INVESTIGATING THE MEDIUM TO LONG TERM SUSTAINABILITY OF AN INTERVENTION TO IMPROVE CARE FOR HYPERTENSION AND DIABETES WITHIN THE PRIMARY HEALTH CARE SETTING IN UGANDA (MELOHAND)

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Title: Investigating the Medium to Long Term Sustainability of an Intervention to Improve Care for Hypertension and Diabetes within the Primary Health Care Setting in Uganda (MeLoHanD).

David Katende

Statement of own work

I, David Katende, confirm that the work presented in this thesis is my own. Wherein, information has been derived from other sources; I confirm that this has been indicated in the thesis.

Signed: [redacted] Date: 29th May 2024

Abstract

Introduction

Although some interventions on non-communicable diseases (NCDs) have been evaluated in sub-Saharan Africa, little is known about their medium to long term sustainability beyond the end of funding.

A cluster randomised trial of a health system intervention to improve NCD care was conducted between 2013 and 2016 in 38 primary care and 6 referral health facilities (HFs) each in Tanzania and Uganda, focusing on hypertension (HT) and type-2 diabetes mellitus (DM). It involved a combination intervention which the trial showed to be highly effective in improving HT AND DM service readiness and quality of care.

This PhD research aimed to assess the sustainability of the intervention at 22 HFs (19 lower-level units that constituted the original intervention arm and 3 referral facilities that also received the intervention) in Uganda, 4 years after the end of the trial.

Methods

This PhD study compared i) the health facility performance (FPS) in terms of health worker knowledge, service availability and readiness (SAR), using a modified WHO SARA tool and, ii) the patient quality-of-care and experience (QoCE) according to national guidelines using a previously validated tool. Cross-sectional data from the original trial (2016) and this study (2020) were compared. Using a pair-matched approach, FPS and QoCE summary scores were compared. Linear regression and random effects Tobit regression models were also analysed.

Additionally, iii) the current capacity and practice to sustain ongoing intervention activities for HT and DM care in these facilities was also assessed in 2020. Through a cross sectional survey, 4 pre-defined domains *(i.e., cognitive participation, coherence, collective action, and reflexive monitoring* were examined with regards to health worker (HW) normalization and 8 pre-defined domains for intervention sustainability *(i.e., organisational capacity, local environment, funding stability, partnerships, communication, evaluation, adaptation, and strategic planning)*, using the normalisation tool and the program sustainability tool (PSAT).

Results

The mean aggregate facility performance (FPS) in 2020 was lower than in 2016: 70.2 (95%CI= 66.0-74.5) vs. 74.8 (95%CI=71.3-78.3) respectively, with no evidence of a significant difference (p=0.18). Mean scores declined in 4 of 5 SAR elements. Only the *availability of guidelines and quality of records* showed some improvement [9.1 (95%CI: 8.2,9.9) (2016) vs 9.7 (95%CI: 9.5,10.6 (2020)]. No exposure independently predicted FPS although patient club functionality was very weakly associated (p=0.09).

QoCE declined slightly to 8.7 (95%CI=8.4-9.1) in 2020 vs 9.5 (95%CI=9.1-9.9) in 2016 (p=0.02) while the proportion of patients receiving adequate quality care also declined slightly to 88.2% from 98.5% respectively, and with no statistical difference (p=0.20). Only the parent district weakly predicted QoCE (p=0.05).

Overall normalization strength was adequate at 4.0 (IQR: 3.8, 4.2) of a possible 5 with no evidence of association with HF level (p=0.40); *cognitive participation* (buy-in) and *reflexive monitoring* (appraisal) were strongest at >4 across all HF levels. All HF levels were also weak (<4) on *collective action* (teamwork) and *coherence* (sense-making); Only collective action differed by level (p<0.002).

Overall intervention sustainability was suboptimal at 3.1 [IQR 1.9,4.1]) of a possible 7 with weak scores on *funding stability* (2.0), supportive *partnerships* (2.2), and *strategic planning* (2.6). Domain differences by facility level were significant for *environmental support* (p=0.02) and *capacity in organisation* (p=0.01). Adequate strength at a mean cut-off of ≥5 did not differ by facility level for any domain.

Conclusions

Four years after the end of research-related support, both service availability and readiness and quality of HT/DM care were surprisingly well preserved. Practice-dependent intervention elements e.g., local organisational context, HW knowledge or dedication (buy-in) were sustained, but external elements e.g., new funding support or attracting new partners to sustain intervention efforts were not sustained.

Sustainability or durability of an HT AND DM intervention in similar primary care settings may remain achievable even with the funding instability and logistical challenges following a research trial's end. Earlier on in the intervention process, health managers and implementors should plan how to sustain any achievements.

Acknowledgements

I would like to thank the UK Medical Research Council (MRC) through the NCD capacity building grant at the Medical Research Council/Uganda Virus Research Institute MRC/UVRI and the London School of Hygiene & Tropical Medicine (LSHTM) Uganda Research Unit (MUL) for funding my PhD and research.

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I dedicate this PhD to the living memories of my late father James Mukungu Sebana and adopted late father Christopher Herbert Nantagya.

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Abbreviations and Glossary

CBO	Community Based Organisation
CD(s)	Chronic Disease(s)
CI	Confidence Interval (usually 95%)
DHO	District Health Office(r)
DM	Diabetes Mellitus
EACDRP	EACDRP – East African Chronic Disease Research Project
FPS	Facility Performance Score(s)
HC	Health Centre (Is, IIs, IIIs, IVs or 1, 2, 3, 4 levels)
HF(s)	Health Facilities
HIV	Human Immuno-deficiency Virus
HSCDP	Health Systems Chronic Disease Project
HS	Health System(s)
HT	Hypertension
HW(s)	Health Workers / Healthcare Workers
IQR	Interquartile Range
LSHTM	London School of Hygiene and Tropical Medicine
LMICs	Low- and Middle-Income Countries
MeLoHanD	Medium to Long term sustainability to improve management of Hypertension and Diabetes within the primary care setting in Uganda
MCH	Maternal and Child Health
MoH	Ministry of Health (Uganda)
MRC	Medical Research Council
NCD(s)	Non-communicable Diseases
NGO	Non-governmental Organisation
NMS	National Medical Stores
NPT	Normalisation Process Theory
UDA	Uganda Diabetic Association - the national diabetic association
PI	Principal Investigator
PSAT	Program Sustainability and Assessment Tool
UVRI	Uganda Virus Research Institute
SAR(A)	Service Availability and Readiness Assessment
SSA	Sub-Saharan Africa
SD	Standard deviation
QoC(E)	Quality of Care (and Experience)
VHT(s)	Village Health Team(s)

