	Test positive	Persons
	Mydriatic 5 field	95.2%	95.2%	0.88 (0.80-0.96)			0%		
7.Henricsson, M. et al 2000	Mydriatic 3 field	93%	91%	0.77 (0.76 – 0.92)	Ophthalmic Nurse	Same images by Ophthalmologist	10%	Excluded	Persons
8.Herbert, H. M. et al 2003	Nonmydriatic (and mydriatic) 1 field	38.2 (27.6-50.1)%	95.5 (91.8- 97.5)%	0.40 (0.27-0.53)	Retina specialist	Dilated slit lamp examination by retina specialist	4%	Excluded	Eyes
9.Ku, J. J. et al 2013	Mydriatic 1 field	74.0 (67.0–80.0)%	92.0 (90.0 – 94.0)%	0.67 (0.60 – 0.74)	Ophthalmologist	Dilated slit lamp examination by ophthalmologist	10.8%	Excluded	Eyes
10.Kuo, H. K. et al 2005	Nonmydriatic 1 field	53.8 (43.7-63.6)%	89.0 (80.9-93.9)%	0.43 (0.30- 0.55)	Retina specialist	Dilated slit lamp examination by ophthalmologist	8%	Excluded	Eyes
11.Lopez-Bastida, J. et al 2007	Nonmydriatic 2 field	92.0 (90.0-94.0)%	96.0 (95.0-98.0)%	0.89	Retina specialist	Dilated slit lamp examination by retina specialist	7.2%	Included after making gradable with mydriasis	Persons
12.Maberley, D. et al 2002	Mydriatic (and nonmydriatic) 1 field	84.4 (73.4-95.3)%	79.2 (69.2-89.2)%	0.62 (0.51- 0.73)	Retina specialist	Dilated slit lamp examination by retina specialist	0%	Not relevant	Eyes
13.Massin, P. et al 2003	Nonmydriatic 5 field	92.0 (86.0- 98.0)%	88.0 (81- 95)%	N/a	Retina specialist	7SF ETDRS	11%	Test positive	Persons
14.Murgatroyd H et al 2003	Nonmydriatic 1 field	83.0 (78.0 – 88.0)%	91.0 (88.0 – 94.0)%	N/a	Retinal readers	Dilated slit lamp examination by ophthalmologist	26.3%	Excluded	Eyes
	Mydriatic 1 field	86.0 (82.0-90.0)%	91.0 (89.0-94.0)%	N/a			5.5%		
	Mydriatic 3 field	90.0 (86.0-93.0)%	90.0 (88.0-93.0)%	N/a			5.3%		
15.Neubauer, A. S. et al 2008	Nonmydriatic 1 field	94.0%	100.0%	0.68	Retina specialist	Dilated slit lamp examination by retina specialist	9.8%	Excluded	Eyes
16.Olson, J. A. et al 2003	Mydriatic 1 field	80.0 (74.0- 86.0)%	88.0 (84.0- 91.0)%	0.65 (0.58- 0.72)	Trained research registrar	Dilated slit lamp examination by ophthalmologist/ registrar	3.5%	Excluded	Persons
	Mydriatic 2 field	83.0 (77.0- 89.0)%	79.0 (75.0- 83.0)%	0.56 (0.49- 0.63)			4.4%		
17.Phiri, R. et al 2006	Nonmydriatic 1 field	86.2 (65.8- 95.3)%	71.2 (58.1-81.1)%	0.57 (0.48-0.66)	Retina specialist or	7SF ETDRS	Not given separately for digital images	Excluded	Eyes

					Ophthalmologist				
18.Scanlon, P. H. et al 2003 (1st article)	Mydriatic 2 field	80.2 (75.2-85.2)%	96.2 (93.2-99.2)%	0.73	Specialist Registrar in Ophthalmology	7SF ETDRS	1.3%	Excluded	Eyes
		82.8 (78.0-87.6)%	92.9 (89.6-96.2)%	0.76		Dilated slit lamp examination by ophthalmologist			
19.Scanlon, P. H. et al 2003 (2nd article)	Nonmydriatic 1 field	86.0 (80.9-91.1)%	76.7 (74.5-78.9)%	N/a	Specialist Registrar in Ophthalmology	Dilated slit lamp examination by ophthalmologist	20.8%	Test positive	Persons
	Mydriatic 2 field	87.8 (83.0- 92.6)%	86.1 (84.2- 87.8)%	N/a			5.6%		
20.Sundling, V. et al 2013	Mydriatic 1 field	67 (62 – 72)%	84 (80 – 89)%	N/a	Optometrists	Two (100% agreement) ophthalmologists	N/a	Gradable images selected for inclusion	Images
21.Suansilpong, A. et al 2008	Nonmydriatic 1 field	65.6 (60.9 – 70.2)%	84.9 (81.4 – 88.4)%	0.48	Endocrinologist	Mydriatic direct and indirect ophthalmoscopy by ophthalmologist	18.8	Excluded	Eyes

8.5 - Additional File 5 - DTA following adjustments in relevant to exclusion of ungradable proportions in the current review

Table 1 – Percentages of ungradable images in each strategy, how it was treated in DTA calculations and adjusted DTA based on proportions of ungradable images reported

Study	Imaging strategy (No: of fields and pupillary status)	Sensitivity (95% CI)	Specificity (95% CI)	Kappa (inter grader agreement) (95%CI)	Grader of Index Test images	Reference Test	Ungradable Percentage of Tests	How ungradable Images were treated by review authors	If analysis was for number of Eyes or Persons
Ahmed, J. et al 2006	Nonmydriatic 3 field	85.71% (73.33-92.90)%	86.64% (81.99-90.24)%	0.587 (0.478-0.696)	Retina specialist	Dilated funduscopic examination by ophthalmologists (87%) or optometrists (13%)	35%	Excluded	Eyes
Aptel, F. et al 2008	Nonmydriatic 1 field	76.92%	99.16%	0.82	Ophthalmologist	Dilated slit lamp examination by ophthalmologist	11.4%	Test positive *(unable to calculate values excluding ungradables*	Eyes
	Nonmydriatic 3 field	92.31%	97.48%	0.90			13.3%		
	Mydriatic 1 field	89.74%	98.32%	0.90			2.5%		
	Mydriatic 3 field	97.44%	98.32%	0.95			3.8%		

								with the given data)	
Baeza, M. et al 2009	Nonmydriatic 1 field	68 (60-75)%	98 (96–100)%	0.679	Ophthalmologist	7SF ETDRS	15.3%	Not specified *(probably test positive) (unable to calculate values excluding ungradables with the given data)*	Not specified (probably persons)
	Nonmydriatic 2 field	76% (70-83)%	97 (94-95)%	0.771			17.1%		
	Nonmydriatic 3 field	79 % (73-86)%	96 (93-99)%	0.771			17.6%		
	Mydriatic 1 field	77% (71-83)%	98 (96-99)%	0.767			1.4%		
	Mydriatic 2 field	86% (81-91)%	95 (92-98)%	0.815			1.6		
	Mydriatic 3 field	85% (80-90)%	94 (91-97)%	0.805			2.1		
Boucher, M. C. et al 2003	Nonmydriatic 2 field	95.4% (88.8-98.2)%	86.4% (77.3- 92.2)%	0.821 (0.734 - 0.907)	Retina specialist	7SF ETDRS	12.2%	Excluded	Eyes
Ding, J. et al 2012	Nonmydriatic 1 field	76.1% (64.4-83.8)%	80.3% (75.3-84.6)%	-	Ophthalmologist	Dilated slit lamp examination by ophthalmologist	27.1%	Excluded	Persons
	Nonmydriatic 2 field	90.7% (67.8-84.4)%	90.7% (67.8-84.4)%	-			28.2%		
	Mydriatic 1 field	77.7% (80.8-95.5)%	76.5% (71.9-80.7)%	-			8.3%		
	Nonmydriatic 1 field	85.6% (77.6-91.5)%	75.6% (70.9-79.9)%	-			8.9%		
Hansen, A. B. et al 2004	Nonmydriatic 5 field	92.50% (86.36-96.00)%	100.00% (89.85-100.00)%	0.84 (0.75-0.94)	Retinal Readers	7SF ETDRS	7%	Excluded	Eyes
	Mydriatic 5 field	93.80% (88.24-96.82)%	100.00 %(90.36-100.00)%	0.87 (0.78-0.96)			0%		
Herbert, H. M. et al 2003	Nonmydriatic (and mydriatic) 1 field	38.2% (27.6-50.1)%	95.5% (91.8-97.5)%	0.40 (0.27-0.53)	Retina specialist	Dilated slit lamp examination by retina specialist	4%	Excluded	Eyes
Ku, J. J. et al 2013	Mydriatic 1 field	74.0% (67.0–80.0)%	92.0% (90.0–94.0)%	0.67 (0.60-0.74)	Ophthalmologist	Dilated slit lamp examination by ophthalmologist	10.8%	Excluded	Eyes
Kuo, H. K. et al 2005	Nonmydriatic 1 field	53.8% (43.7-63.6)%	89.0% (80.9-93.9)%	0.43 (0.30- 0.55)	Retina specialist	Dilated slit lamp examination by ophthalmologist	8%	Excluded	Eyes
Lopez-Bastida, J. et al 2007	Nonmydriatic 2 field	92.0% (90.0-94.0)%	96.0% (95.0-98.0)%	0.89	Retina specialist	Dilated slit lamp examination by retina specialist	7.2%	Excluded *(*Included after making gradable with mydriasis)*	Persons

Maberley, D. et al 2002	Mydriatic (and nonmydriatic) 1 field	84.4% (73.4-95.3)%	79.2% (69.2-89.2)%	0.62 (0.51- 0.73)	Retina specialist	Dilated slit lamp examination by retina specialist	0%	Not relevant	Eyes
Massin, P. et al 2003	Nonmydriatic 5 field	80.85% (67.46-89.58)%	86.59% (77.55-92.34)%	0.67 (0.53-0.80)	Retina specialist	7SF ETDRS	11%	Excluded	Eyes
Murgatroyd H et al 2003	Nonmydriatic 1 field	83.0% (78.0 - 88.0)%	91.0% (88.0 - 94.0)%	-	Retinal readers	Dilated slit lamp examination by ophthalmologist	26.3%	Excluded	Eyes
	Mydriatic 1 field	86.0% (82.0-90.0)%	91.0% (89.0-94.0)%	-			5.5%		
	Mydriatic 3 field	90.0% (86.0-93.0)%	90.0% (88.0-93.0)%	-			5.3%		
Neubauer, A. S. et al 2008	Nonmydriatic 1 field	77.78% (45.26-93.68)%	94.59% (82.30-98.50)%	0.72 (0.47-0.98)	Retina specialist	Dilated slit lamp examination by retina specialist	9.8%	Excluded	Eyes
Olson, J. A. et al 2003	Mydriatic 1 field	80.0% (74.0-86.0)%	88.0% (84.0-91.0)%	0.65 (0.58- 0.72)	Trained research registrar	Dilated slit lamp examination by ophthalmologist/ registrar	3.5%	Excluded	Persons
	Mydriatic 2 field	83.0% (77.0-89.0)%	79.0% (75.0-83.0)%	0.56 (0.49- 0.63)			4.4%		
Phiri, R. et al 2006	Nonmydriatic 1 field	86.2% (65.8-95.3)%	71.2% (58.1-81.1)%	0.57 (0.48-0.66)	Retina specialist or Ophthalmologist	7SF ETDRS	Not given separately for digital images	Excluded	Eyes
Scanlon, P. H. et al 2003 (1st article)	Mydriatic 2 field	80.2% (75.2-85.2)%	96.2% (93.2-99.2)%	0.73	Specialist Registrar in Ophthalmology	7SF ETDRS	1.3%	Excluded	Eyes
		82.8% (78.0-87.6)%	92.9% (89.6-96.2)%	0.76		Dilated slit lamp examination by ophthalmologist			
Scanlon, P. H. et al 2003 (2nd article)	Nonmydriatic 1 field	77.84% (73.21-81.87)%	80.67% (77.91-83.16)%	0.54 (0.49-0.59)	Specialist Registrar in Ophthalmology	Dilated slit lamp examination by ophthalmologist	20.8%	Excluded	Persons
	Mydriatic 2 field	86.88% (83.41-89.71)%	67.48% (64.55-70.29)%	0.46 (0.42-0.50)			5.6%		

8.6 - Additional File 6 - Forest plots of DTA variation by type of reference standard and by the level of service delivery (by clinic settings)

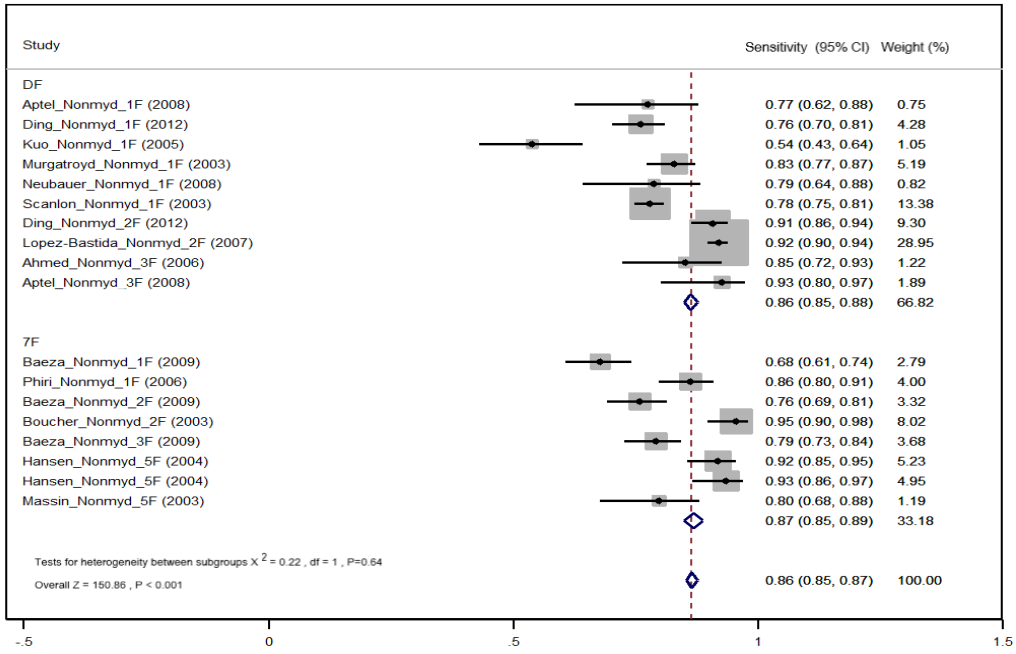


Figure 1. Forest plot of summary estimates of sensitivity of non-mydriatic imaging using different reference standards (7F – 7 field ETDRS imaging, DF – mydriatic bio-microscopy/ophthalmoscopy)

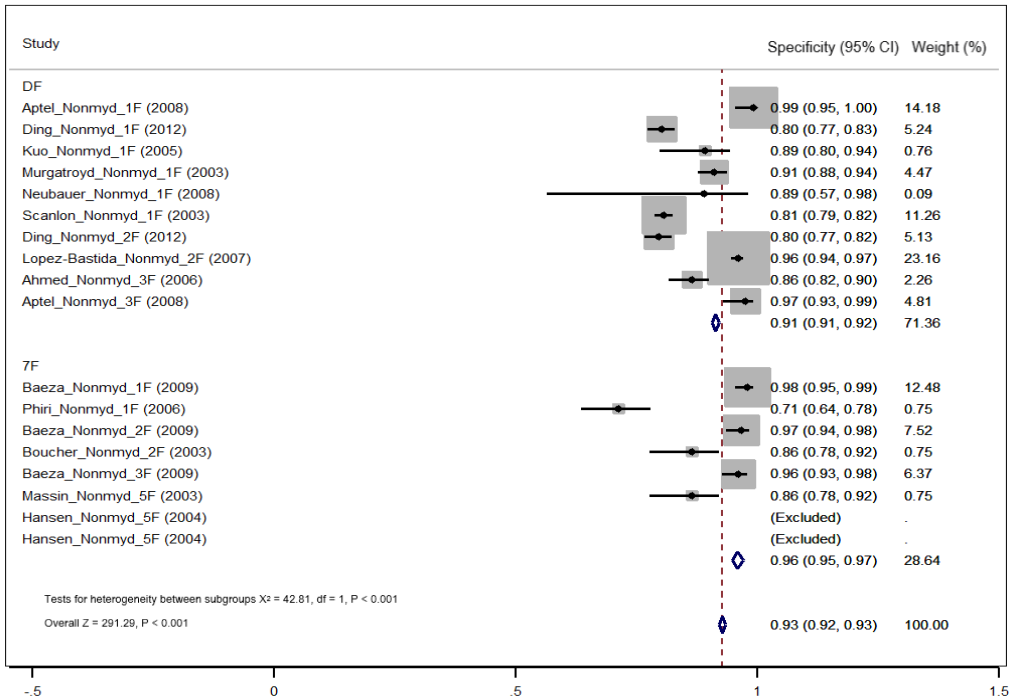


Figure 2. Forest plot of summary estimates of specificity of non-mydriatic imaging using different reference standards (7F – 7 field ETDRS imaging, DF – mydriatic bio-microscopy/ophthalmoscopy)