Chapter 1: Background

1.1. Introduction

Non-communicable diseases were predicted to account for over 70% of all disease burden in the developing countries in 2020 from just under 50% in 1990 (2). The current burden of non-communicable diseases (NCDs) accounts for 71% of all global deaths (41 million people) each year (3). Annually, 15 million NCD deaths occur between 30 and 69 years and over 85% of these "premature" deaths occur in Low- and Middle- Income Countries (LMICs) including Uganda (3). In sub-Saharan Africa, the all-age total disability-adjusted-life-years (DALYs) due to NCDs increased by 67% between 1990 and 2017 reflecting an increase in the proportion of total DALYs attributable to NCDs (from 19 to 30% of the total burden). Most of this increase can be explained by population growth and ageing (3).

As these countries undergo this epidemiological transition within a health system largely fashioned on addressing communicable diseases to one that now must continue to address infections like malaria, HIV/AIDS, or tuberculosis (TB) while also facing an increasing burden of chronic non-communicable diseases; the already limited resources available to them then become severely constrained. As a result of this resource mismatch, curative services are often prioritised over preventive ones due to the urgency of care. In LMICs, many NCDs including most cases of hypertension go unnoticed and are not seen at health services due to little to no active case finding for them (4)(5).

In Uganda, 31% of deaths in Uganda (2019) were due to non-communicable diseases and injuries (NCDIs) compared with 14% in 1990 (3) and 2022 estimates put this at 34% (2). Based on literature search, population studies, facility reporting, and modeled estimations, in 2017, 37% of all DALYs and 41% of all deaths in Uganda were due to NCDIs, and this indicates that the relative burden of NCDs has also doubled over the past two decades (UINCD Report 2015-2020)(6). About 60% of all DALYs due to NCDs are estimated to occur before the age of 40 (UINCD Report 2015-2020)(6).

Wesonga et al (2016), in a national STEPS survey estimated the prevalence of 1 or more modifiable NCD risk factors at over 94% indicating that NCDs in Uganda may be largely preventable (7). 58% of all recorded deaths in a community-based cohort occurred outside of a health facility, the proportion was highest for those dying from NCDs (69.6%)(8). However, even

among those that find their way to health facilities early enough the majority present to higher level facilities as their first point of call (4, 5) as lower-level facilities are often little prepared as a result of an untrained (4) or poorly motivated or routinely absent health workforce (6, 7), lack of basic equipment and drugs (4), inappropriate referrals (4) and little to no support supervision (4) or observance of standard treatment guidelines (4). This is often confounded by a lack of a national NCD policy (8) and little public awareness of the problem (9).

Although a call to global action has been taken since the UN General Assembly (UNGASS) resolutions on NCDs control and prevention in 2011 (10) there is still limited domestic and global investment to address NCDs and this response to NCDs among the poorest countries also requires addressing essential poverty and integrated health service delivery strategies (10, 11) which means there is need to complement the existing UN/WHO agenda that mainly seeks to prevent behavioral risk factors and associated disease conditions.

Consequently, at the same UNGASS meeting heads of states committed to both NCD prevention and improvement of services but follow up UN meetings have showed that these improvements have been slow (12).

Uganda has made some efforts towards establishing an NCD platform. These efforts have included establishing a full-fledged NCD department at the Ministry of Health (MoH), instituting a national NCD policy (13, 14), and constituting a technical working group that advises on NCD policies in a broad and multisectoral way on NCD risk reduction, creating awareness and public and private sector screening for NCDs. However, these efforts remain hampered by inadequate public sector funding for NCDs (15) which has elevated the role of external partners in shaping the development and implementation of NCD policies and programs in Uganda (11). Also the sub-optimal recruitment of technical experts and managers for NCDs at the MoH has been a barrier to the effective coordination and communication across multiple governmental and non-governmental platforms in the NCD arena (11). The same applies at the lower district health team level where most NCD focal technical persons are usually co-opted from other existing platforms such as the HIV or TB district focal persons rather than recruiting a dedicated individual. A national non-communicable diseases and injuries commission which is a public-private sector partnership was established in 2019 to help bridge this gap in expertise at national level. However, the glaring gaps at the primary care level as outlined previously remain.

Although several research-driven interventions within primary care settings aimed at improving care for non-communicable diseases have been reported in sub-Saharan Africa (SSA) (16); the majority of these have been either clinic-based or community-based with components of training and capacity building (or task shifting) embedded within (17-19). Although the short-term effectiveness or immediate sustainability of these interventions has also been widely reported; however, little is known about their medium to long term effectiveness over 2-5 years after the intervention. This lack of information on longer term sustainability may be in part because the post-intervention scale-up is not robust enough to document the health system (HS) processes and health outcomes of interest, as the funding is often limited in the post-intervention period. Critically understanding to what extent this impact on sustainability has been, may help address what essential processes research-driven interventions may need to include in their designs and whether these processes could deliver on the expected health outcomes and health policy changes in a sustainable way at the primary care level. Additionally, as part of the East African Chronic Disease Research Project (EACDRP), although several NCDs were evaluated in the earlier preparatory studies only HT and DM were intervened upon as part of the randomised trial implementation and subsequent evaluation. These two conditions were found to have a high burden and were also strategically important to the region (1, 4, 20, 21).

This was what inspired this PhD research as I geared up to investigating the **Me**dium to **Lo**ng term sustainability of an intervention to improve care for **H**ypertension **an**d **D**iabetes within the primary health care setting in Uganda (**MeLoHanD**).