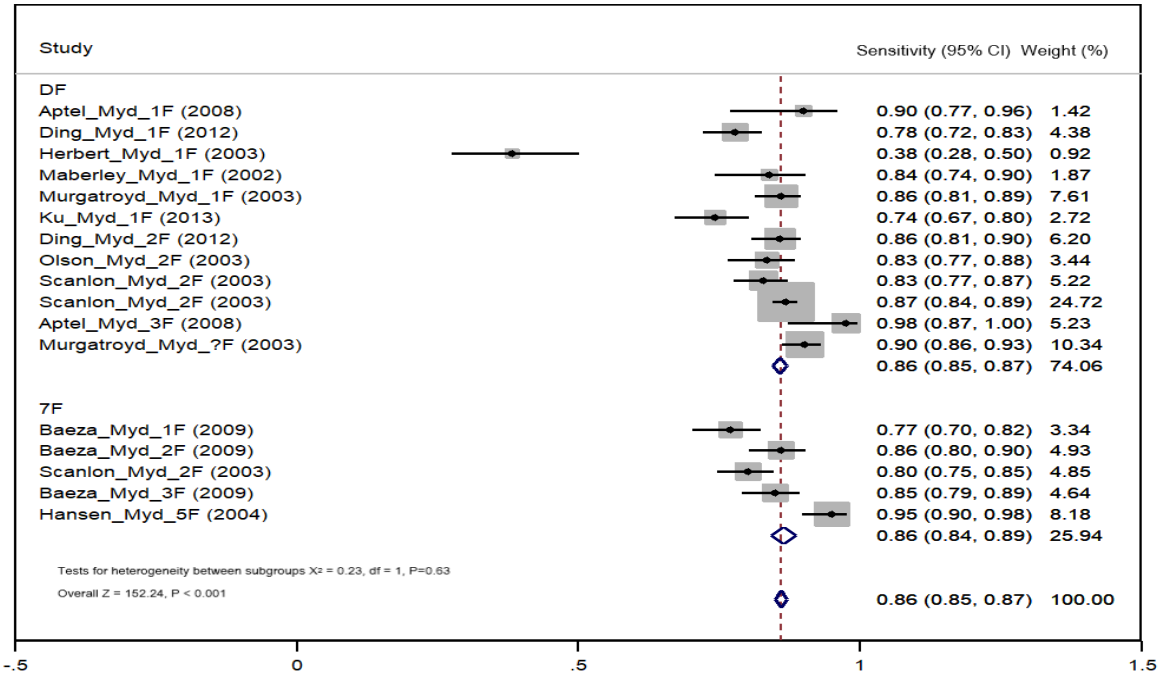


Figure 3. Forest plot of summary estimates of sensitivity of mydriatic imaging using different reference standards (7F – 7 field ETDRS imaging, DF – mydriatic bio-microscopy/ophthalmoscopy)

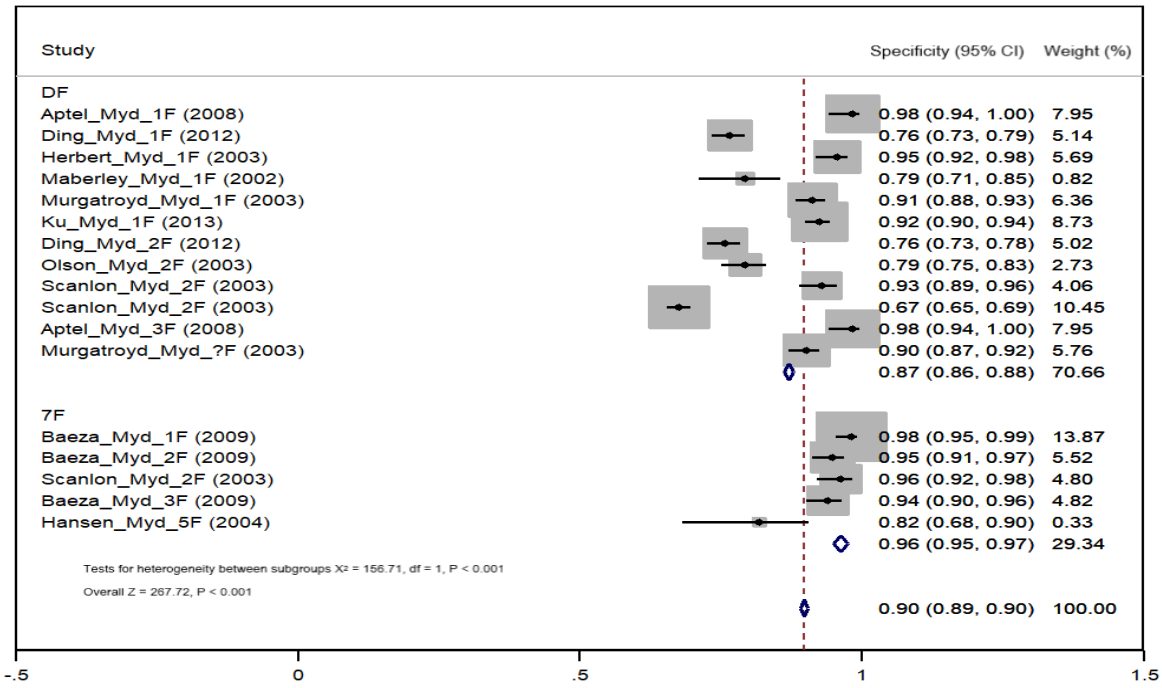


Figure 4. Forest plot of summary estimates of specificity of mydriatic imaging using different reference standards (7F – 7 field ETDRS imaging, DF – mydriatic bio-microscopy/ophthalmoscopy)

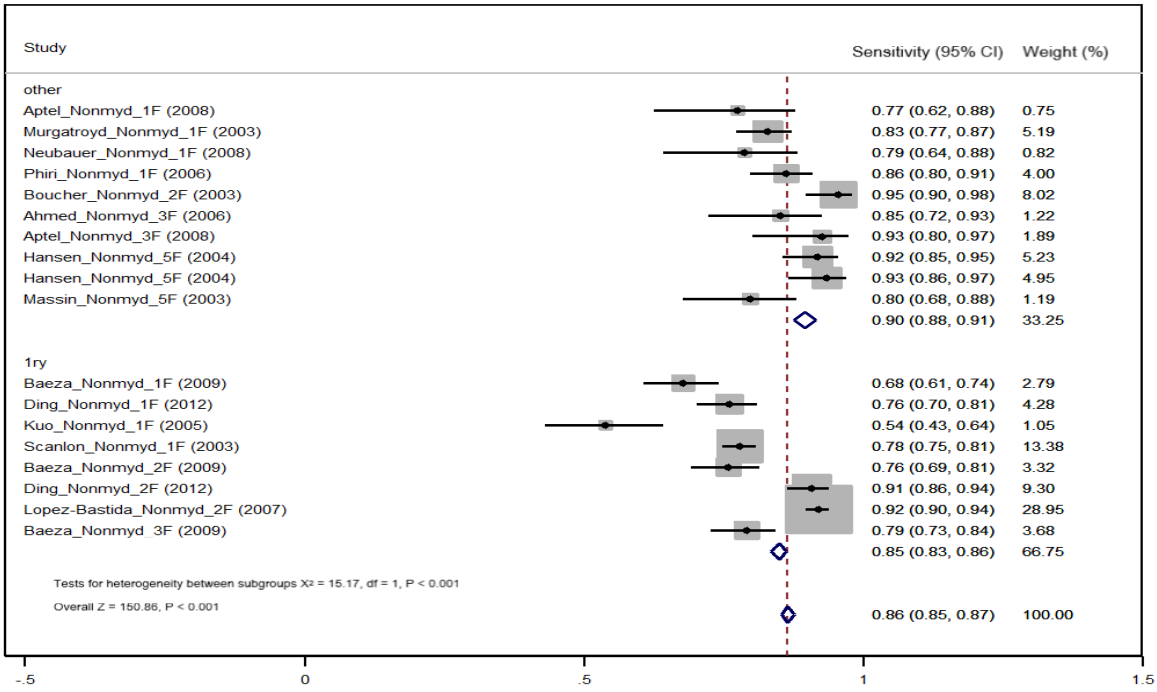


Figure 5. Forest plot of summary estimates of sensitivity of non-mydriatic imaging in different settings (Primary – primary level of service delivery, Other - levels other than primary)

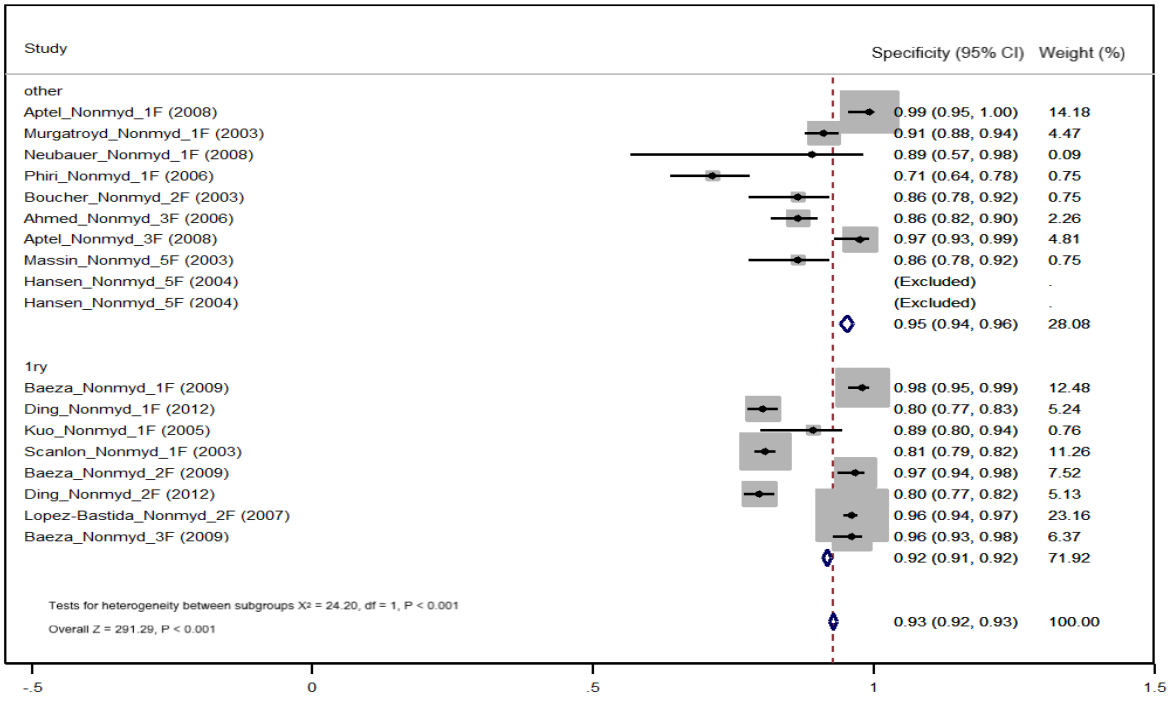


Figure 6. Forest plot of summary estimates of specificity of non-mydriatic imaging in different settings (Primary – primary level of service delivery, Other – levels other than primary)

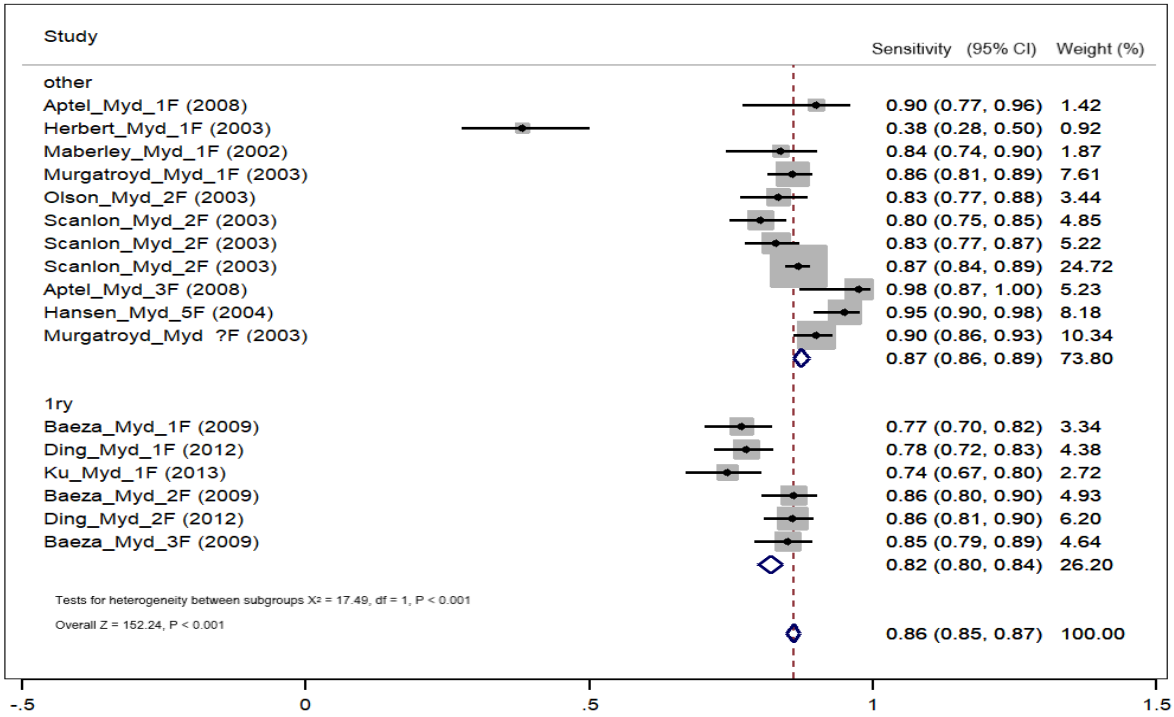


Figure 7. Forest plot of summary estimates of sensitivity of mydriatic imaging in different settings (Primary – primary level of service delivery, Other – levels other than primary)

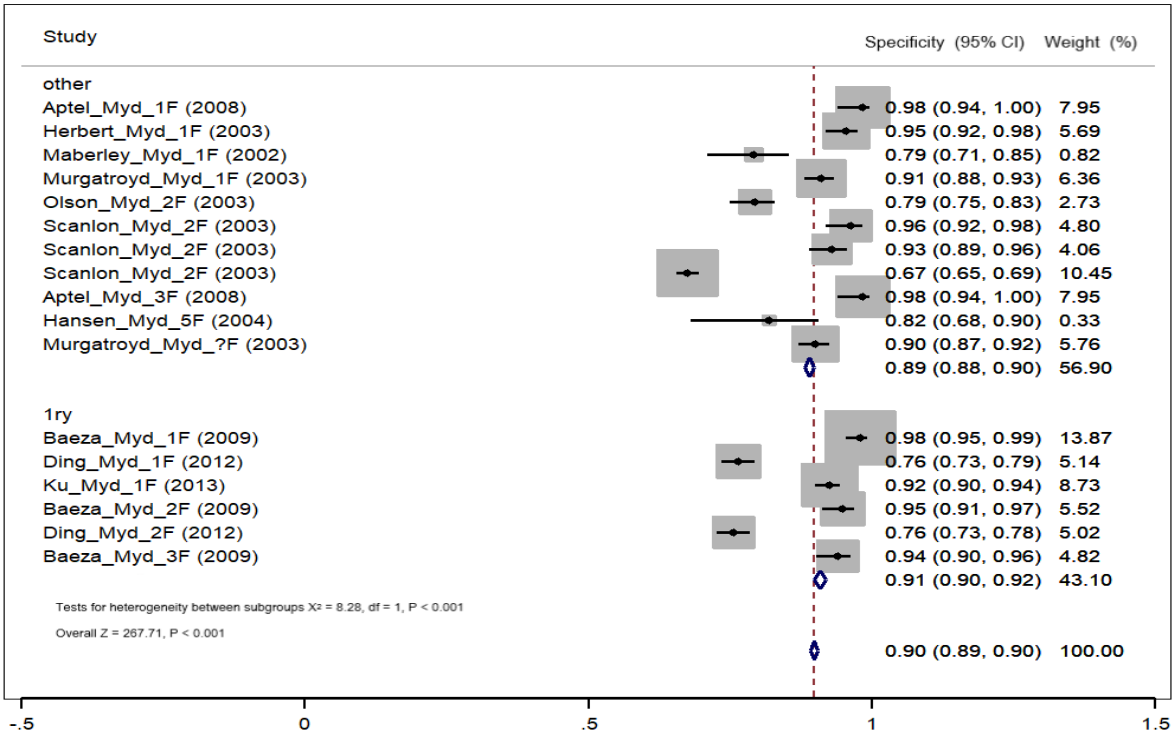


Figure 8. Forest plot of summary estimates of specificity of mydriatic imaging in different settings (Primary – primary level of service delivery, Other – levels other than primary)

8.7 - Additional file 7 – Forest plots of DTA by different index test human resources

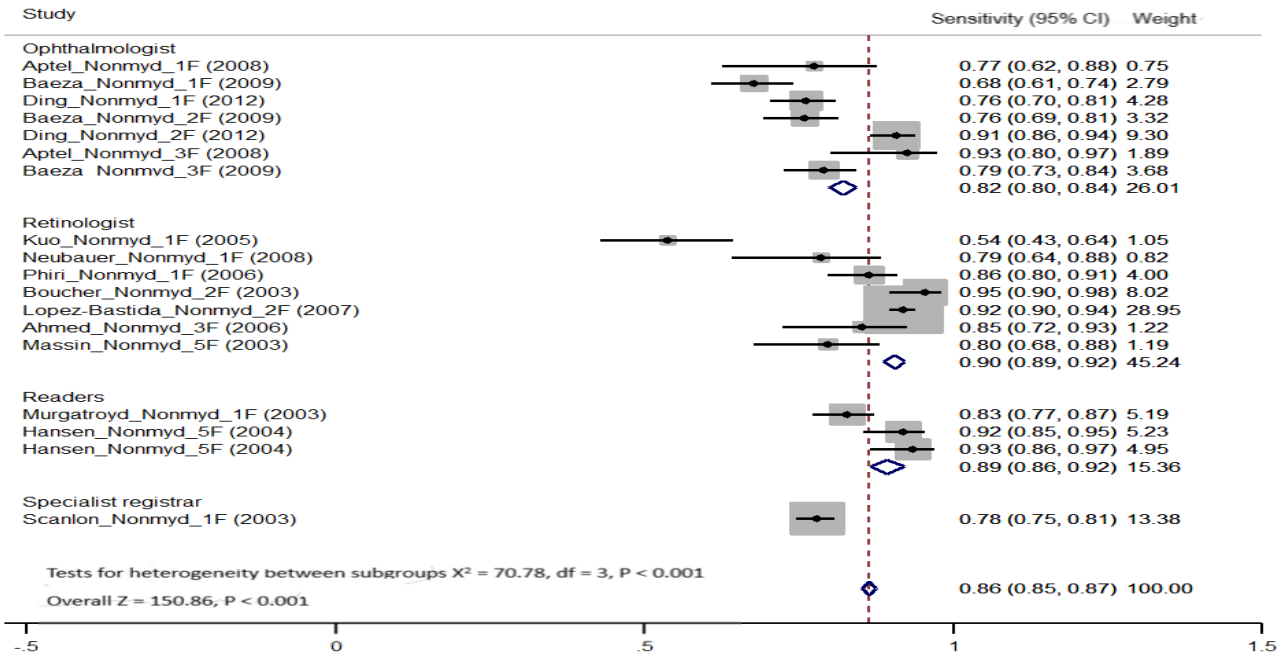


Figure 1. Forest plot of summary estimates of sensitivity of non-mydriatic imaging by different index test graders