1.2. Role of the candidate

1.2.1. My specific role in previous work leading up to this research question

I have been involved in preparatory studies to establish the burden of NCDs in Uganda under the East African Chronic Disease Research Project (EACDRP) as the Uganda survey team leader for the population and health facility survey whose findings have been published in a paper by Kavishe and Biraro et al, 2013 (20). It was estimated that the prevalence for HT and DM was 19-26% and 2-4% within Wakiso and Mpigi districts (Figure 1) respectively and these findings have

since been confirmed by Guwatudde et al, 2015 (22) and Bahendeka et al,2016 (23) in a national STEPS survey.

As part of that preparatory work, I also led the Uganda team in a survey assessing the readiness of primary care facilities for this increasing burden of NCDs, DM and HT particularly. Lower-level units were little prepared to manage NCDs while most DM and HT patients were being seen at higher-level units or hospitals. Lower-level units were also ill-equipped even with essential NCD drugs and basic diagnostic equipment and health workers at this level also lacked the knowledge and experience to manage these conditions (4). Similar findings have later been documented at national level (5), (24).

Arising out of these earlier findings, a health systems intervention to improve NCD services at the primary care level, was designed, and evaluated through a randomised controlled trial conducted from 2013 to 2016 in Uganda and Tanzania (the EACDRP trial) (1) (Appendix G). This combination intervention consisted of a package of key strategic elements such as improved screening for HT AND DMs, health worker (HW) training, provision of essential HT AND DM medicines and guidelines and support supervision (**Table 2**). I was the research coordinator of the EACDRP trial in Uganda.

My specific roles in the EACDRP research project and the trial included:

As a study team leader with the earlier preparatory studies,

- Provide intellectual input to conduct of the study, analysis of data, interpretation and write up of results.
- Providing clinical oversight to survey participants.
- Supervision of other team members in the performance of the preparatory surveys.
- Data quality control and assurance e.g., doing consistency and range checks
- Liaising with community leaders to plan home visits.
- Tracking field consumables.
- Tracking reviewing and interpreting laboratory results from the population survey.

As a study co-ordinator with the intervention roll-out and evaluation,

- Participating in the generation, development and review of the study protocol and other study materials e.g., source documents, SOPs, consent forms

- Collating the study protocols (specifically, refining the evaluation protocol).
- Refining and profiling the study budgets.
- Obtaining scientific and ethical approvals for the main trial and other related sub-studies.
- Coordinating a multi-disciplinary team that included a survey team, costing team, and a social science team
- Helping to facilitate the involvement of partner institutions and collaborators with the project e.g., collaborating academic institutions, MOH, district health teams, hospital teams
- Contributing to the Identification and recruitment of suitable study teams for both the intervention and evaluation
- Coordinating and conducting study specific trainings
- Overseeing logistical and administrative needs that support scientific outputs e.g., financial, transport, or laboratory
- Contributing to the writing of briefs and progress reports for various stakeholders/collaborators – (synopses, progress reports)
- Ensuring timely and accurate collection of data for research purposes through routine data checks for completeness and accuracy
- Supervising other study team members e.g., doctors, nurses, field workers
- Participating in writing study report and manuscripts for peer reviewed publication
- Preparing and presenting oral/poster presentations on behalf of the project.

1.2.2. My role in the current work

As the principal investigator, I have developed the original research concept of this PhD project (MeLoHanD) and refined it with guidance from HG, MJN and KB as well as input from my advisory committee. I obtained the necessary ethical approvals, recruited, and trained study staff, secured the collaboration of health care providers and other stakeholders. I revised and updated the old study tools as well as developed the new study tools, supervised data collection and entry, and was responsible for overseeing the data management. I also developed the data analysis plan (Appendix B) with the support of KB, MJN and HG. I performed all the analyses under the supervision of KB, MJN and HG.

For the manuscripts out of this work, I wrote the first drafts, got feedback from my supervisors HG, MJN and KB as well as other co-authors and submitted the final drafts for publication as corresponding author. For those papers reviewed or published at the time of submission of this thesis, I responded to reviewers' comments and revised the manuscripts as necessary.

1.3. Thesis structure

This thesis is organised in the 'research paper' style format. Chapter 1 provides background information, chapter 2-4 describes the general methods, and chapters 5-6 comprises final manuscripts that have been submitted to peer-reviewed journals and subsequently published. The manuscripts included:

- Katende, D., Kasamba, I., Sekitoleko, I. et al. Medium-to-long term sustainability of a health systems intervention to improve service readiness and quality of non-communicable disease (NCD) patient care and experience at primary care settings in Uganda. BMC Health Serv Res 23, 1022 (2023). https://doi.org/10.1186/s12913-023-09983-7

- Katende, D., Nalweyiso, N., Nabulime, G. et al. Sustainability capacity and health worker normalisation of a successful non-communicable disease (NCD) health systems intervention within primary care settings in Uganda: a quantitative approach to a qualitative question. BMC Health Serv Res 23, 970 (2023). https://doi.org/10.1186/s12913-023-09948-w

Chapter 7 gives work done as part of the MeLoHanD project that may not be immediately publishable but nonetheless gives useful background to this evaluation overall. It includes the role of patient clubs and findings from the stakeholder interviews on supervision and intervention implementation at the various levels of health care. On section 7.1 - my work on this section involved designing the data collections tools on patient club functionality, leading the interviews, analysing the data, and writing up. Gertrude Nabulime and Norah Nalweyiso as part of the MeLoHanD team helped me with documenting some of the non-study information, interviewing and write up. With Section 7.2, this section includes the qualitative work that was collected through guided stakeholder study-exit meetings and interviews with selected HF leaders by facility level as well as former intervention officers, district and MoH officials.
My work on this section involved designing data collections tools and interview guides, leading the interviews, preliminary analysis of transcribed interviews. I was assisted in this by a team

that included**:** Kevin Nakuya with interviewing, transcribing, analysing, and writing up; Gertrude Nabulime and Norah Nalweyiso with interviewing and writing up; and Flavia Zalwango with analysing and writing up.

Chapter 8 is a summary discussion of the main study findings, methodological strengths and challenges of this research project, some ongoing studies that are related to this work, and concluding remarks. The data collection tools, analysis plan, and ethics approvals are provided in the appendices.

1.4. Funding

This MeLoHanD PhD research project was jointly funded by the UK Medical Research Council (MRC) under the NCD capacity building grant (ANReP) through the MRC UVRI and LSHTM Uganda Research Unit (MUL) under MRC/UKRI Grant Reference Number: MC_UP_1204/16. The funds were provided through the MUL's training budget.

1.5. The HT AND DM intervention during the EACDRP trial: setting, components, and results

The East-African Chronic Disease Research Programme (EACDRP) involved a series of preparatory studies on the extent of chronic diseases (CDs) in Uganda and Tanzania (4, 21); the findings led to the development of an intervention and its evaluation through a cluster randomised trial (ISRCTN 27340385) (1) (Appendix G).

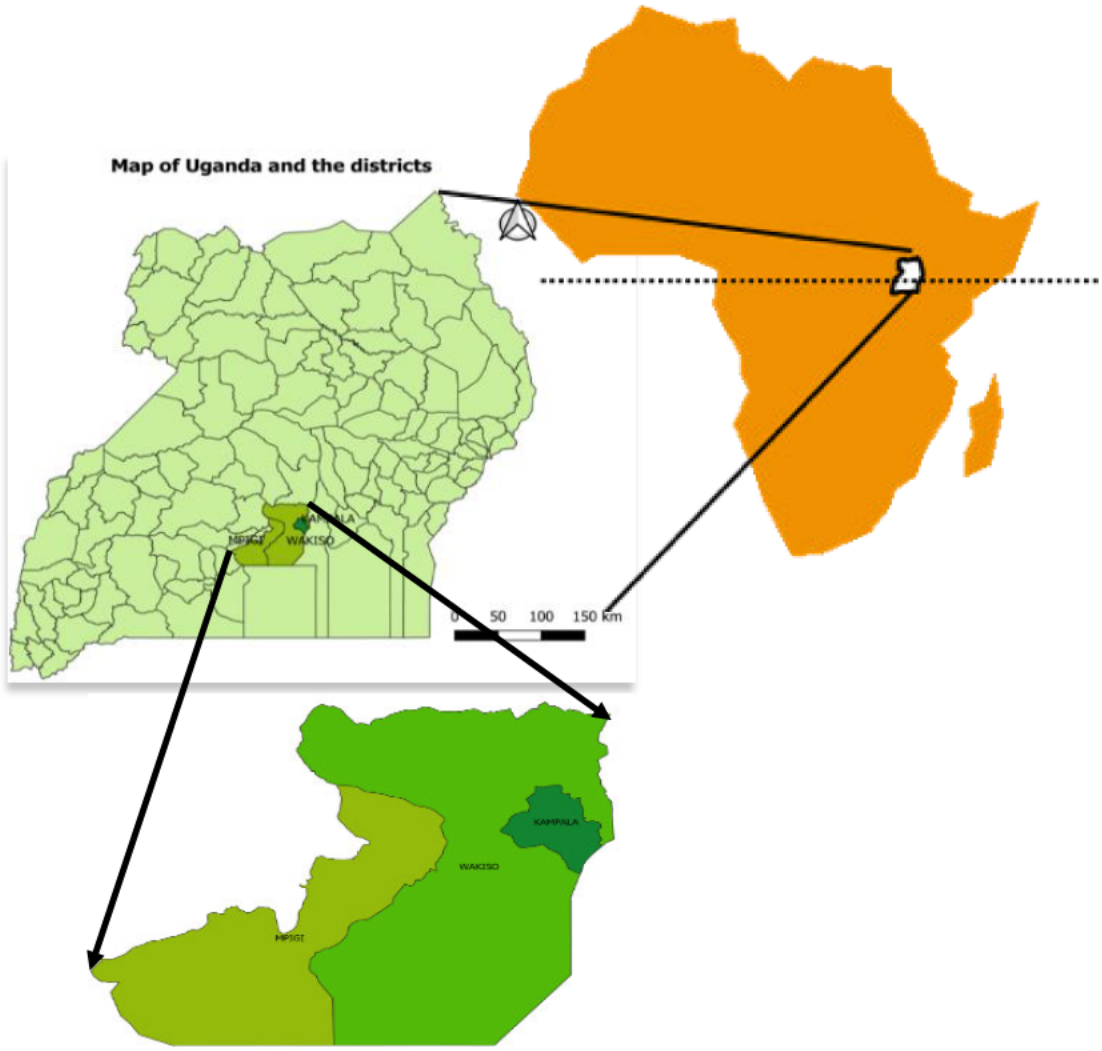

Figure 1 - Map showing the geographical location of the EACDRP trial districts within Uganda

Description of the public health facility structure in Uganda

The simplest fixed unit of the Uganda's public health structure is a health centre II or dispensary (HCII) at the village or parish level – this is usually manned by a nurse and only handles simple ailments and out-patient day care. Just above this with limited capacity for in-patient care and maternity unit is the health centre III (HCIII) at the sub-county level. This unit is overseen by a midwife or clinical officer (non-MD clinician). HCIIs and HCIIIs are usually overseen and supervised by the health centre IV (HCIV) and/or district hospitals at the county or district level – depending on district size – smaller districts usually have a HCIV doubling as the district hospital. HCIVs are headed by a medical doctor or public health specialist (**Table *1***).

Each district's health resource, staffing and infrastructure is overseen and supervised by the district health team headed by the district health officer (DHO) usually a public health specialist.

Each DHO reports to the MoH directly or indirectly through the line department e.g., the NCD department (**Table *1***).

Regional hospitals usually cover a region or several districts and mainly offer specialist services e.g., ophthalmic care. These are directly supervised by MoH (**Error! Reference source not found.**).

Private not-for-profit HFs e.g., faith-based hospitals are also usually supported by the district and MoH health teams and in tandem support public health activities within their catchment. They are also allocated a HF level structure like the public HFs basing on their catchment, infrastructure, and supervisory oversight.