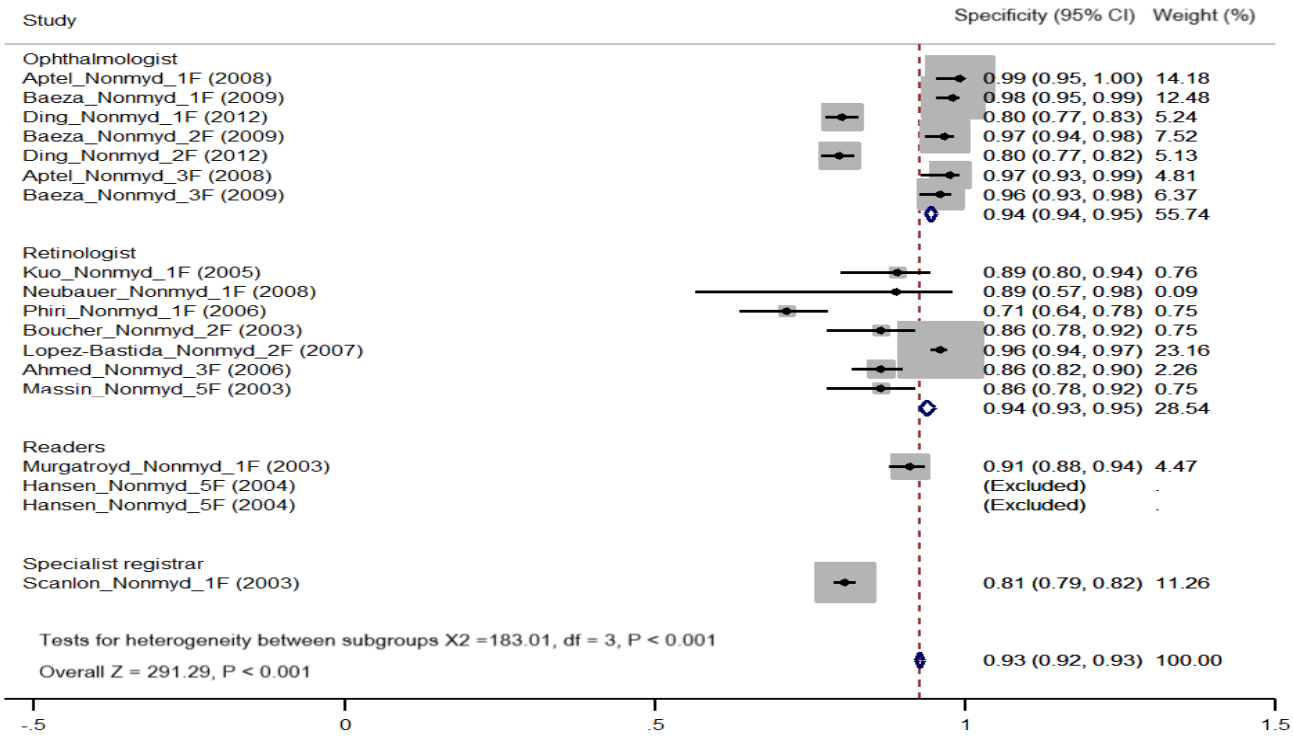


Figure 2. Forest plot of summary estimates of specificity of non-mydriatic imaging by different index test graders

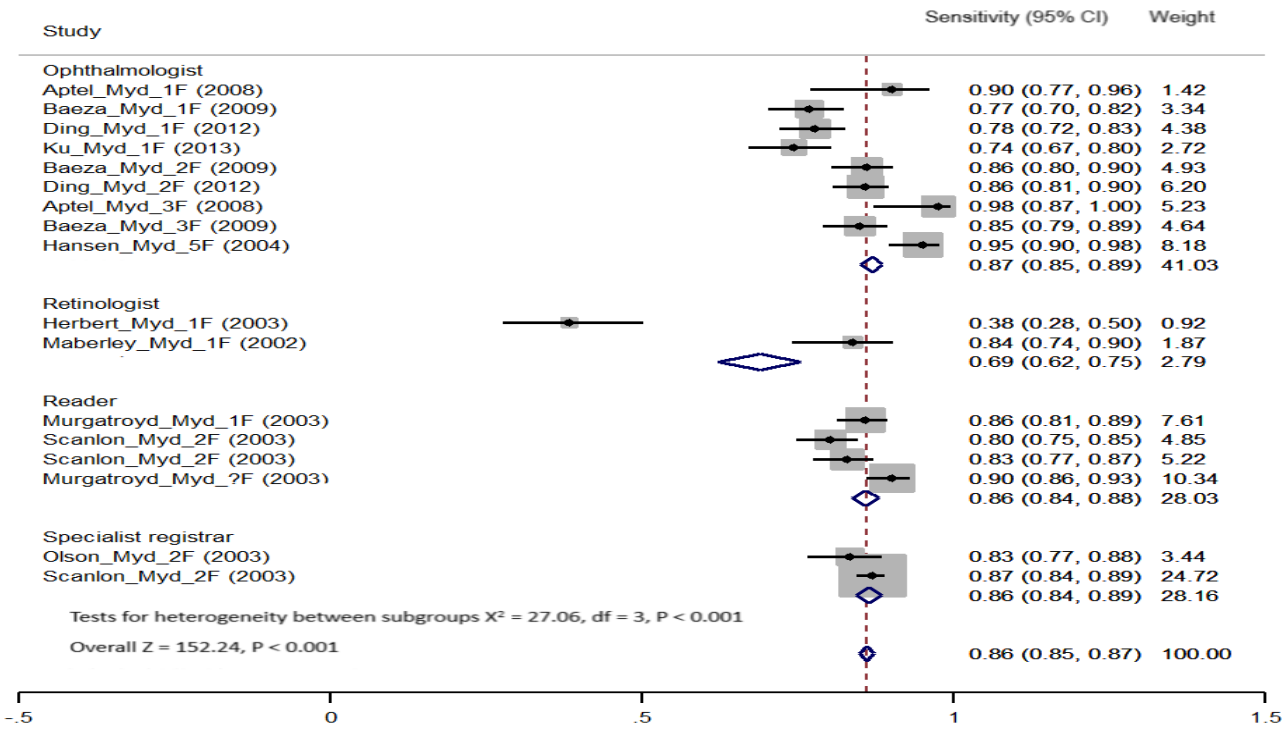


Figure 3. Forest plot of summary estimates of sensitivity of mydriatic imaging by different index test graders

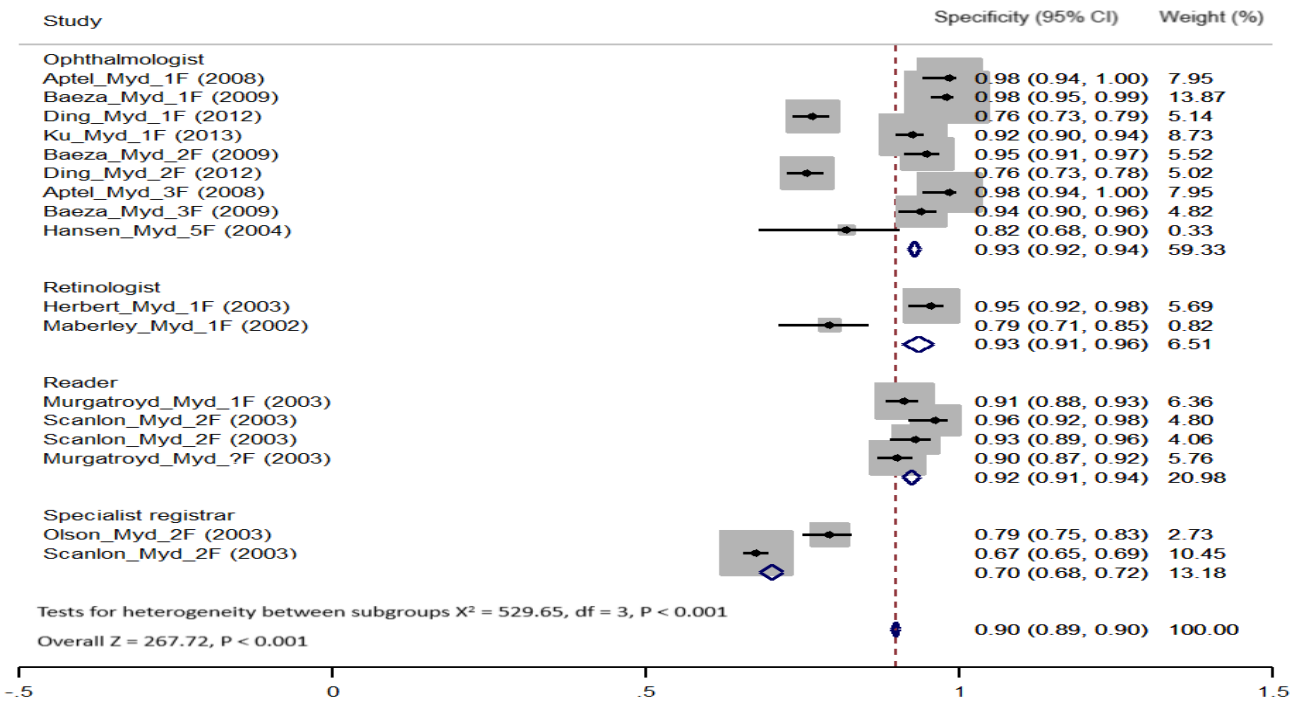


Figure 4. Forest plot of summary estimates of sensitivity of mydriatic imaging by different index test graders

8.8 - Additional file 8 – Forest plots of sub-analyses – DTA using same participant undergoing imaging before and after pupil dilatation

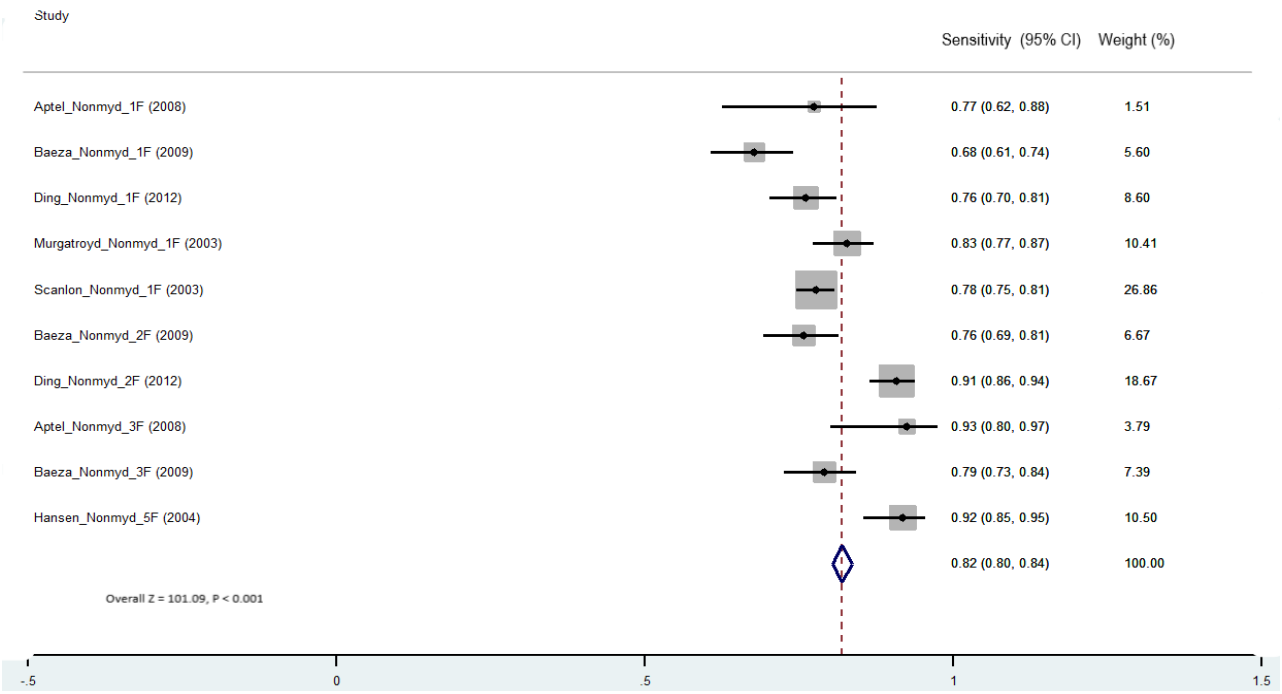


Figure 1. Forest plot of summary estimates of sensitivity of non-mydriatic imaging using same participant undergoing imaging before and after pupil dilatation

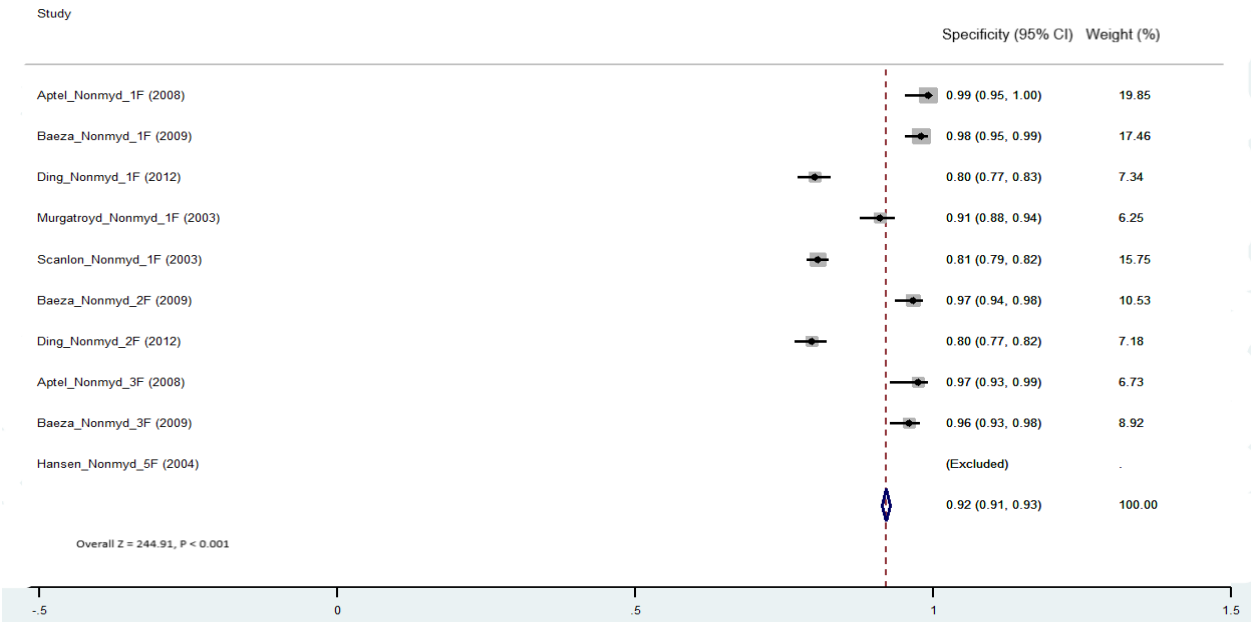


Figure 2. Forest plot of summary estimates of specificity of non-mydriatic imaging using same participant undergoing imaging before and after pupil dilatation

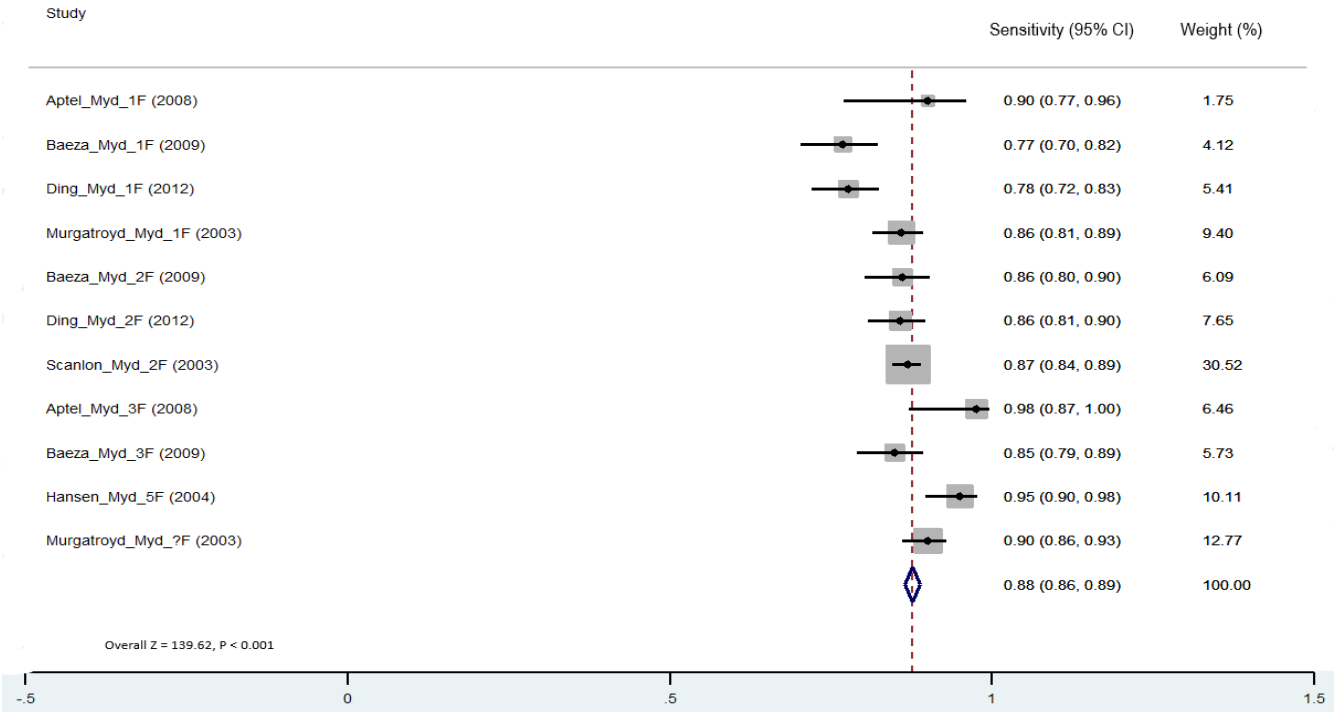


Figure 3. Forest plot of summary estimates of sensitivity of mydriatic imaging using same participant undergoing imaging before and after pupil dilatation