Table 1 - Description of the levels of public health service delivery in Uganda

Health Facility Level[Ψ]	Political or Administrative Level	Catchment Target Population	Main Function or Infrastructural Requirement	Facility head/Supervisor* title and/or their educational background
Regional Hospital	Region or several districts	>2 million	General and specialist services e.g.,	Medical director (e.g., MD+MPH)
District Health Office	District	500,000 to 2 million	Resource distribution, staffing	DHO-er (e.g., MD+MPH)
District Hospital/HCIV	District or constituency	100,000 to 500,000	50-100 in-patient beds, general theatre,	Medical director (e.g., MD+/-MPH)
HCIII	Sub-county	30,000	10-20 in-patient beds, maternity unit, a simple	Non-MD clinician or Mid-wife
HCII	Parish or several villages	5,000 to 10,000	1–2 day-care beds, first line emergency and out-	Nurse
HCI	Village	1,000-5,000	Mobile outreach post	Nursing assistant or Health visitor

EACDRP trial setting

In Uganda, the EACDRP trial was implemented across 44 public and not-for-profit private primary care health facilities (HFs) at three levels of care (**Table *1***). These included 6 referral facilities (2 hospitals and 4 HCIVs) and 38 health centres (HCIIIs & HCIIs) in Wakiso and Mpigi districts (Figure 1 & Figure 2). The 38 HFs were randomly allocated (1:1) to the intervention and control arms. The 6 referral facilities were all received the intervention to maintain a referral linkage for all HFs. The trial was implemented between 2013-2016, with a 9–12-month piloting phase for honing and scaling up of the intervention in all participating health facilities.

The EACDRP trial aimed to test whether a combination intervention could improve the HS response to NCDs particularly HT and DM at different levels of care but with a focus on primary care settings. The combination intervention consisted of a package of key strategic elements

such as improved screening for HT and DM, health worker (HW) training, provision of essential HT and DM medicines and guidelines and support supervision (**Table 2**) (Figure 3).

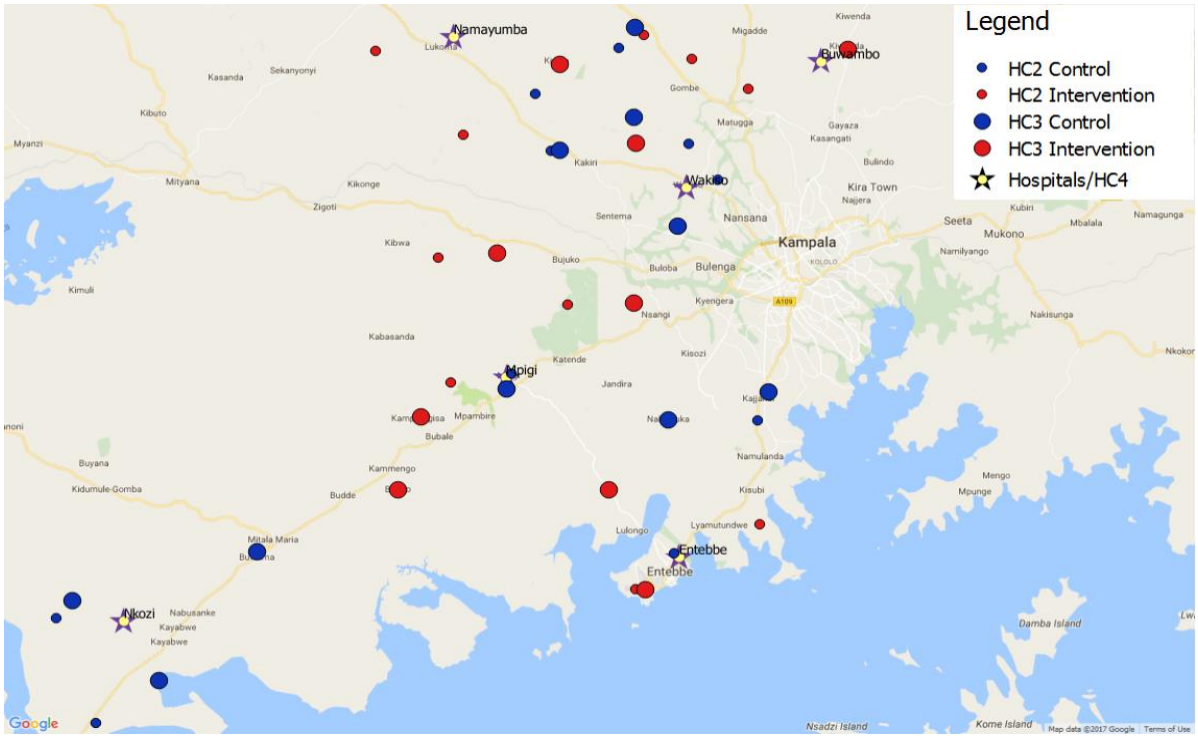

Figure 2 - Map showing distribution of intervention/control facilities of the EACDRP trial by health facility level in Uganda

Summary of the EACDRP trial (also see reference (1) and appendix G)

At the end of the trial in 2016, there was an evaluation to assess HF service readiness and quality of patient care. This was done through an inspection of each of the intervention and control facilities, a survey of HWs in each facility, and a survey of a random sample of 4 HT and DM patients in each facility. The surveys used standardised tools and questionnaires.

The EACDRP (also HSCDP in Uganda) trial demonstrated significant improvements in the HF's HT and DM service readiness in both countries, with large differences between intervention and control facilities in the availability of functional basic equipment e.g., BP machines, weight, and height measures (1) (**Table 4** and Appendix G).

Table 2 - Elements of the combination intervention package of the EACDRP trial

1. ***Improvement of chronic NCD services at lower-level health facilities (HFs) by strengthening their role as first contact for care and prevention of chronic NCDs, with a focus on HT and DM.***

   Lower-level health facilities are: HCIIIs & HCIIs in Uganda; HCs and dispensaries in Tanzania.
   NCD Services include:
   - Screening, diagnosis, treatment, patient monitoring, drug refills & health education.
   - Referral of cases with complications or non-response to available medications
   - Community outreach for screening and disease education where possible and feasible

2. ***Improvement of chronic NCD services at higher level facilities***
   Higher level facilities include hospital and, in Uganda, HCIVs
   NCD Services include:
   - primary care services for nearby communities as outlined in (1) above
   - referral care services for complicated cases from lower-level facilities

3. ***Training of health care workers (staff in outpatient departments of participating facilities)***
   Three-day training courses, conducted in conjunction with relevant departments in ministry of health (MoH) and district health teams and based on national NCD management guidelines, covering essential outpatient services with emphasis on acquisition of practical skills. Training materials and job aids adapted from national MoH and national diabetes associations.