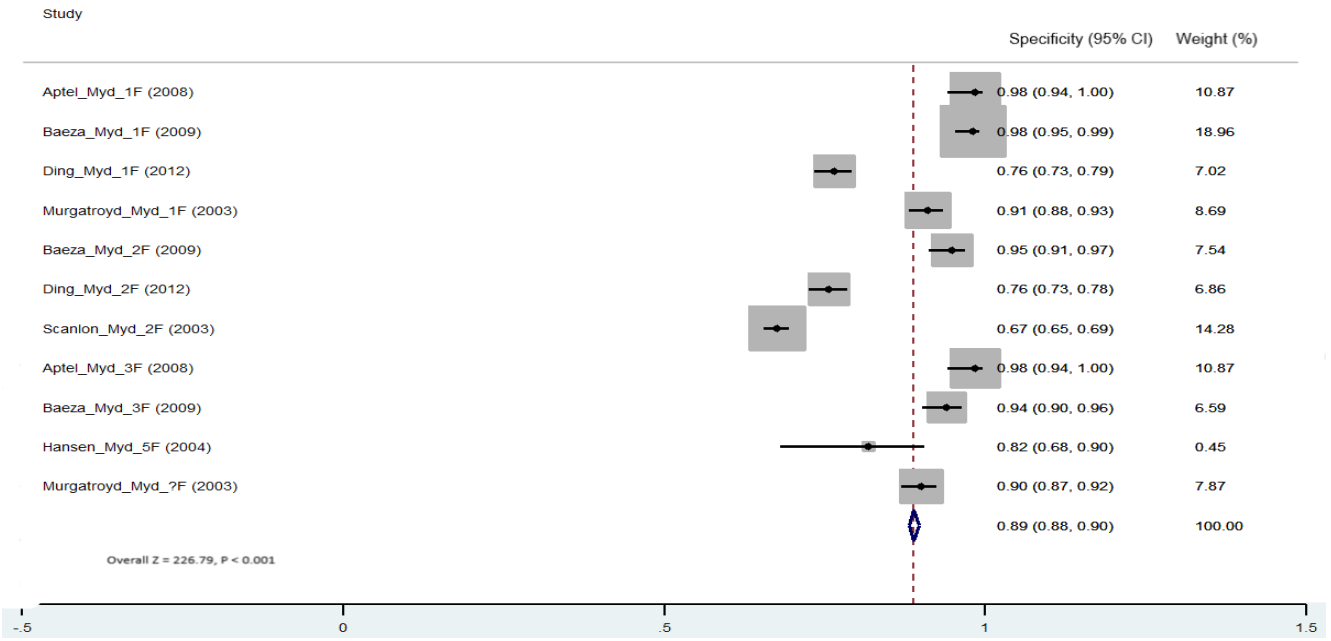


Figure 4. Forest plot of summary estimates of specificity of mydriatic imaging using same participant undergoing imaging before and after pupil dilatation

8.9 - Additional file 9 - DTA parameters by pupil status and field strategy using HSROC curves

Table 1. DTA parameters by pupil status and field strategy using HSROC curves

	Nonmydriatic imaging (1F)	Nonmydriatic imaging (2F)	Nonmydriatic imaging (>2F)	Mydriatic imaging (1F)	Mydriatic imaging (2F)	Mydriatic imaging (>2F)
Diagnostic odds ratio (DOR) (SE) (95% CI)	30.61 (11.7) (14.4-64.7)	103.46 (40.6) (47.8-223.5)	182.43 (145.2) (38.3-868.5)	43.4 (19.7) (17.8-105.9)	38.1 (13.2) (19.3-75.1)	140 (76.1) (48.2-406.7)
Sensitivity (SE) (95% CI)	75.8% (3.1) (69.1-81.4)	89.9% (3.0) (82.1-94.5)	87.0% (2.8) (80.2-91.7)	77.1% (5.1) (65.6-85.6)	84.3% (1.1) (81.9-86.5)	91.5% (2.6) (84.7-95.4)
Specificity (SE) (95% CI)	90.7% (3.4%) (81.3-95.6)	92% (3.0) (82.1-94.5)	96.4% (2.2) (88.4-98.9)	92.7% (2.6) (85.7-96.4)	87.5% (4.2) (76.5-93.8)	92.8% (2.6) (85.5-96.5)
LR+ (positive likelihood ratio)	8.2 (2.9) (4.0-16.5)	11.2 (4.4) (5.1-24.5)	24.5 (15.6) (7.0-85.8)	10.6 (3.8) (5.3-21.5)	6.7 (2.2) (3.5-13.1)	12.7 (4.7) (6.1-26.4)
LR- (negative likelihood ratio)	0.26 (0.03) (0.2-0.3)	0.10 (0.03) (0.06-0.19)	0.13 (0.03) (0.08-0.21)	0.24 (0.05) (0.15-0.38)	0.17 (0.01) (0.15-0.19)	0.09 (0.02) (0.04-0.16)
1/LR- (inverse of negative likelihood ratio)	3.7 (0.45) (2.9-4.7)	9.1 (2.6) (5.2-16.1)	7.4 (1.7) (4.6-11.7)	4.05 (0.90) (2.6-6.2)	5.6 (0.32) (5.0-6.2)	11.0 (3.4) (5.9-20.4)

Appendix 9

9.1 - Additional File 1.

Figure 1. Evaluation of image quality - levels of gradability based on the proportion of the image which can be graded

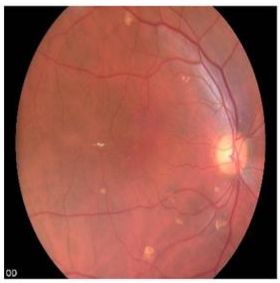
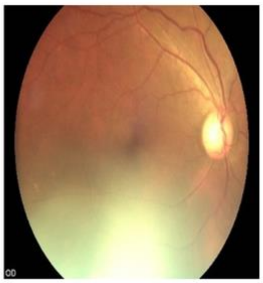
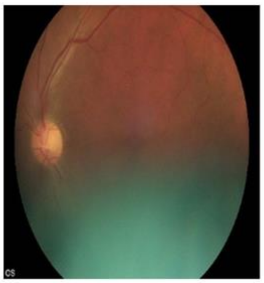
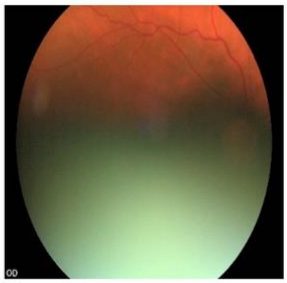
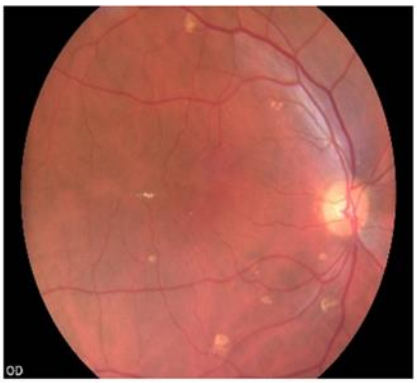
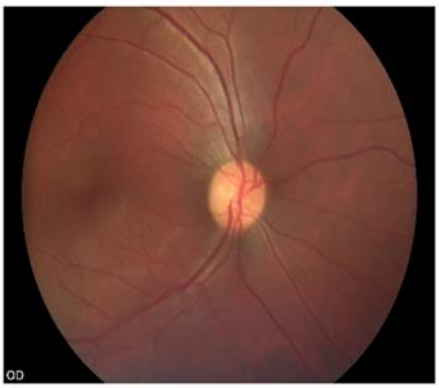
Gradable			Ungradable
100% Gradable	75% Gradable	50% Gradable	<50% Visible
			

Figure 2. Two retinal images captured

Field 1. Centered on the macula	Field 2. Centered on the optic disc
	

Additional File 1. DR Classification system

Table 1. Adapted diabetic retinopathy classification for the validation study

Signs	No DR (R0)	Mild BDR[d] / NPDR[e] (R1)	Moderate BDR / NPDR (R2)	Severe NPDR (R3)	Proliferative DR (PDR[f]) (R4)
Microaneurysms	No	Few	Multiple	Multiple	Present
Hard Exudates [a]	No	Few	Multiple	Multiple	Present
Cotton wool spots	No	Occasional	Multiple	Multiple	Present
Intra retinal haemorrhage [a]	No	Few	>20 in 1-3 quadrants	>20 in 4 quadrants	Present
Venous beading	No	Occasional	Present in 1-2 quadrants	Present in >2 quadrants	Present
IRMA [b]	No	No	Present ~1 quadrant	Prominent >1 quadrant	Present
NVD [c]	No	No	No	No	Present
NVE [c]	No	No	No	No	Present
Vitreous / pre-retinal haemorrhage	No	No	No	No	Present - advanced PDR
Traction	No	No	No	No	Present - advanced PDR
Fibrosis	No	No	No	No	Present - advanced PDR

[a] Not within the definition of maculopathy

[b] Intra retinal microvascular abnormalities

[c] Neo-vascularisations over the disc / elsewhere

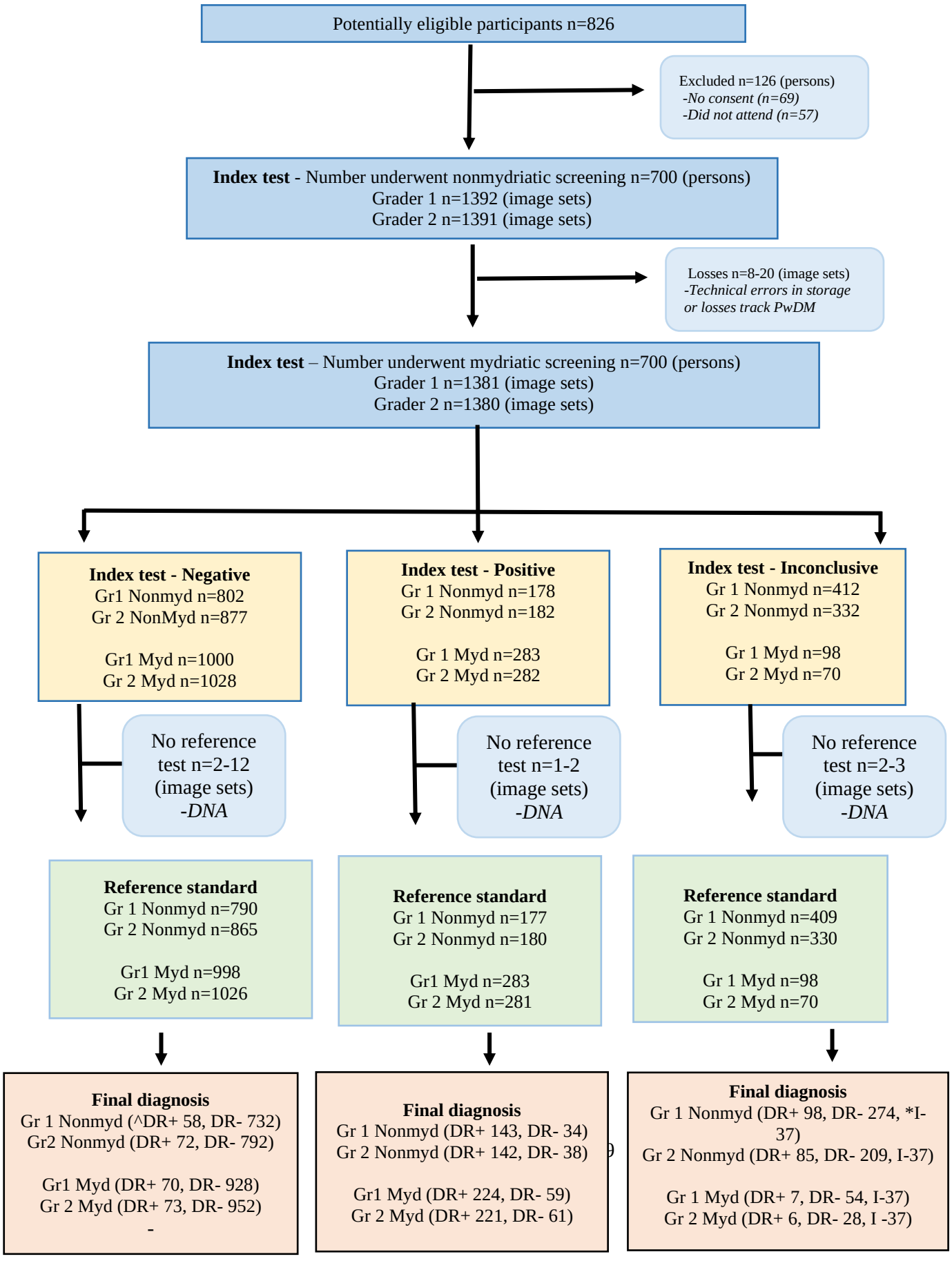
[d] Background DR, [e] NPDR – Non-proliferative DR, [f] PDR-Proliferative DR

Table 2. Macular signs classification

	Maculopathy absent (M0)	Maculopathy present (M1)
Signs up to 2-disc diameters from the centre of fovea	No signs	Presence of hard exudate/s and / or blot haemorrhage/s (Referable)

9.2 - Additional File 2. Detailed flow chart of the number of participants and image sets used in the analysis

(Gr 1-Grader 1, Gr2-Grader 2, Nonmyd-Nonmydriatic, Myd-Mydriatic, DNA-did not attend, ^for any DR, DR+ any DR positive, DR- no DR, *I-Inconclusive) (According to the STARD guidelines)



9.3 - Additional File 3.

Table 1. Prevalence of lens opacity and other condition that would affect image gradability and reference test examination

	Nonmydriatic imaging	**Mydriatic imaging**	**Reference test - Mydriatic**	**Prevalence of DR and Macular signs among ungradable**
	Grader 1*	**Grader 1**		
Number gradable	980 (70%)	1283 (91.6%)	1342 (95.8%)	
Number ungradable	412 (29.4%)	98 (7.0%)	40 (2.8%)	
Missing image files or data	8 (0.6%)	19 (1.4%)	18 (1.3%) (did not attend for reference test)	
Lens status	Lens opacity 285 (69.2%) Nuclear opalescence NO 1 – 41 NO 2 – 60 NO 3 – 108 NO 4 – 40 NO 5 – 14 NO 6 – 8 Mature 12 Congenital 2 Posterior subcapsular opacity 218 P1 – 21 P2 – 22 P3 – 15 P4 – 5 P 5 – 4 Cortical cataract C1 – 4 C2 – 7 C3 – 2	Lens opacity 78 (79.6%) Nuclear opalescence NO 1 – 4 NO 2 – 5 NO 3 – 24 NO 4 – 16 NO 5 – 9 NO 6 – 8 Mature – 12 Posterior subcapsular opacity 58 P1 – 3 P2 – 3 P 3 – 6 P 4 – 4 P 5 – 4 Cortical cataract C2 - 1	Lens opacity 37 (92.5%) Nuclear opalescence NO 6 only – 10 NO 5 only – 3 NO 4 only – 4 Other combinations NO5 and P2 – 2 NO4 and P4 – 4 NO 4 and P 3 – 1 NO 3 and P3 – 1 Mature cataract 12	Prevalence of DR among the ungradable images (non-mydriatic) R0 274 66.5% R1 82 19.9% R2 7 1.7% R3 3 0.7% R4 6 1.5% R9 37 9.0% Missing 3 0.7% Prevalence of maculopathy among the ungradable images in nonmydriatic M0 336 81.6% M1 29 7.0% M9 44 10.7% Total 409 99.3% Missing 3 0.7%
	Lens clear 122 (29.6%) clear phakic 40	Lens clear 15 (15.3%) Clear phakic 5 Pesudophakic 10	N/A	Prevalence of DR among the ungradable images (mydriatic) R0 54 55.1 R1 4 4.1 R4 3 3.1

	Aphakic 2 Pseudophakik 80			R9 37 37.8 Prevalence of maculopathy among the ungradable images in mydriatic M0 57 58.2 M1 1 1.0 M9 40 40.8
Posterior capsule status	PCO+ 20	PCO+ 3	PCO + 1	
Corneal status	Corneal opacity 02 (minor)	No	No	
Other conditions	Phthysical 1	Phthysical 1	Phthysical 1	
	Eviscerated 1	Eviscerated 1	Eviscerated 1	
Mean pupil diameter	2.01 mm SE 0.004 (95% CI 2.007 – 2.026) mm	6.023 mm SE 0.032 (95% CI 5.96 – 6.08) mm		

*The image set of highest ungradability proportion recorded by the grader 1 considered here.

9.4 - Additional File 4.

Table 1. DTA for two step grading process - (DTA for gradable nonmydriatic images and nonmydriatic ungradable eyes classified based on mydriatic grading)

Index Test		Sensitivity (95% CI) (%)	Specificity (95% CI) (%)	PPV (95% CI) (%)	NPV (95% CI) (%)	Kappa (95% CI) (%)
Any DR grading						
Two Step Grading *						
	Grader 1	75.6 (70.8, 79.98)	90.8 (85.6, 92.4)	72.5 (67.7, 77.1)	92.0 (90.2, 93.6)	0.65 (0.61, 0.70)
	Grader 2	72.5 (67.6, 77.1)	93.5 (91.8, 94.8)	78.1 (73.3, 82.5)	91.4 (89.6, 92.9)	0.68 (0.63, 0.72)
Referable DR grading ^						
Two Step Grading						
	Grader 1	81.1 (72.9, 87.8)	95.4 (94.2, 96.5)	59.7 (51.6, 67.5)	98.4 (97.6, 98.9)	0.66 (0.59, 0.73)
	Grader 2	82.1 (74.0, 88.6)	97.1 (96.1, 97.9)	70.2 (61.8, 77.7)	98.5 (97.7, 99.1)	0.73 (0.67, 0.80)

*All non-mydriatic imaging ungradable eyes were replaced by mydriatic grading. The ungradable images even after dilating pupils considered as screen positive.