4. ***Provision of treatment guidelines and job aids on HT and DM care,*** based on current national policies and endorsed by the MoH

5. ***Provision of essential medicines for HT and DM and establishment of a buffer medicine stock***
   A buffer stock would also be provided at the end of the evaluation to mitigate any stock shortfalls over a 9–12-month period as national and district responded to the new demands.

6. ***Provision of essential documentation for recording and reporting***
   such as chronic NCD registers and patient files, in line with guidelines from MoH and in collaboration with the national Diabetes Associations

7. ***Provision of essential equipment and consumables to participating health facilities.***
   these include nationally approved and available brands of sphygmomanometers, stethoscopes, weighing scales, glucometers, stadiometers, and thermometers as well as glucometer strips and urine dipsticks.

8. ***Improvement and institution of appropriate referral procedures***
   using simple referral and back-referral forms to facilitate these processes; back referrals were made for those stable patients that could be satisfactorily managed at a lower level.

9. ***Supervision and continued training***
   Visits to health facilities within 2 weeks of initial training by EACDRP staff, thereafter monthly visits conducted jointly with chronic diseases control officers from the district health team.

10. ***Facilitation and support of community outreach activities***
    using the opportunity of community outreach activities already conducted by health facility staff to incorporate focused health education on NCDs and HT and DM disease detection where feasible.

For example, the intervention resulted in significantly better HF performance scores (determined by a combination of the facility inspection score and HW knowledge on HT and DM). In both countries, the mean performance score in the intervention facilities was nearly double that in the control (74 vs 43 in Tanzania, and 81 vs 40 in Uganda) (1) (**Table *3***).

Table 3 - Intervention effect on overall HT and DM service readiness (mean score for physical inspection and HW knowledge)

Country	Intervention	Control	Adjusted mean difference	p value
	Mean (SE)	Mean (SE)		
Tanzania	74.0 (1.65)	42.5 (1.73)	31.5 (26.7 to 36.2)	<.0001
Uganda	80.5 (1.00)	39.7 (1.00)	40.9 (38.0 to 43.7)	<.0001

Apart from the main outcomes, the EACDRP trial period (2013-2016) in Uganda saw over 40,000 individuals screened for HT and DM in the intervention facilities. Of those screened, over 8000 patients with newly detected HT and DM were enrolled into care at these facilities, where over 250 HWs were trained in the management of uncomplicated HT and DM, using simple guidelines and algorithms.

Table 4 - Key results from the EACDRP trial

Improving the health systems response to chronic non-communicable diseases at primary care facilities in Uganda and Tanzania: results from a cluster-randomised controlled trial

ABSTRACT (from paper (1) submitted to BMC Medicine for review)

Introduction: Non-communicable diseases (NCDs), particularly hypertension (HT) and diabetes-II (DM), are increasing fast in sub-Saharan Africa. Primary care (PC) services are not well prepared to cope with this epidemic. Using a cluster-randomised trial, we tested a combination intervention to improve HT/DM service availability and readiness (SAR) and quality of care (QoC) at PC services in Tanzania and Uganda.
Methods: The intervention comprised health worker (HW) training and supervision; provision of guidelines, basic equipment, and medicines; improved referral guidelines, focusing on health centres (HCs) and dispensaries in Tanzania, and HCs-III and HCs-II in Uganda. 19 HCs and 18 dispensaries were randomised 1:1 in Tanzania & 20 HCs-III and 18 HCs-II in Uganda. Effectiveness was evaluated through cross-sectional surveys 2 years after intervention start, comparing intervention and control facilities against 2 co-primary outcomes, using pre-defined scoring criteria: (i) SAR, with 60% of possible points determined through facility inspection and 40% through HW knowledge tests. (ii) QoC received by 4 HT/DM patients per facility. Changes in service utilisation over time were documented.
Results: A total of 245 PC HWs were trained and 709 facility support supervision visits conducted. After 2 years, intervention HFs achieved an average of 77.0 (SD 6.2) on the SAR score compared with 41.1 (SD 7.6) in control HFs. 89% of intervention facilities reached a SAR score of >=70, but no control facilities. Intervention facilities were much more likely to have NCD guidelines and working equipment available and in use; and to have conducted health education and HT/DM case finding. 86% of HWs at intervention facilities scored ≥70 in knowledge tests on case scenarios vs. 63% of control HWs. An average of 63 HT/DM patients were seen per intervention facility in the quarter before the evaluation (control: 14 patients). For the QoC assessment, 248 HT/DM patients were reviewed. In intervention facilities, 93% of cases were adequately managed (i.e., total score≥7) vs. only 15% in control facilities (p<0.001). These large effects were observed in Tanzania and Uganda, and across low- and mid-level HFs.
Conclusion: The intervention package was highly effective in improving the response to NCDs at PC facilities.

Figure 3 - Picture collage showing different aspects to the HS intervention - staff training, basic equipment (stadiometer) installation and usage

Chapter 2: Literature review

2.1. NCD interventions within primary care settings in sub-Saharan Africa

There is an increasing burden of NCDs in SSA generally whilst the prevalence of infectious diseases is still substantial (25), (26); HS in SSA are not well prepared for this increasing NCD burden while weak at the primary care level (21), (4). In Uganda, hypertension (HT) and diabetes mellitus (DM) prevalence are estimated at 26% and 1%, respectively, in a recent National NCD STEPS survey (22) whereas prevalence in the central districts of Wakiso and Mpigi lies between 19-26% and 2-4% respectively (27). This increase in disease burden has created a new demand for NCD services at primary care facilities which have until recently only been structured to manage acute or infectious conditions (4).

Several research-driven interventions within primary care settings aimed at improving care for non-communicable diseases (NCDs) have been reported in sub-Saharan Africa (SSA) (16). The majority of these have been either clinic-based or community-based with components of training and capacity building (or task shifting) embedded within. The short-term effectiveness or immediate sustainability of these interventions has also been widely reported e.g., the effectiveness of task-shifting to improve NCD management in South Africa and Kenya (17, 19, 28); however, little is known about their medium to long term effectiveness over 2-5 years after the intervention. This lack of information on longer term sustainability may be in part because the post-intervention scale-up is not robust enough to document the health system (HS) processes and health outcomes of interest as the funding is often limited in the post-intervention period. Critically understanding to what extent this impact on sustainability has been, may help address what essential processes research-driven interventions may need to include in their designs and whether these processes could deliver on the expected health outcomes and health policy changes in a sustainable way.