^ Moderate NPDR and above. Maculopathy not considered.

9.5 - Additional File 5.

Table 1. Intra-grader agreement analysis of double grading
(sample size 15% of each 100 image sets)

	Grader 1 vs Grader 1 (1st vs 2nd)	Grader 1 vs Grader 2 (1st attempt)	Grader 2 vs Grader 2 (1st vs 2nd)	Grader 2 vs Grader 1 (2nd attempt)
Binary gradability of images (irrespective of the pupil status) (kappa) (95% CI)	0.48 (0.34,0.62)	0.83 (0.71, 0.95)	0.85 (0.72, 0.97)	0.51 (0.37, 0.64)
Retinopathy grading agreement (at each level of R1, 2, 3 and 4; Weighted linear kappa) (k) (95% CI)	0.69 (0.60, 0.78)	0.82 (0.76, 0.89)	0.66 (0.58, 0.73)	0.74 (0.66, 0.83)
Agreement of detection of macular signs (k) (95% CI)	0.58 (0.45, 0.72)	0.75 (0.65, 0.85)	0.71 (0.59, 0.82)	0.75 (0.65, 0.85)

Appendix 10

10.1 - Additional File 1 - Search on health educational interventions / material on improving the referral uptake

Table 1. Search Terms

Terms for search of material –	Main sources of the adapted material –
1 Diabetes Mellitus 2 Diabetes Complications 3 Diabetic Retinopathy 4 Health Education 5 Patient Education 6 Health Promotion 7 Diabetic Retinopathy Screening 8 Diabetic Retinopathy Blindness	-National Health Services – United Kingdom. -University of Melbourne – Australia -Diabetic Eye Screening Program – Northern Ireland -National Eye Health Education Program – United States -Diabetes UK -National Health Services – Scotland -Diabetic Retinopathy Screening Program for Aboriginal People – Australia -Public Health Agency – Canada -Royal National Institute of Blindness – United Kingdom -Health Promotion Board – Ministry of Health – Singapore -Moorfields Eye Hospital – United Kingdom -Queen Elizabeth Hospital – Birmingham – United Kingdom -National Eye Institute – United States -Vision Initiative – Victoria – Australia -Department of Health – Australia -International Diabetes Federation -Retina Group – Washington – United States -National Library of Medicine – United States -The Eye Centre – Video Library -Diabetes UK – Learning Zone -Medline Plus – Video Archives

Table 2. Summary of the electronic search of HE material on DR and DRS.

Type	Total number of items retrieved in search	DM	DR	DRS	DR Rx	DR All	Number of items eligible in adaptation	Number of items with high PEMAT Score [>50% of the score]	Number of items used in adaptation
Poster	28	16	--	12	--	--	18	09	01
Leaflet & brochure	33	03	13	13	04	--	29	17 Brochures 12 Leaflets	12
Videos	24	02	11	05	06	--	22	13	9
Tip sheets	07	02	04	--	01	--	04	04	4

Info graphics & flipcharts	31	09	10	07	05	--	22	12	7
Information Articles	81	24	41	14	02		--	N/A	-
Banner	10	--	--	10	--		01	01	-
Web based education	216	32	59	12	11	102	--	N/A	-
Resource & ideas	13	04	02	01	--	06	--	N/A	-
Audio	04	--	01	03	--	--	--	N/A	-
Software applications (Apps)	02	02	--	--	--	--	--	N/A	-
	449						96	68	33

10.2 - Additional File 2 - HE material

[Attached separately below]

2.1 - Multimedia File 1 - Video script and frames [videos enclosed in a compact disc]

2.2 - Multimedia File 2 - Leaflet in 3 languages

10.3 - Additional File 3 – Topic guides for field testing of the HEI – for service users and service providers

[Version 1.2_June/2018]

Date and Time of the SSI – ……

Names of the investigators –…….
Place of the interview – …….
Participant study ID-……...

Introduction –

Background information –
"Ayubowan (Greeting), …Introduction of the moderator and the investigator…"
"Do you remember you received a leaflet and video 2-3 weeks ago when you were in the medical clinic. Today we want to get your opinion on these, because, as you know, this sugar/diabetic eye ailment is a major problem in our country. It is important to us to understand what people think about these materials and how we might improve them.
Now you know that diabetes can affect your eyes, as it affects your kidneys. The high sugar levels in your body, due to sugar disease, leads to changes at the back of your eyes leading to vision loss. However, this can be prevented if you checked your eyes on time.

The things we discuss will be very confidential and we will not be attaching your name or any details that anyone can identify you when reporting your answers. You can also stop the interview at any time if you wish".

*Instructions - The leaflet and video should be assessed separately 1st – Leaflet, 2nd Video

10.3.1 - Additional file 3 - Table 1. Topic guide for PwDM

General Topic Guide	Specific topic related to Leaflet	Specific topic related to Video
[Introductory topic] 1.What are the usual sources of getting information on your eye problems?	N/A	N/A
[Acceptability] 2.In general, what did you think about the (intervention)?	In general, what did you think about the leaflet? What did you prefer most (Leaflet/video)? Do you think you need both?	In general, what did you think about the video? What did you prefer most (Leaflet / Video)? Do you think you need both?
[Comprehensibility] 3.What did you understand after going through the video / leaflet given to you by your physician few days / few weeks ago	What was the subject explained in the leaflet?	What was the story shown in the video? What was explained by the lady in the video?
[Delivery] [Acceptability] 4. How was it delivered to you?	What setting? Did they take their time to discuss it? Was there enough time? Did you need extra explanation and time to discuss it? Probe – How do you feel to receive it at your medical clinic – by your physician? What is the best place to distribute this leaflet (in a hospital)? Who do you think as the best person to deliver this? Where? And What setting? Why do you think like that? Probe – What are your thoughts on place of delivery and person who delivered the HE intervention?	What setting? Did they take their time to discuss it? How the video was shown to you? Probe – How do you feel to receive it at your medical clinic – by your physician? Was there enough time? Did you need extra explanation and time to discuss it / watch it? What is the best place to show the video (in a hospital)? Where? And What setting? Why do you think like that? Probe – What are your thoughts on place of delivery and person who delivered the HE intervention?
	Hand over a leaflet to the participant	*Start showing the video, segment by segment*
[Comprehension and Understandability]		

5.What do you understand in each medium (Leaflet and Video separately) in each section?	*[Go through the leaflet page by page – specifically asking about the pictures / diagrams / texts]* Show me anything that you could not understand? Probe - Please show me (encircle) the information that you cannot understand properly – in the leaflet? Any technical or medical terms you found difficult? What do you understand by the picture in the front-page? Images at 2nd page? What do you understand the numbers and figures given in the front page? Can you follow the map given here? Can you tell me the steps mentioned here in the flow chart – things to be done when you are at eye clinic? *If not understood / could not follow?* Why couldn't you understand those statements / pictures / illustrations?	*[Go through each segment of the video while pausing it at each segment]* Tell me any segments / statements that could not understand in the video? Probe - Show me the statements that you could not follow in the video? Any technical or medical terms you found difficult? Were you able to understand the animations / graphics shown in describing the developing the diabetic eye ailment? Eye examination at medical clinic? Referral uptake at next level of National Eye Hospital? *If not understood / could not follow?* Why couldn't you understand those statements / animations / video segments?
[Readability]	Overall did you find it easy to read? Probe - Language style, usage of terms, font size? Were you able to read the text easily? Were the size of the letters large enough for you? Probe – What do you think about the layout and design of the leaflet For illiterate people – How did you manage to readout it for you? Who supported you in that? What were the difficulties you had in that?	Was it easy to follow the dialogues and statements said in the video? Probe – What do you think about the narration in the video? Do you like the story? Any technical terms you found difficult?
[Actionability] 6.What is the key message that you got in each intervention in seeking care at eye clinic?	What do you think are the key messages that you will take away from this? What is the message about referrals? Is it clear?	What do you think are the key messages that you will take away from this? What is the message about referrals? Is it clear?
[Usability] 7. Did you use the given material at home or anywhere else (shared with friends / neighbours / other patients at clinic)?	Did you take the leaflet home and share it with the family members? Did anyone read it? What did they say? If so, how did that go? Any difficulties? If not – Why?	Did you take the given DVD? Do you have facilities to watch it? What were difficulties you had in viewing the video? If not shared – Why?
[Suggestions] 8.Any suggestions to improve?		Would you like to suggest any modifications to the leaflet to make

	Would you like to suggest any modifications to the leaflet to make more appealing to our community / culture? Probe – Your suggestions to gain confidence in the diabetic community in order to use this health educational intervention. Probe – Does it need to be different for men / women; older men / women ?	more appealing to our community / culture? Probe – Your suggestions to gain confidence in the diabetic community in order to use this health educational intervention. Probe – Does it need to be different for men / women; older men / women ?
9. Anything else important that we haven't covered in this intervention?	Anything else important that we haven't covered which you think is important when trying to promote improved uptake of DR assessment at eye surgeons' clinic following referral? Overall how you would rate the Leaflet? Probe – 0 = not very good, 9=excellent	Anything else important that we haven't covered which you think is important when trying to promote improved uptake of DR assessment at eye surgeons' clinic following referral? Overall how you would rate the Video? Probe – 0 = not very good, 9=excellent

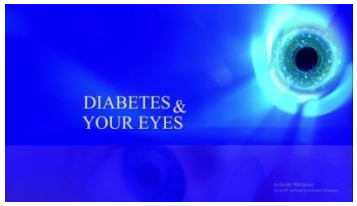
10.3.2 - Additional file 3 - Table 2. Topic guide for the providers

General topic guide
[Introductory topic]
1) How would you describe overall experience of this new health educational intervention? Probe – Whether you think this would be useful to improve uptake of DR assessment and treatment services at next level of ophthalmologist's / retinologist's clinic by the people with referable level DR.
[Acceptability] [by the provider – not the patients]
2) What is your opinion on suitability of health educational intervention to medical clinics of the Western province of Sri Lanka? Probe – Your opinion on suitability of medium of delivery to the context. Probe – Do you think the medical clinic as the best place to deliver?
[Comprehensibility]
3) What is your understanding about appropriateness of content to the context? Probe – Whether the content and language style is understandable to our community. Does it give a right message to people with referable level DR? Probe – What is your opinion of organization of the content, layout and designs?
[Delivery]
4) What is your opinion on time taken for delivering the intervention to a service user? Probe – Does it interrupt the usual patient flow? Does it affect the usual process of consultation of people with diabetes?
[Technical difficulties] [Barriers to deliver]
5) What were the difficulties faced by graders / educators in delivering health educational intervention?

Probe – Problems in language, content / terminology, interaction with service users, difficulties in multi-tasking (giving prescriptions, checking blood pressure, DR screening and delivering health educational intervention).
[User acceptability as perceived by providers]
6) What were the service users' responses to the proposed health educational intervention? Probe - How would you describe the service users' responses to the intervention? Do you think it is an innovative method to improve the uptake of assessment and treatment services compared to the conventional method? [Actionability] Probe – Do you think that patients will attend to eye clinic following this intervention? Probe – Are there clear instructions, visual aids, steps to follow?
[Usability as an intervention]
7) What is your opinion on acceptability of the intervention in medical clinics in long run considering different characteristics of service users? Probe – with people with different level of education, different literacy levels, different attitudes towards seeking medical care at the clinic?
[Understandability or learnability for the providers] [not for patients]
8) What were the problems associated with learning of health educational intervention (by educators)? Probe – Are you familiar with medium and mode of delivery? Do you require training on mode of delivering health educational intervention?
[Suggestions]
9) In your opinion will this intervention enhance the performance of provider with regard to educating the service users on DR? Probe - Would this support comprehensive management of a diabetic patient?
10) What are your suggestions to further improve this intervention?

10.2 - Additional File 2

Additional File 2.1 - Outline and script in English and local languages (Sinhala and Tamil) of the video health educational Intervention

Video Picture Frames	English	Sinhala	Tamil
1st Segment    	Run time in seconds - 00:01 **Diabetes and your eyes.** 00:04 Sugar disease harms your eye sight. 00:06	දියවැඩියාවයි ඔබේ ඇසයි. ඇසේ පෙනුමට හානිකර සීනි. දියවැඩියා ඇස් රෝගයෙන් පෙනුම අඩුවීම හා අන්ධවීම වලක්වා ගැනීමට ඔබට උපදෙස්.	'நீரிழிவும் உங்கள் கண்களும்' “பார்வையை பறிக்கும் சீனி“ நீரிழிவுக்கான கண் நோயிலிருந்து உங்கள்

	Your guide to protect your eye sight from diabetic retinopathy or diabetic eye ailment. 00:15 **Are you aware that diabetes causes visual loss?**	දියවැඩියාවෙන් ඇස් පෙනීම අඩුවීමට හෝ අන්ධවීමට හැකිබව ඔබ දන්නවාද?	கண்களை பாதுகாப்பதற்கான வழிகாட்டி நீரிழிவினால் கண்பார்வையை இழக்க நேரிடலாம் என்பது உங்களுக்கு தெரியுமா?
	00.19 In Sri Lanka for every 100 people above 20 years of age at least 20 people have diabetes.	ශ්‍රී ලංකාවේ වයස අවුරුදු 20ට වැඩි සියදෙනෙකුගෙන් විසි දෙනෙකුට පමණ දියවැඩියාව ඇත.	இலங்கையில் 20 வயதுக்கு மேற்பட்ட ஒவ்வொரு நூறு பேரில் ஆகக்குறைந்தது இருபது பேர் நீரிழிவினால் பாதிக்கப்பட்டிருக்கின்றனர்.
	00.28 That means in an average family of 5 people 1 could have diabetes.	ශ්‍රී ලංකාවේ එක පවුලක වැඩිහිටි පස් දෙනෙකු සැලකූ විට ඉන් එක් අයෙක් දියවැඩියා රෝගියෙකු විය හැක.	இலங்கையில் ஒரு குடும்பத்தில் வளர்ந்தோர் 5 பேரில் ஒருவர் நீரிழிவு நோயாளராக இருக்கலாம்
	Substantial number of these people's eyes could've already been affected by diabetes.	ඔවුන්ගෙන් වැඩි පිරිසකගේ ඇස් දියවැඩියාවෙන් හානි වී අන්ධභාවයට පත්වීමේ හැකියාව ඇත.	இவர்களின் குறிப்பிடத்தக்களவு நபர்களின் கண்கள்
		ඔවුන්ගෙන් සෑම තුන්දෙනෙකුගෙන් එක් අයෙකුම දියවැඩියා ඇස් රෝගයෙන් පෙලෙන අතර ඔබ එයින් එක් අයෙකු විය හැකිය.	

 	For every 3 people with diabetes, 1 can have diabetic eye ailment. You could be one of them.		ஏற்கனவே நீரிழிவினால் பாதிக்கப்பட்டிருக்கலாம். அவர்களில் மூவரில் ஒருவருக்கு நீரிழிவுக் கண் நோய் இருக்கலாம் என்பதோடு நீங்கள் அதில் ஒருவராக இருக்கலாம்.
2nd Segment 	00:50 **What is diabetic eye ailment?** 00:54 *I have diabetes for more than 20 years, one day I lost vision in my right eye suddenly. And I presented to emergency eye clinic at eye hospital.*	දියවැඩියා ඇස් රෝගය යනු කුමක්ද? මට දියවැඩියාව හැදිලා දැන් අවුරුදු 20ක් වෙනවා. හිටපු ගමන් මගෙ දකුණු ඇහේ පෙනීම නැතිවෙලා ගියා. මම එවෙලෙම ඇස් රෝහලේ හදිශි ප්‍රතිකාර ඒකකයට ගියා.	நீரிழிவுக் கண் நோய் என்றால் என்ன? எனக்கு நீரிழிவுக் கண்நோய் ஏற்பட்டு 20 வருடங்களுக்கு மேலாகின்றது. ஒருநாள் திடீரென்று எனது வலது

	*There doctors found a sudden bleeding inside my eye due to diabetes. I underwent a big operation to clear the blood inside my eye.*	දොස්තරලා මට කිව්වේ දියවැඩියාව නිසා ඇසේ ඇතුලට ලේ ගලලා පෙනීම නැතිවෙලා කියලා. ඊලහට මගේ ඇහේ ලොකු සැත්කමක් කරලා ලේ ටික අයින් කලා.	கண் தெரியாமல் போனது. உடனே கண் வைத்தியசாலையில் அவசர சிகிச்சை பிரிவுக்கு சென்றேன். நீரிழிவினால் கண்ணின் உட்புறத்தில் இரத்தம் கசிந்து கண் தெரியாமல் போய்விட்டது என்று வைத்தியர்கள் என்னிடம் கூறினார்கள். கண்ணில் பெரிய சத்திர சிகிச்சை செய்து இரத்தத்தை அகற்றினார்கள்.
	*Last 20 years I was always concentrating on my family matters and I could not pay much attention to my own health. There I got to know that this type of an incident could have been prevented at an early stage.*	පහුගිය අවුරුදු 20, 30 ඇතුලත ගොඩක් පවුලේ ප්‍රශ්ණ තිබුන නිසා මගේ ලෙඩ ගැන මට බලන්න බැරිව ගියා. එදා තමයි මම දැනගත්තේ අවුරුද්දක් පාසා ඇස් බලන්න ඕන කියලා.	கடந்த 20 வருடங்களாக நான் எனது குடும்ப பிரச்சினை பற்றி மாத்திரமே கவனம் செலுத்தியதனால் என்னை பற்றி கவனத்தில் எடுக்கவில்லை. வருடா வருடம் கண்ணை பரிசோதித்துக்கொள்ள