A recent systematic review of NCD Interventions in SSA indicated that of the 12 studies that fulfilled the inclusion criteria within primary care models 11 studies were quantitative and one used mixed methods. The latter showed that prevention, case detection and management of disease were emergent themes (29).

Generally, there have only been few HS or implementation-type interventions on NCDs in SSA perhaps due to the laggard public sector response and resource priorities. For example, in Uganda, government support has mainly been for creating awareness, passive screening, and behavioural risk reduction (30). Research driven NCD interventions in SSA have also mostly targeted disease management or curative services rather than direct HS support or testing. The little to no investment in the public sector makes it difficult to discern the true intervention effect size and the durability or sustainability of such an effect is usually not investigated further and often remains largely unknown. My work under this thesis aims to address this knowledge gap.

2.2. Defining sustainability

Sustainability of a health intervention has been defined as "the continued use of intervention components (or elements) and activities for the continued achievement of desirable health outcomes within a population of interest" (31). However, Shediac-Rizkallah and Bone gave a more comprehensive definition with three components (i) continued benefits to those who received the health services when the interventions started and to new participants when the supporting funds were discontinued, (ii) continued implementation of intervention activities in an organisation following discontinuation of financial support and (iii) community empowerment to improve their health by continuing the intervention activities after its end (32).

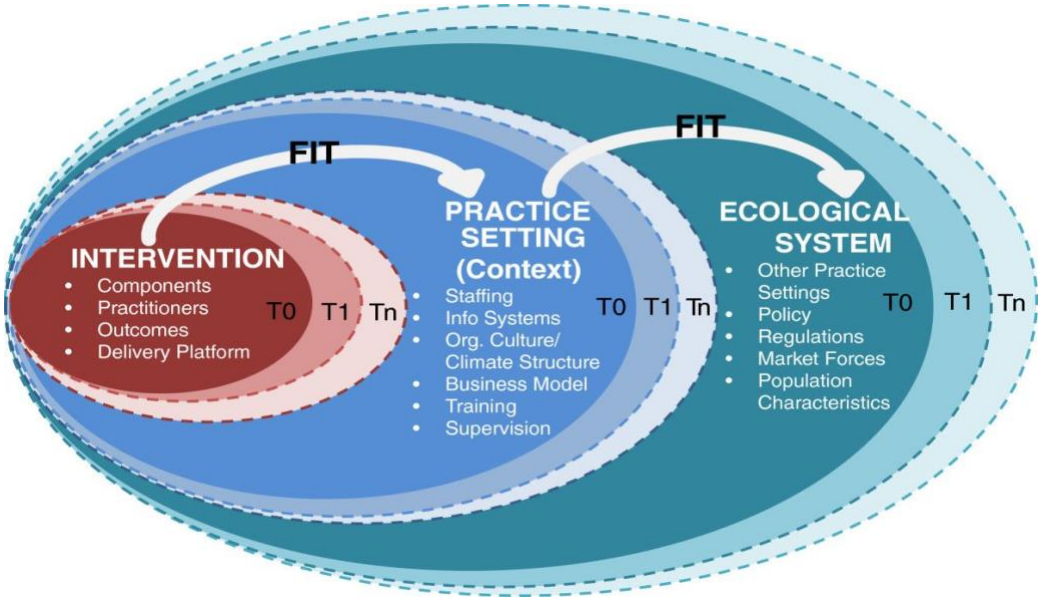

Figure 4 - The Dynamic sustainability framework as described by Chambers et al, 2013 - illustrating the goal of maximizing the fit between interventions, practice settings, and the broader ecological system over time (represented by T0, T1…, Tn), each of which has constituent components that may vary.

Sustainability framework.

Chambers et al, argue that interventions are not static and that there is an ongoing dynamism from implementation to continuation or institutionalisation, and from efficacy to effectiveness, with ongoing adaptation from learning and problem solving, particularly in the absence of financial support (33) (Figure 4). The authors termed this the 'dynamic sustainability framework' (Figure 4).The adaptation phase is thought to integrate and institutionalise the intervention within the local organisation and local (or cultural) context.

Voltage drop and Program drift.

The dynamic sustainability framework also recognises that as an intervention moves from testing to continuation with little support supervision, then a 'program drift' becomes inevitable (which refers to that decrease in yield or benefit as deviation from manualised protocols occurs when delivering an intervention in the real world) in addition to a 'voltage drop' (which is the expected decrease in yield from efficacy to effectiveness into real world use) (33).

2.3. Normalisation.

An important cogwheel in achieving sustainability of any intervention is institutionalisation or normalisation [1]. Normalisation process theory (NPT) describes how complex interventions

become incorporated into routine everyday practice (34). It looks at how such interventions work from early implementation to continuation and embedding within routine practice to the point at which they "disappear from view" (i.e., become normalised) (34). Normalisation is not irreversible, and practices can be de-normalised over time as well. NPT consists of four main components or domains: coherence (sense-making); cognitive participation (or engagement); collective action (or work done to enable the intervention to happen); and reflexive monitoring (or formal and informal appraisal of the benefits and costs to the intervention) (34). These components are not linear or one-dimensional and have dynamic relationships with each other and other domains within the sustainability framework of an intervention, such as the organisational context, or local context or social norms (34). It is widely agreed that when assessing sustainability, it is not always necessary to sustain all original programme or intervention activities (16).

2.4. Postulated conceptual framework of sustainability after EACDRP trial

I postulated that during the implementation period of the EACDRP trial, five domains became consolidated and optimised (Figure 5). These included design and implementation; organisational capacity; enabling environment; community embeddedness; and local context. These can also be considered the distal outcomes.

Intermediary or intervening outcomes (such as continuation of HT and DM services, HW normalisation) relate to those outcomes through which the distal outcomes may be acting in the post-intervention phase e.g., good design and implementation may be directly impacting continuation and institutionalisation of the intervention.