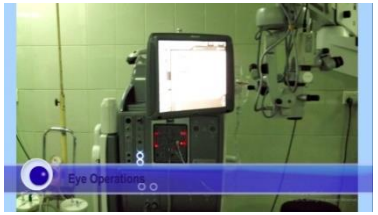
			வேண்டும் என்பதனை அன்று தான் நான் தெரிஞ்சுகொண்டேன்.
3rd Segment   	01.05 *High blood sugar due to diabetes lead to diabetic eye disease. Diabetes affects the blood tubes which supply the light sensitive layer at the back of the eye which is called retina.* 01.29 *These blood tubes start bleeding in diabetes. Then weak blood tubes grow abnormally at the back of your eyes then bleed or leak which you cannot see from outside affecting your eye sight.*	දියවැඩියාව නිසා ලේ වල ඇති අධික සීනි මට්ටම දියවැඩියා ඇස් රෝගයට හේතු වෙනවා. එමඟින් ඔබේ ඇසට පෙනුම ලබාදෙන ඇසේ පිටුපස ඇති ස්නායු පටලය එහෙම නැත්නම් දෘෂ්ටි විතානයේ ලේ නහරවලට බලපෑම් ඇතිකරනවා. පළමුව මේ ලේ නහර වලින් ඉතා සුළු වශයෙන් රුධිර වහනය වීමට පටන්ගන්නවා. ඉන්පසුව මෙම රුධිර නාල දුර්වල වී අසාමාන්‍ය ලෙස වර්ධනය වී තදුරටත් රුධිර ගැලීම් හෝ රුධිර කාන්දු වීම් සිදුවී, ඔබගේ පෙනීමට හානි සිදුවෙනවා. මෙය ඇසේ පිටුපසින් සිදුවන නිසා ඔබට ඇසේ ඉදිරිපසින් මෙය බලාගත නොහැකි.	“இரத்தத்தில் அதிகளவான சீனி இந்த நீரிழிவுக் கண் நோய் ஏற்பட வழிவகுக்கின்றது நீரிழிவு நோயானது கண்ணின் பின்புறத்திலுள்ள பார்வையை வழங்கும் நரம்பு மண்டலத்திலுள்ள இரத்தக் குழாய்களை பாதிக்கின்றது. நீரிழிவு நோயின்போது இந்த இரத்தக் குழாய்களிலிருந்து இரத்தம் கசிய ஆரம்பிக்கும். பின்னர் இந்த பலவீனமான இரத்தக் குழாய்கள் அசாதாரணமான முறையில் வளர்ச்சியடைந்து இரத்தம்

  	*This can progress in to vision loss and blindness if not detected and treated at correct stage.*	මෙය හරි වේලාවට හඳුනාගෙන ප්‍රතිකාර කලේ නැත්නම් ඔබගේ පෙනුම අඩුවීමට හෝ අවසානයේ අන්ධභාවයට වුනත් පත්වෙන්න පුළුවන්.	சிந்துவதனால் அல்லது கசிவதனால் கண்பார்வை பாதிப்படைவதுடன் அதனை வெளிப்புறத்திலிருந்து காண முடியாது. சரியான நேரத்தில் அடையாளம் கண்டு சிகிச்சை பெறாவிட்டால் இந்நிலை மோசமடைந்து கண்பார்வை குறைவடைவதற்கு அல்லது இழப்பதற்கு அது வழிவகுக்கலாம்.“.
4th Segment	02.07 **How would your eyes be checked at the medical clinic?**	වෛද්‍ය සායනයේදී ඔබගේ ඇස් පරීක්ෂාකරන්නේ කෙසේද?	மருத்துவ பரிசோதனையில் உங்கள் கண்கள் எவ்வாறு பரிசோதிக்கப்படும்?

  	02:11 Your doctor will examine your eyes using a special eye camera and eye drop will be instilled in your eyes to have a better view of the back of the inside of your eyes. You will have blurring for short period of time. But the outcome of examination is more beneficial than the difficulties. Further, this is a routine method done on everybody that you do not need to worry about.	ඔබගේ වෛද්‍යවරයා විසින් විශේෂිත කැමරාවක් මඟින් ඇස් පරීක්ෂා කරනු ඇත. එහිදී ඔබගේ ඇසේ අතුලත පිටුපස හොඳින් පරීක්ෂා කිරීමට ඇසට බිංදු දමනු ලැබේ. එවිට ඇසේ බොඳවීමක් තාවකාලිකව ඇතිවිය හැකිවුවද එම පරීක්ෂණයේ ප්‍රථිපල එම ඇතිවන අපහසුතාවට වඩා වාසි සහගත වේ. තවද මෙය සෑම අයෙකුගේම නිතර සිදුකරන පරීක්ෂාවක් බැවින් ඔබ ඒ සඳහා බියවිය යුතු නැත.	“உங்கள் வைத்தியர் விசேட கமரா ஒன்றின் மூலம் நீரிழிவுக் கண் நோய் இருக்கின்றதா என பரிசோதித்துப் பார்ப்பார். கண்ணின் பின்பகுதியினை உட்பக்கத்தால் தெளிவாக பார்ப்பதற்கு விசேட சொட்டு மருந்து சில துளிகள் கண்ணுக்கு விடப்படும். பார்வை தற்காலிகமாக மங்களாக தெரியும் என்றாலும் அந்த அசௌகரியத்தை விட பரிசோதனையின் பலன் அதிகமானதாகும். மேலும் இது எல்லோருக்கும் வழமையாக மேற்கொள்ளும் பரிசோதனை என்பதனால் அது தொடர்பாக பயப்படத் தேவையில்லை“

 			
	02:38 **What you will have to do next?** 02:43 Small number of people will be referred to eye clinic of the National Eye Hospital Colombo, if found to have the disease or to have a better look at your eyes. If not, you will be asked to go under go same eye examination at the medical clinic in one year time.	**වෛද්‍යසායනයේ ඇස් පරීක්ෂාවෙන් පසුව ඔබ සිදුකල යුත්තේ කුමක්ද?** දියවැඩියා ඇස් රෝගය ඇති සුළු පිරිසක් තවදුරටත් ඇස් ඇතුලත හොඳින් පරීක්ෂා කිරීමට කොළඹ ජාතික අක්ෂි රෝහලේ ඇස් සායනයට යොමුකරනු ඇත. එසේ නැතහොත්, ඔබට දියවැඩියා ඇස් රෝග ලක්ෂන දැනට නොමැතිනම් හෝ මෙම අවස්ථාවේ ඇත්තෙ සුළු රෝග ලක්ෂණ පමනක් නම් නැවත වසරකට පසු පරීක්ෂා කලයුතුබව පවසනු ඇත.	**நீங்கள் அடுத்து என்ன செய்வீர்கள்?** **நீரிழிவுக் கண் நோய் அறிகுறிகள் இருந்தால் அல்லது கண்களை மேலும் சிறந்த முறையில் பரிசோதித்துப் பார்ப்பதற்கு சிறு அளவிலான நபர்களை தேசிய கண்**

			வைத்தியசாலையின் மருத்துவ பரிசோதனைக்கு சிபாரிசு செய்து அணுப்பப்படுவீர்கள். அவ்வாறு இல்லாவிட்டால் இந்த கண் பரிசோதனையை ஒரு வருடத்தின் பின்னர் மீண்டும் செய்துகொள்ளுமாறு கேட்டுக்கொள்ளப்படுவீர்கள்.
	03:01 **Why should you undergo eye examination at National Eye Hospital?** 03:06 National Eye Hospital Colombo has all the advanced investigation and treatment facilities for this condition. There you will be well instructed on what to do next depending on the status of your eyes or found to have advanced eye problem.	ඔබ කොළඹ ජාතික අක්ෂි රෝහලේ ඇස් පඉක්ෂාවට සහභාගි විය යුත්තේ ඇයි? කොළඹ ජාතික අක්ෂි රෝහලේ මෙම දියවැඩියා ඇස් රෝගය සඳහා අවශ්‍ය නවීනතම පරීක්ෂන හා ප්‍රතිකාර ක්‍රම ඇත. එහිදී, ඔබගේ රෝගයේ තත්වය අනුව හෝ උත්සන්නභාවය අනුව මීලඟට සිදුකලයුතු දෑ පිලිබඳව උපදෙස් ලබාදෙනු ඇත.	தேசிய கண் வைத்தியசாலையில் கண் மருத்துவ பரிசோதனையினை ஏன் செய்துகொள்ள வேண்டும்? கொழும்பு தேசிய கண் வைத்தியசாலையில் நீரிழிவு கண் நோய்க்கான

			சகலவித முன்னேற்றகரமான பரிசோதனைகளுக்கும் சிகிச்சைகளுக்குமான வசதிகள் உள்ளன. அங்கு, உங்களின் நீரிழிவுக் கண்ணோயின் தீவிரத் தன்மைக்கேற்ப அடுத்த என்ன செய்ய வேண்டும் என்பது தொடர்பாக சரியான முறையில் வழிநடாத்துவார்கள்.
	*03:24* *You have diabetic eye disease which require treatment. We have to start treatments immediately.* *03:30* *Doctor, I have undergone cataract surgery and I am using spectacles as*	ඔබට දියවැඩියා ඇස් රෝගය ප්‍රතිකාර කලයුතු මට්ටමට තියනවා ඉක්මනින්ම ප්‍රතිකාරවලට යොමුවෙන්න ඕන. ඩොක්ටර්, මගෙ ඇස්වල සූදු හැදිලා ඔපරේෂන් කරලා කාව දාල තියෙන්නේ, මම කන්නාඩිත් පාවිච්චි කරනවා. මගේ	உங்களுக்க சிகிச்சை பெற வேண்டிய அளவில் நீரிழிவுக் கண் நோய் இருக்கின்றது. உடனடியாக சிகிச்சையை ஆரம்பிக்க வேண்டும். டாக்டர், கண்ணில் வெண்படல அறுவை

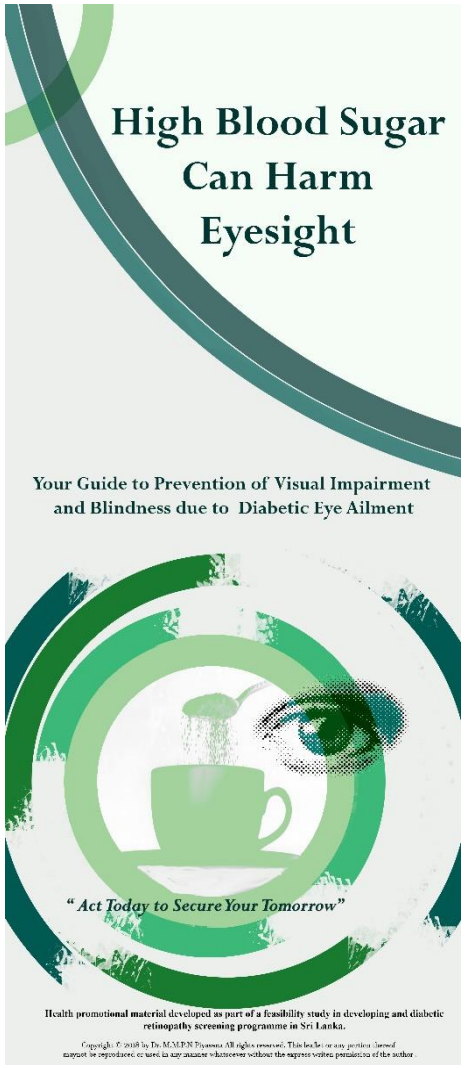
	*well. I do not have any problem with my sight.* 03:40 *This can occur with another eye disease so treating one condition does not protect against diabetic eye disease.*	ඇස්වල පෙනීම කිසිම ප්‍රශ්ණයක් නැනේ. දියවැඩියා ඇස් රෝගය වෙනත් රෝග සමඟ ඇතිවිය හැකි අතර එම රෝගවලට කරන ප්‍රතිකාරවලින් දියවැඩියා ඇස් රෝගය සුවවන්නේ නෑ.	சிகிச்சை செய்து கண்ணாடியும் பாவிக்கின்றேன் தானே. பார்வையில் எந்தவித பிரச்சினையும் இல்லையே. நீரிழிவுக் கண் நோயானது வேறு கண் நோய்களுடனும் ஏற்படலாம். எனினும் அவற்றுக்கு எடுத்துக்கொள்ளும் சிகிச்சை மூலம் நீரிழிவுக் கண் நோயை குணப்படுத்த முடியாது
	03:49 **Why is it important to check early and regularly for diabetic eye ailment?**	**දියවැඩියා ඇස් රෝගය පෙරහඳුනා ගැනීමේ පරීක්ෂනයට මුල් අවස්ථාවෙම හා ක්‍රමවත්ව සහභාගි වීමේ වැදගත්කම කුමක්ද?**	. நீரிழிவுக் கண் நோய் கண்டுபிடிக்கும் பரிசோதனையை ஆரம்பகட்டத்திலும் ஒழுங்கு முறையாகவும் செய்துகொள்வது ஏன் முக்கியமானது?
	03:56 *Main feature of this condition is, you would not feel any symptoms related with diabetic eye disease at early stages.*	ඔබ දැනගත යුතුයි දියවැඩියා ඇස් රෝගයේ ප්‍රදානතම කරුනක් වන්නේ මූල් අවස්ථාවලදී කිසිදු රෝග ලක්ෂණයක් නොපෙන්වීමයි. පෙර	இந்த நோயின் பிரதான பண்பு அதன் ஆரம்ப

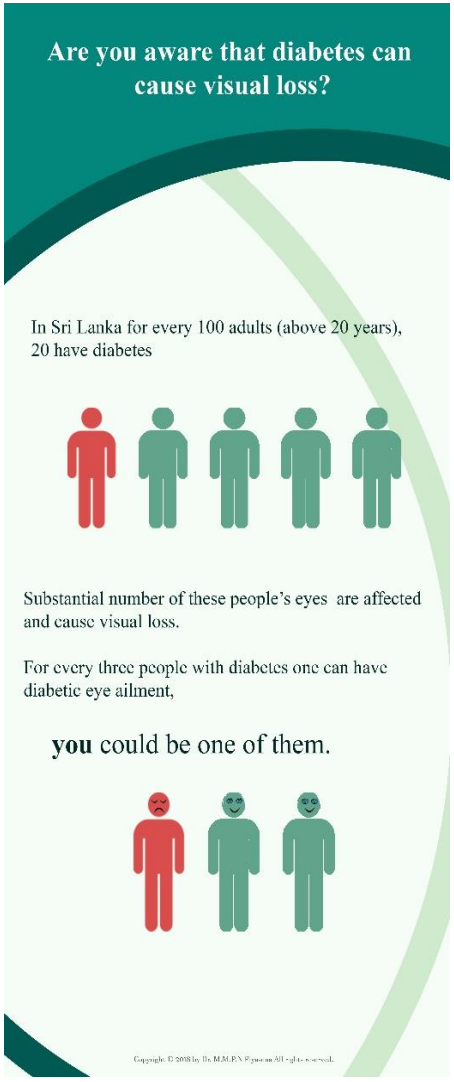
 	*Testing early or screening can detect changes at back of your eyes at an early stage before you aware of them. Treatments can work very well, if detected and treated.*	හඳුනාගැනීමේ පරීක්ෂාවක් මඟින් ඔබ රෝග ලක්ෂණ දැනගැනීමට පෙර රෝගය හඳුනාගත හැකි වෙනවා. මුල් අවස්ථාවේම රෝගය හඳුනාගෙන ප්‍රතිකාර කිරීම මඟින් එම ප්‍රතිකාර ඉතා සාර්තකවන අතර අන්ධභාවය වලක්වාගන්න පුළුවන්.	கட்டங்களில் அது தொடர்பான எந்தவொரு அறிகுறியையும் காட்டாதிருப்பதாகும். நீங்கள் அந்த நோய் அறிகுறிகளை உணர்வதற்கு முன்னரே அதற்கான கண்டுபிடிப்பு பரிசோதனையின் மூலம் அதனை அடையாளம் காணலாம். இம்மாற்றங்களை முன்கூட்டியே அடையாளம் கண்டு சிகிச்சை பெற்றால் அது வெற்றியளிக்கலாம்.

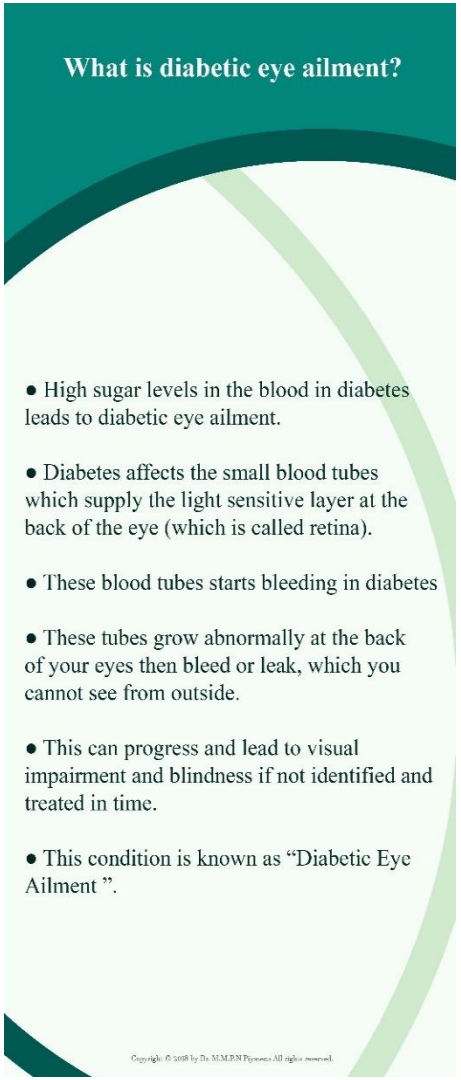
			
	04:18 *Now I know this could have been prevented by early eye checking and treatment. I know one of my friends lost vision in both eyes. He had undergone lens implantation as well. However, now he has lost vision in both eyes due to this diabetic eye ailment and he has very weak eyes. Therefore, I urge all of you to go annual eye checking as we celebrate Sri Lankan New Year in each year in April. Protect your eyes from this diabetic eye ailment.*	එහෙම කරලා ප්‍රතිකාරයක් කෙරුවානම් මෙහෙම දෙයක් වෙන්නේ නෑ. මගේ යාළුවෙක් ඉන්නවා ඇස් දෙකම පේන්නේ නෑ. එයාව ඇස් වාට්ටු ගෙනිල්ලා කාච දැම්මා. දැන් දියවැඩියාව නිසා ඇස් දෙකම නරක් වෙලා. ඒක නිසා පෙනීම දුර්වලම වෙලා. මම ඔයාලා සියලු දෙනාටම කියන්නේ අවුරුද්දෙන් අවුරුද්ද අප්‍රේල් මාසේ සිංහල දෙමළ අලුත් අවුරුද්ද සමරනවා වගේ අවුරුද්දක් පාසා ඇස් රෝහලට ගිහින් ඇස් පරීක්ෂා කරලා මේ දියවැඩියා රෝගයෙන් ඇස් දෙක පරිස්සම් කරගන්න කියලා.	கண்களை ஆரம்ப கட்டத்தில் பரிசோதனை செய்து அதற்கு சிகிச்சை எடுத்திருந்தால் இதனை தடுத்துக்கொள்ள இருந்தது என்று இப்போது எனக்கு தெரியும். எனக்கு தெரிந்த ஒரு நண்பர் இருக்கின்றார் அவரது இரண்டு கண்களது பார்வையும் இழந்துவிட்டார். அவர் கண்களுக்கு வில்லையும் பொருத்தி இருக்கிறார். என்றாலும் நீரிழிவு கண் நோய் காரணமாக இரண்டு கண்களும் தெரியாமல் போயுள்ளது. கண்கள்

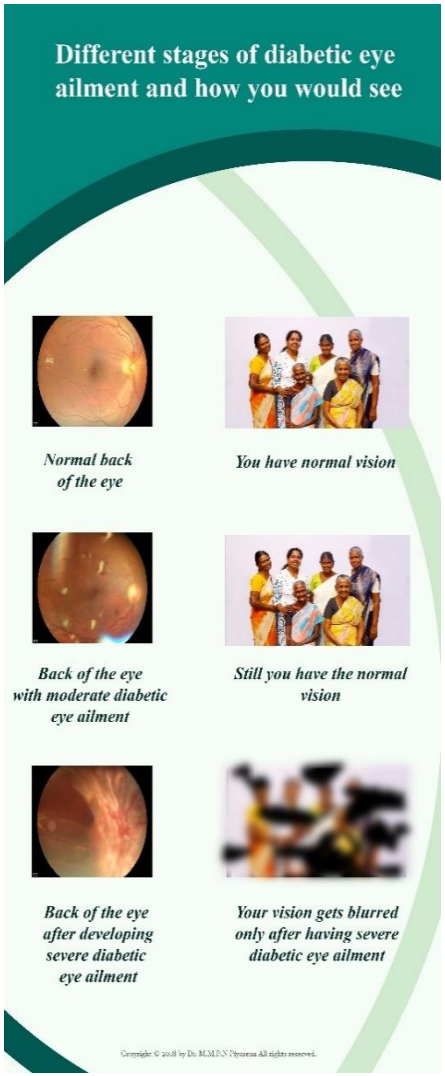
 	04:55 (End)		இப்போது மிகவும் மோசமான நிலையில் உள்ளது. எனவே வருடா வருடம் சித்திரை மாதம் சிங்கள தமிழ் புத்தாண்டை கொண்டாடுவது போல வருடா வருடம் கண்களையும் பரிசோதித்து இந்த நீரிழிவு நோயிலிருந்து கண்களை பாதுகாத்துக்கொள்ளுமாறு வேண்டிக் கொள்கிறேன்.

Additional File 2.2 - Leaflet Health Educational Intervention in English and local languages (Sinhala and Tamil)









Can we prevent this condition by undergoing cataract surgery or using spectacles for reading or seeing people or objects from a distance?

- Diabetic eye changes should not be confused with cataract or spectacles.
- We use spectacles to correct defects in the outer most part of the eye or due to changes in the lens power.
- The cataract surgery and intra ocular lens implantation will be done when natural lens become opaque and thick.
- Therefore, usage of spectacles or undergoing cataract surgery would not prevent you from getting the diabetic eye changes.
- Further there are no "eye drops or local remedies" that prevent this condition.
- Because of that you will have to undergo diabetic eye examination even after undergoing cataract surgery or even if you are using spectacles (or even if you have any other eye disease/s).

Why is it important to check early and regularly for diabetic eye ailment ?

- Main feature of this condition is, you would not feel any symptoms related with diabetic eye ailment at the early stages.
- Checking eyes early, can detect changes at back of your eyes, before you are aware of them.
- If these changes are detected in time, treatment is very effective at preventing sight loss.
- It is therefore important to have your eyes checked regulary.

How would your eyes be checked at medical clinic ?

- Your doctor will examine your eyes using a special eye camera.

- Eye drops will be instilled to your eyes to have a better view of the back of your eyes.
- You should not worry about the difficulties you have after the drops, since these will become normal after weaning off the effect of drugs.

What you should do after eye examination at medical clinic?

- The outcome of eye examination will be informed by your doctor at the medical clinic.
- You will be referred to National Eye Hospital - Colombo eye clinic, if found to have diabetic eye ailment which requires further assessment/ investigation.

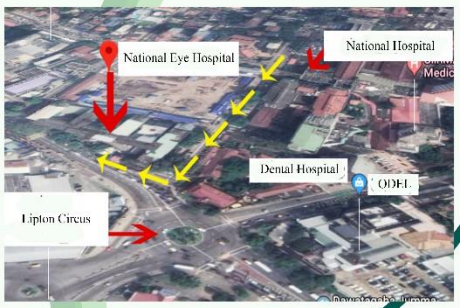
Or else:

- You will be asked to undergo same eye examination in one-year time, if there are no signs of diabetic eye ailment or minor signs which do not require further assesment at this stage.
- Please note that here we will examine only for diabetic eye ailment and you may present to any eye clinic if you have any other eye problem/s.

Steps to follow to go to eye clinic

- National eye hospital Colombo has all the advanced treatment and investigation facilities for diabetic eye ailment, at no cost!
- You will be treated by specialized eye doctors there.

Find the location of the eye clinic using folowing map



What you should do at eye clinic?

Enter in to National Eye Hospital through gate number 4 and go to the OPD number issuing counter.

There, you will have to obtain an OPD ticket by providing name, age and place of residence

Afterwards check your vision at room number 10.

After checking acuity you will be directed to the relevant eye clinic according to your OPD number

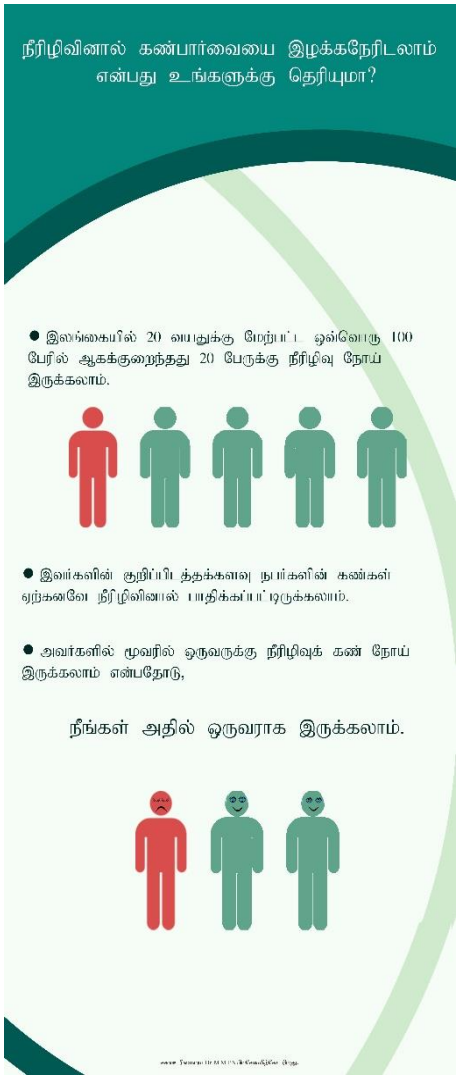
- Afterwards doctor will provide instructions of further steps and management plan.

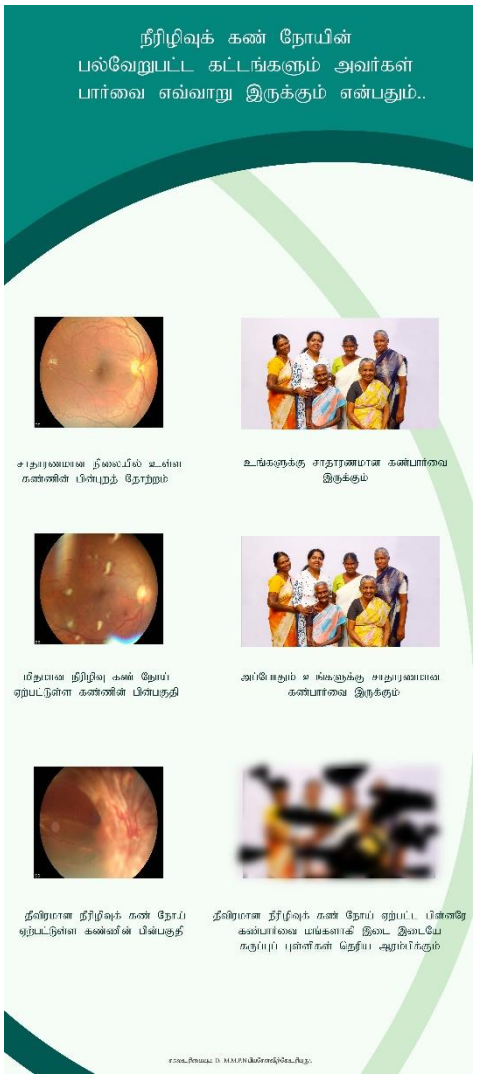
Please remember the followings when you come for your next visit

- Bring your pair of glasses (spectacles) and contact lenses you wear along with lens solution for contacts.
- You may asked to bring someone to escort you to the appointment.
- Eye drops may affect your vision for a few hours, so you should not drive/ ride bicycles/ trishaws after your appointent.
- You should ask and make clear about the next steps from your eye doctor before you leave the clinic.
- Please note down the next appointment date, time and room number back of this booklet.
- Please remember to bring clinic notes, previous eye examination reports when coming for the next visit.

Date	Hospital name	Clinic room number

Leaflet - Tamil medium





கட்ராக் அறுவை சிகிச்சை மூலம் அல்லது மூக்குக் கண்ணாடி பாவிப்பதன் மூலம் நீரிழிவுக் கண் நோயினை தடுக்க முடியுமா?

● நீரிழிவுக் கண் நோயை மூக்குக் கண்ணாடி மற்றும் கட்ராக் நோயுடன் குழப்பிக்கொள்ளவேண்டாம்

● நாம் கண்ணாடி பாவிப்பது கண்ணில் வெளிப்புறத்திலுள்ள (கருவிழி) குறைபாடுகளை திருத்திக்கொள்வதற்கு அல்லது வில்லையின் பார்வை ஆற்றலை மாற்றுவதற்கு ஆகும்.

● இயற்கையான எமது கண்வில்லை தடிப்பாகி ஒளி ஊடுருவமுடியாத நிலைக்கு வரும் பொழுது இந்த விழிவெண்படல சிகிச்சையும் கண்ணின் உள்ளே வில்லை பொருத்துவதும் மேற்கொள்ளப்படுகிறது.

● அதனால் வெண்படலம் அகற்றும் அறுவை சிகிச்சை செய்தாலும் மூக்குக் கண்ணாடி பயன்படுத்தினாலும் நீரிழிவு விழித்திரை நோய் ஏற்படுவதனை தடுக்க முடியாது.

● அவ்வாறே நீரிழிவு கண் நோயை சொட்டு மருந்துகள் மற்றும் கைமருந்துகள் மூலம் தடுத்துக் கொள்ள முடியாது.

● எனவே வெண்படலம் அகற்றும் அறுவை சிகிச்சை செய்தாலும் மூக்குக் கண்ணாடி பயன்படுத்தினாலும் (வேறு கண் நோய்களுக்கான சிகிச்சை பெற்றிருந்தாலும்) நீரிழிவு கண் நோயை கண்டு பிடிக்கும் பரிசோதனையை செய்தல் வேண்டும்.

நீரிழிவு விழித்திரை நோயினை கண்டுபிடிக்கும் பரிசோதனையை செய்துகொள்வது ஏன் முக்கியமானது?

● இந்த நோயின் ஆரம்பகட்டங்களில் அது தொடர்பான எந்தவொரு அறிகுறியினையும் காட்டாதிருப்பது அதன் பிரதான பண்பாகும்.

● நீங்கள் அந்த நோய் அறிகுறிகளை உணர்வதற்கு முன்னரே அதற்கான கண்டுபிடிப்பு பரிசோதனையின் மூலம் அதனை அடையாளம் கண்டுகொள்ளலாம்.

● இம்மாற்றங்களை முன்கூட்டியே அடையாளம் கண்டு சிகிச்சைபெற்றால் அது வெற்றியளிக்கலாம் என்பதோடு அதன் மூலம் பார்வை குறைவதனை அல்லது பார்வை இழப்பதனை தடுத்துக்கொள்ளலாம்.

● எனவே தொடர்ச்சியாக கண்களை பரிசோதனை செய்துகொள்வது முக்கியமானது.

மருத்துவ பரிசோதனையில் (கிளினிக்) உங்கள் கண்கள் எவ்வாறு பரிசோதிக்கப்படும்?

● உங்கள் வைத்தியர் விசேட கமரா ஒன்றின் மூலம் நீரிழிவுக் கண் நோய் இருக்கின்றதா என பரிசோதித்துப் பார்ப்பார்.

● கண்ணின் பின்பகுதியினை உட்பக்கத்தால் தெளிவாக பார்ப்பதற்கு விசேட சொட்டுமருந்து சில துளிகள் கண்ணில் விடப்படும்.

● துளிகள் கண்ணுக்கு விடப்பட்ட பின்னர் சிறிய அசௌகரியம் ஏற்பட்டாலும் அதன் செயற்பாடு சிலமணித்தியாலங்களில் குறைவடைவதனால் அது தொடர்பாக பயப்பட வேண்டியதில்லை.

நீங்கள் அடுத்து என்ன செய்வீர்கள்?

● கண் பரிசோதனை அறிக்கையை வைத்தியர் மருத்துவ சந்திப்பின்போது உங்களுக்கு அறிவிப்பார்.

● அவ்வாறு பரிசோதித்த பின் மேலதிக மதிப்பீடு செய்யப்பட வேண்டிய நிலையில் நீரிழிவு கண் நோய் அறிகுறிகள் இருந்தால் மேலதிக பரிசோதனைக்காக கொழும்பு கண் தேசிய வைத்தியசாலைக்கு செல்லுமாறு ஆலோசனை வழங்கப்படும்.

அல்லது

● அங்கு உங்களுக்கு நீரிழிவு கண் நோய் அறிகுறிகள் இல்லாதிருப்பின் அல்லது மேலதிக மதிப்பீடு தேவைப்படாத அறிகுறிகள் சிறியளவு இருப்பின் மீண்டும் ஒருவருடத்தின் பின்னர் இதே போன்றதொரு கண் பரிசோதனையைச் செய்யுமாறு கேட்டுக்கொள்ளப்படுவீர்.

● குறிப்பு - இங்கு நீரிழிவு கண் தொடர்பாக மாத்திரமே பரிசோதிக்கப்படும். உங்களுக்கு வேறு ஏதாவது கண் தொடர்பான பிரச்சினைகள் இருப்பின் வேறு கண் பரிசோதனைகளுக்கு செல்லவேண்டும் என்பதனை கருத்திற் கொள்ளவும்.

கண்
பரிசோதனைக்கு செல்வதற்கு பின்பற்றவேண்டிய படிமுறைகள்

● தேசிய கண் வைத்தியசாலையில் நீரிழிவுக் கண் நோய்க்கான சகலவித முன்னேற்றமான பரிசோதனைகளுக்கும் சிகிச்சைகளுக்குமான வசதிகள் இலவசமாக செய்து கொடுக்கப்படுகின்றது.

● நீரிழிவுகண் நோய் தொடர்பாக தேர்ச்சிபெற்ற வைத்தியர்களால் அங்கு சிகிச்சையளிக்கப்படும்.

கண் மருத்துவ பரிசோதனை பிரிவிற்கு செல்வதற்கு பின்வரும் வரைபடத்தை பயன்படுத்தவும்

கண்களை பரிசோதித்த பின்னர் நீங்கள் என்ன செய்யவேண்டும்?

கொழும்பு, தேசிய கண் வைத்தியசாலையின் கம் இலக்க வாயிற் கதவினால் உள்ளே வந்து வெளி நோயாளருக்கான இலக்கம் வழங்கப்படும் விசாரணைக் கூடத்திற்கு செல்லவும்

அங்கு உங்களுடைய பெயர், வயது,விலாசம் போன்ற தகவல்களை வழங்கி வெளிநோயாளர் பிரிவின் மருத்துவ சீட்டைப் பெறவேண்டும்

பின்னர் 10ம் இலக்க அறையில் கண் பார்வையினை பரிசோதித்துக்-கொள்ளவும்

பார்வையை பரிசோதித்த பின்னர் உங்கள் வெளிநோயாளர் இலக்கத்தின்படி உரிய கண் மருத்துவ பரிசோதனைக்கு அனுப்பப்படுவீர்கள்.

● பின்னர்அடுத்தகட்ட செயற்பாடுகளுக்காகவும் திட்டமிடலுக்காகவும் கண் வைத்தியர் அறிவுறுத்தல்களை வழங்குவார்.

அடுத்த முறை வரும்போது பின்வருவனவற்றை நினைவில் வைத்துக்கொள்ளுங்கள்

● நீங்கள் அணியும் மூக்குக்கண்ணாடி, கண் வில்லை, மற்றும் அதற்காக பயன்படுத்தும் திரவம் என்பவற்றை எடுத்து வரவும்

● அடுத்த சந்திப்பிற்கு வரும்போது இன்னொருவரையும் துணைக்கு அழைத்து வரும்படி கேட்கப்படலாம்

● கண் சொட்டுமருந்தினால் வைத்திய சந்திப்பின் பின்னரும் பார்வை சில மணிநேரம் பாதிக்கப்படலாம். எனவே வாகனம் செலுத்தவோ, மோட்டார் சைக்கிள், முச்சக்கரவண்டி ஓட்டவோ கூடாது.

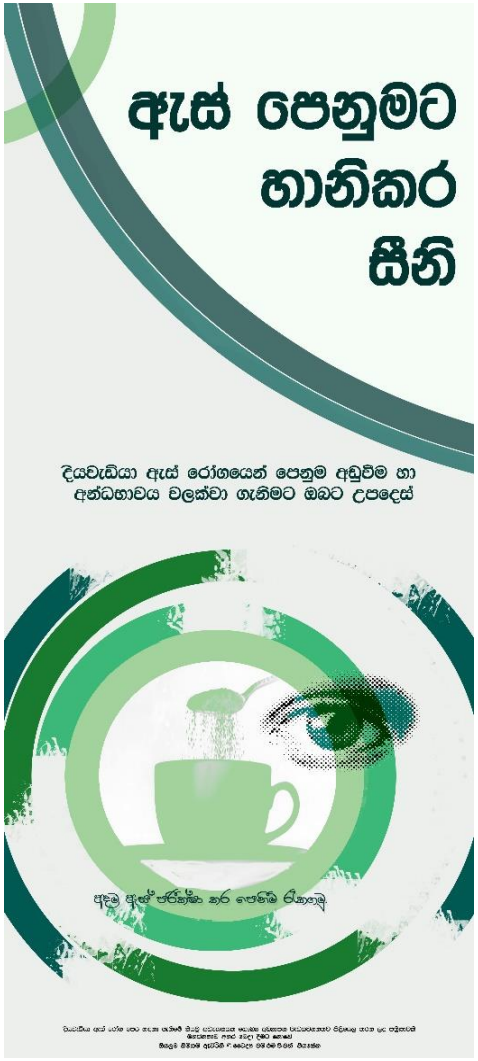
● நீங்கள் வைத்தியசாலையை விட்டு வெளியேறுவதற்கு முன்னர் அடுத்தகட்ட நடவடிக்கைகள் தொடர்பாக கண் வைத்தியரிடம் தெளிவாக கேட்டு தெரிந்து கொள்ளவேண்டும்.

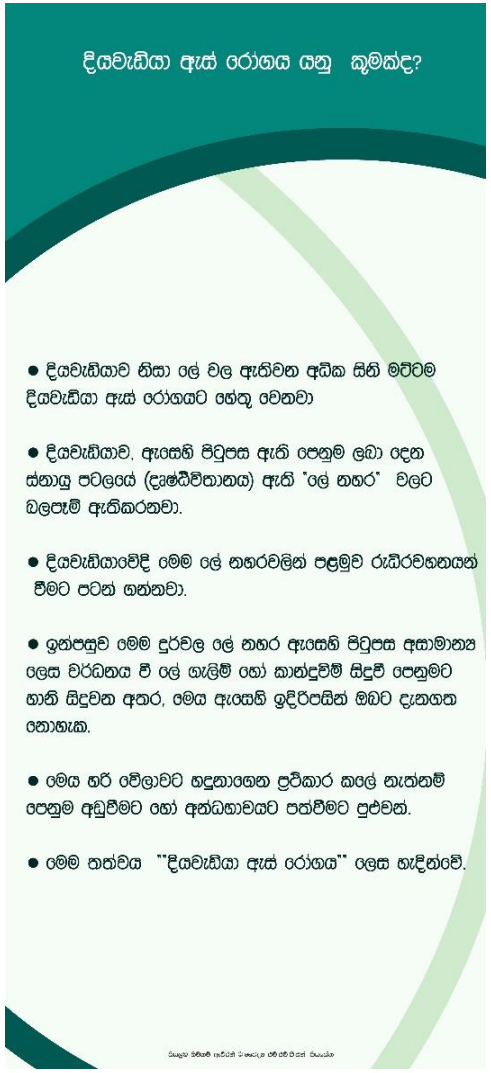
● இங்கு மீண்டும் வர வேண்டியதிகதி, நேரம் மற்றும் அறையின் இலக்கம் என்பவற்றை இதன் மறுபக்கத்தில் குறித்துக்கொள்ளவும்

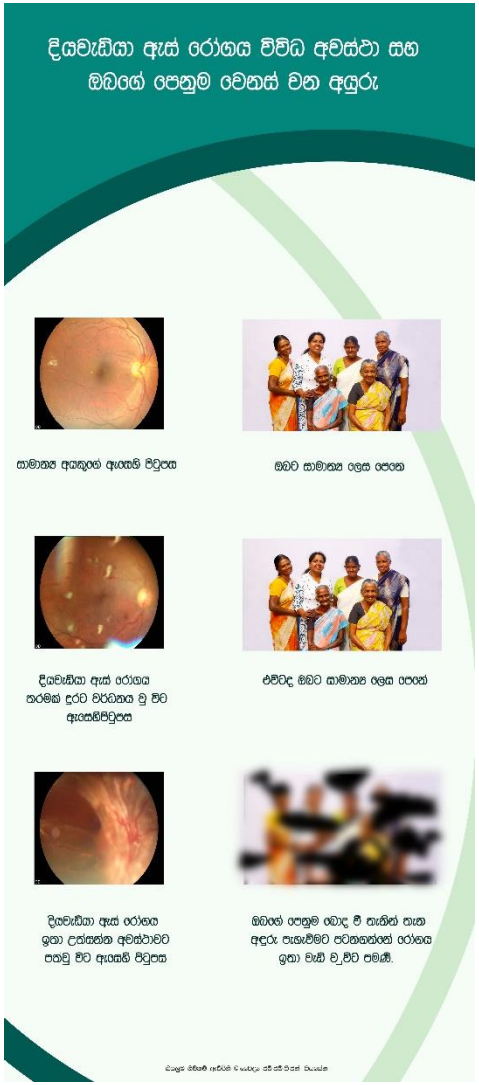
● மீண்டும் கண் மருத்துவ பரிசோதனைக்கு வரும் போது உங்கள் மருத்துவகுறிப்பு,கடந்தமருத்துவ பரிசோதனை அறிக்கைகள் என்பவற்றை எடுத்துவரவும்

திகதி	வைத்தியசாலையின் பெயர்	அறை இலக்கம்

Leaflet - Sinhala medium







ඇසේ සුදු ඉවත්කිරීමේ සැත්කම් හා ඇස් කණ්ණාඩි මඟින් දියවැඩියා ඇස් රෝගය වලක්වා ගත හැකිද?

- දියවැඩියා ඇස් රෝගය, ඇසෙහි සුදු හෝ කණ්ණාඩි පැළඳීම සමඟ පටලවා නොගත යුතුය.
- අප කණ්ණාඩි කුට්ටමක් පැළඳුවුයේ ඇසෙහි ඉදිරිපසින් ඇති කළු ඉංගිරියාවේ හෝ කාචයේ වෙනස්කම් මඟ හරවා ගැනීමටයි.
- සුදු ඉවත්කිරීමේ සැත්කම සිදුකරනු ලබන්නේ ඇසෙහි කාචය ඉණකම් වී විනිවිද නොපෙනෙන මට්ටමට පත්වූ විටයි.
- එමනිසා ඇසේ සුදු ඉවත්කිරීමේ සැත්කමින් හෝ කණ්ණාඩි මඟින් දියවැඩියා ඇස් රෝගය වලක්වා ගත නොහැකිය.
- එසේම බෙහෙත් බිංදු, අත් බෙහෙත්,ආදිය මඟින් දියවැඩියා ඇස් රෝග වලක්වා ගත නොහැකිය.
- එමනිසා ඔබ ඇසේ සුදු ඉවත්කිරීමේ සැත්කම් සිදුකල පසුවත්, ඇස්කණ්ණාඩි පැළඳීම සිදුකලත්, (වෙනත් ඇස් රෝග ප්‍රතිකාර සිදුකර ඇතත්) දියවැඩියා ඇස් රෝගය පෙර හඳුනා ගැනීමේ පරීක්ෂාවට සහභාගී විය යුතු වේ.

දියවැඩියා ඇස් රෝගය පෙර හඳුනා ගැනීමේ පරීක්ෂණයට මුල් අවස්ථාවේදී ක්‍රමවත්ව සහභාගිවීමේ ඇති වැදගත්කම කුමක්ද?

- දියවැඩියා ඇස් රෝගය ප්‍රධාන ලක්ෂණයක් වන්නේ, මුල් අවස්ථාවලදී කිසිදු රෝග ලක්ෂණයක් නොපෙන්වීමයි.
- පෙර හඳුනාගැනීමේදී ඇස් පරීක්ෂාවක් මඟින් ඔබ රෝග ලක්ෂණ දැන ගැනීමට පෙර රෝගය හඳුනා ගතහැකිවේ.
- මෙම වෙනස්කම් කල්තියා හඳුනාගෙන ප්‍රතිකාර කළහොත්, එය සාර්ථක වන අතර එමඟින් පෙනුම අඩුවීම හෝ අන්ධභාවය වලක්වා ගත හැකිවේ.
- එමනිසා ක්‍රමානුකූලව ඇස් පරීක්ෂා කිරීම ඉතා වැදගත්වේ.

වෛද්‍ය සායනයේදී ඔබගේ ඇස් පරීක්ෂා කරන්නේ කෙසේද?

- ඔබගේ වෛද්‍යවරයා විසින් විශේෂිත කැමරාවක් මඟින් දියවැඩියා ඇස් රෝගය පරීක්ෂාකරනු ඇත.

- එහිදී ඇසෙහි ඇතුලත පිටුපස හොඳින් පරීක්ෂා කිරීමට ඇසට බිංදු දමනු ලැබේ.
- ඇසට බිංදු දැමීමෙන් පසුව ඔබට සුළු අපහසුතා ඇතිවුවද, එමබිංදු වල ක්‍රියාකාරිත්වය පැය කිහිපයකින් පහවයන බැවින්, ඔබ ඒ සදහා බිය විය යුතු නැත.

වෛද්‍ය සායනයේදී ඇස් පරීක්ෂාවෙන් පසුව ඔබ සිදුකළයුත්තේ කුමක්ද?

- දියවැඩියා ඇස් රෝග පරීක්ෂාවේ ප්‍රථිඵල වෛද්‍යවරයා විසින් පවසනු ඇත.
- එම පරීක්ෂාවෙන් පසුව ඔබට දියවැඩියා ඇස් රෝග ලක්ෂණ ඇත්නම් වැඩිදුර පරීක්ෂාවක් සඳහා කොළඹ ජාතික අක්ෂි රෝහල වෙත යොමුකරනු ලැබේ.

එසේ නැතහොත්,

- එහිදී ඔබට දියවැඩියා ඇස් රෝග ලක්ෂණ දැනට නොමැතිනම් හෝ මෙම අවස්ථාවේ ඔබට ඇත්තේ සුළු රෝග ලක්ෂණ පමණක් නම් වසරකින් නැවත ඇස් පරීක්ෂා කළයුතු බව දනවනු ලැබේ.
- මෙහිදී දියවැඩියා ඇස් රෝගය සඳහා පමණක් පරීක්ෂා කරන බැවින් වෙනත් ඇස් රෝග ඇත්නම්, ඒ සඳහා අදාල සායනය වලට සහභාගී වියයුතු බව සලකන්න.

අක්ෂි සායනය වෙත යාමට අනුගමනය කළයුතු පියවර:

- කොළඹ ජාතික අක්ෂි රෝහලේ මෙම දියවැඩියා ඇස් රෝගය සඳහා අවශ්‍ය නවීනතම පරීක්ෂණ හා ප්‍රතිකාර ක්‍රම ඇත.
- දියවැඩියා ඇස් රෝගය සඳහා විශේෂඥ වෛද්‍යවරු විසින් එහිදී ඔබට ප්‍රතිකාර කරනු ඇත.

අක්ෂි සායනයට යාම සඳහා පහත මාර්ග සටහන අනුගමනය කරන්න.

අක්ෂි සායනය ඔබ සිදු කළයුත්තේ කුමක්ද?

ගේට්ටු අංක 4න් ඇස් රෝහලට ඇතුළු වී OPD/ඔපීඩී අංක නිකුත් කරන කවුළුව වෙත යන්න.

එහිදී ඔබගේ නම,ගම වයස විස්තර ලබා දී බාහිර රෝගී අංශයේ සායනික තුණ්ඩුවක් ලබා ගන්න.

ඉන්පසු මූලික පෙනුම පරීක්ෂා කරන කාමර අංක(10) වෙත යන්න.

පෙනීම පරීක්ෂා කළ පසුව ඔබගේ අංකයේ අනුපිළිවෙල අනුව අදාල අක්ෂි සායනය වෙත යොමුකරනු ඇත.

- ඉන්පසුව අක්ෂි වෛද්‍යවරයා විසින් ඉදිරියට ගත යුතු පියවර හා ප්‍රතිකාර පිළිබඳව ඔබට උපදෙස් ලබාදෙනු ඇත.

ඔබ නැවත ඇස් පරීක්ෂාවට හෝ වැඩිදුර පරීක්ෂා/ප්‍රතිකාරවලට පැමිණෙන විට මතක තබා ගත යුතු කරුණු

- ඔබ කණ්ණාඩි පාවිච්චි කරන්නේ නම් කණ්නාඩි කූට්ටම හෝ සිවි කාව පාවිච්චි කරන්නේ නම් සිවි කාව සහ අදාල දියරය රැගෙන එමට මතක තබාගන්න.

- තවත් අයකු සමග පැමිණෙන ලෙස උපදෙස් දුන් විට ඒ අනුව ක්‍රියාකරන්න.

- ඇසට දියර බිංදු දැම්මෙන් පසු පැය කිහිපයක් යනතුරු සුළු වොද වීමක් ඇතිවන බැවින් රිය පැදවීම/ බයිසිකල්/ත්‍රී රෝද පැදවීම සිදුනොකළ යුතුයි.

- රෝහලෙන් පිටවීමට පෙර ඉදිරි පියවර පිළිබඳව අක්ෂි වෛද්‍යවරයාගෙන් පැහැදිලිව අසා දැනගත යුතුයි.

- මෙහිදී නැවත පැමිණිය යුතු දිනය, වේලාව,කාමර අංකය,පිටුපස පිටුවෙහි සටහන් කරගන්න.

- ඊළඟට සායනයට පැමිණෙන විට ඔබගේ සායන තුණ්ඩුවේ අංකය,පසුගිය ඇස් පරීක්ෂණ වාර්තා ගෙන එමට මතක තබා ගන්න.

දිනය	රෝහලේ නම	සායන කාමර අංකය

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To-Mapa Mudiyanselage Prabhath Nishantha Piyasena

London School of Hygiene and Tropical Medicine - UK

Thesis Title - A Feasibility Study to Develop an Integrated Diabetic Retinopathy Screening Programme in the Western Province of Sri Lanka

I/We agree that our work indicated below as an adviser / co-supervisor / local investigator / co-reviewer of this project work can be included in its/their submitted/published format in your thesis.

Title of the Article	Name	Date	Sign
1.Systematic Review on Barriers and Facilitators for Access to Diabetic Retinopathy Screening Services in Different Income Setting - PLoS ONE. 2019;14(4): e0198979. https://doi.org/10.1371/journal.pone.0198979	Jennifer L.Y. Yip	19th March 2019	[redacted]
	Clare Gilbert	08th March 2019	
	Maria Zuurmond	11th March 2019	
	Tunde Peto	08th March 2019	
	Iris Gordon	08th March 2019	
	Suwin Hewage	09th March 2019	
	Sureshkumar Kamalakannan	08th March 2019	

2.Systematic Review and Meta-Analysis of Diagnostic Accuracy of Detection of Any Level of Diabetic Retinopathy Using Digital Retinal Imaging. BMC Systematic Reviews 2018. 7:18 https://doi.org/10.1186/s13643-018-0846-y.	Jennifer L.Y. Yip	19th March 2019	[redacted]
	Clare Gilbert	08th March 2019	
	Tunde Peto	08th March 2019	
	Iris Gordon	08th March 2019	
	Suwin Hewage	09th March 2019	
	Sureshkumar Kamalakannan	08th March 2019	
3.A Qualitative Study on Barriers and Enablers to Uptake of Diabetic Retinopathy Screening by People with Diabetes in the Western Province of Sri Lanka. BMC-Tropical Medicine and Health. 201947:34. PMCID: PMC6525343 DOI: 10.1186/s41182-019-0160-y	Jennifer L.Y. Yip	19th March 2019	
	Clare Gilbert	8th March 2019	
	Tunde Peto	08th March 2019	
	Mahesh Premarathna	11th Dec 2018	
	Maria Zuurmond	11th March 2019	
4.Service Providers' Perspectives on Barriers and Enablers to Provision of Diabetic Retinopathy Screening Services in the Western Province of Sri Lanka (Submitted and reviewed - BMC Health Services Research)	Jennifer L.Y. Yip	19th March 2019	
	Clare Gilbert	08th March 2019	
	Maria Zuurmond	11th March 2019	
5.Development and Validation of a Diabetic Retinopathy Screening Intervention Using a Hand Held Non-Mydriatic Digital Retinal Camera	Jennifer L.Y. Yip	19th March 2019	

by Physician Graders at a Tertiary Level Medical Clinic - Protocol for a Validation Study. JMIR Res Protoc 2018;7(12): e10900. DOI: 10.2196/10900. PMID: 30530458. PMCID: 6305894.	Clare Gilbert	08th March 2019	[redacted]
	David MacLeod	11th March 2019	
	Tunde Peto	08th March 2019	
	Charith Fonseka	03rd Dec 2018	
	Aruna Kulatunga	[redacted]	
	Kapila Banduthilake	03rd Dec 2018	
	Mangala Dhanapala	03rd Dec 2018	
	D.M.H.N.Dassanayaka	03rd Dec 2018	
	Lalani Pathirana	[redacted]	
6.Diagnostic Test Accuracy of Diabetic Retinopathy Screening by Physician Graders Using a Hand Held Non-Mydriatic Retinal Camera at a Tertiary Level Medical Clinic. BMC-Ophthalmology. 2019;19(1):89 PMID: 30961576 PMCID: PMC6454614 DOI: 10.1186/s12886-019-1092-3	Jennifer L.Y. Yip	19th March 2019	
	David MacLeod	11th March 2019	
	Min Kim	11th March 2019	
7. Process of adaptation, development and assessment of acceptability of a health educational intervention to improve referral uptake by people with diabetes in Sri Lanka. BMC-Public Health. 2019; 19: 614. doi: 10.1186/s12889-019-6880-4. PMID: 31113393	Jennifer L.Y. Yip	19th March 2019	
	Maria Zuurmond	11th March 2019	

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