Immediate outcomes include the direct outcomes or indicators which were measured such as service readiness, service utilisation, quality of care or normalisation strength. Due to the dynamism of the sustainability framework, each domain or distal outcome may influence one or more similar indicators. This postulated framework helped to look through areas and steps of my PhD research. I mostly refer to it in the discussion on chapter 8.

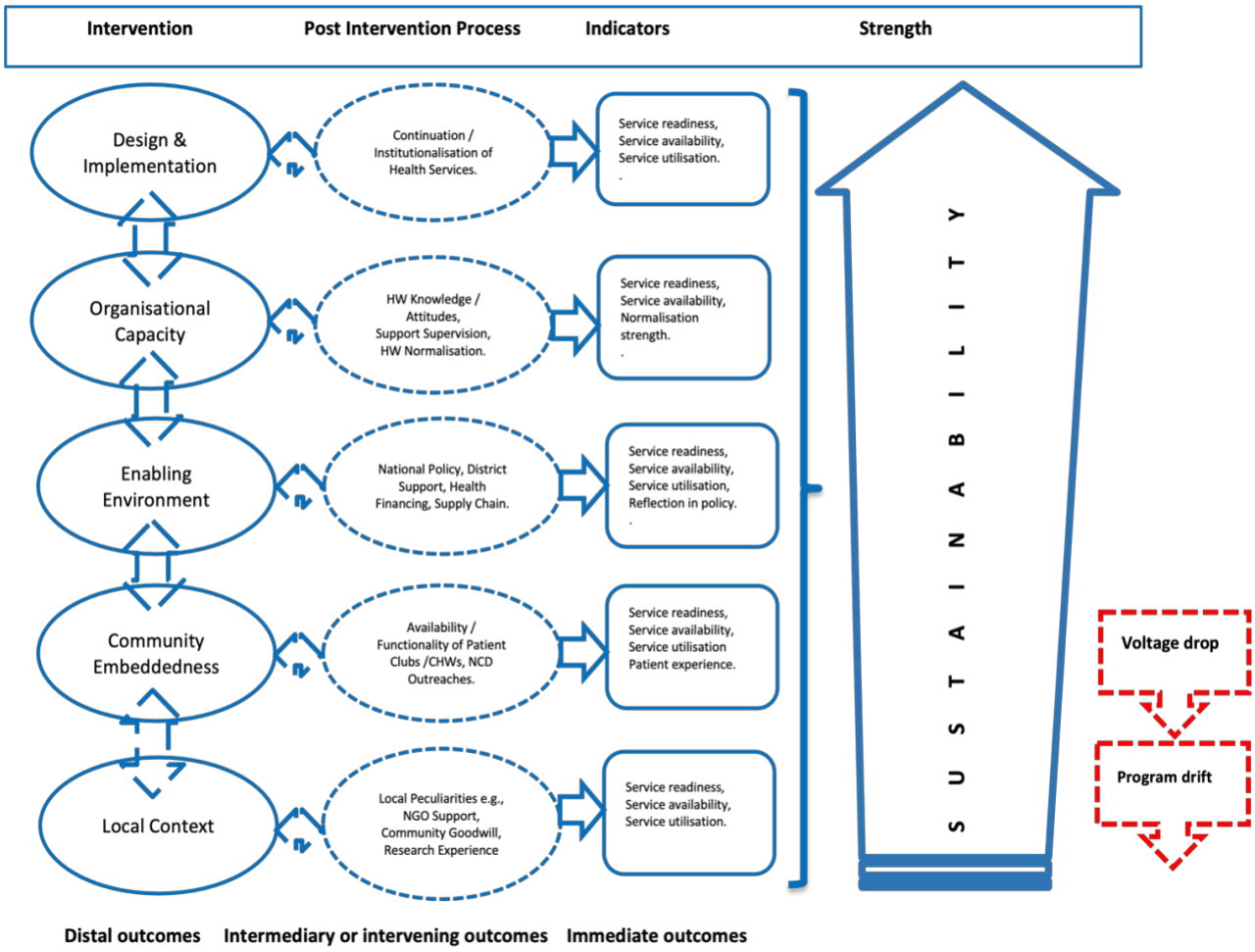

Figure 5 - Postulated conceptual framework

2.5. Efforts geared towards ensuring sustainability and the important role of patient clubs.

When the EACDRP trial ended in late 2016, the main challenge became how to keep the quality of health services and whether the quality could be further improved. Any deterioration in quality of services would mean that sustainability and ultimately retention of patients in HT and DM care was likely to worsen. Several efforts were made during and just after the EACDRP trial geared towards ensuring long term sustainability of these HT and DM services. Such efforts included involvement of the ministerial and local governance structure in all intervention planning workshops, review meetings with the district health officials to advocate and plan for inclusion of HT and DM drugs and supplies in their line budgets, dissemination of preliminary study findings, and handover of important intervention documents e.g., HT and DM register templates at decision making levels both at the ministry and district.

All HFs were given a 6 to 9-month buffer of HT and DM drugs at trial close out. During the penultimate rounds of support supervision visits, the study team noticed an initiative that

hitherto only existed at the district hospital or HCIV level (where it had had been introduced through local chapters of the national diabetic association (UDA)) but had now also started spontaneously at some of the lower-level intervention HFs with busier HT and DM clinics. It involved the setting up of patient-centred clubs in anticipation of the trial end. This initiative had also been encouraged by the district authorities as a stopgap measure in case there was a lapse in the scaling up of district HT and DM drug supplies to levels able to meet the new demand after the buffer stocks were depleted. These patient clubs were voluntary and involved the organisation of HT and DM patients into a communal fund managed by them and into which they invested a small fee at regular intervals. The fund was used to assist patients with their treatment, by procuring drugs or supplies with a high stock out rate, e.g., bendrofluazide or glucose test strips, to address periods during which the freely provided HF supplies from the official supply system were not available. The creation of patient clubs was supported by the study team albeit only in an advisory capacity in all the HFs where they had been initiated.

2.6. Opportunity to evaluate EACDRP trial sustainability further

The EACDRP trial provides a unique opportunity to critically assess and understand differences in HT and DM services readiness and quality of HT and DM care that may have developed in the intervention facilities over time, and the important drivers of durability and sustainability of HT and DM services. Importantly, it provides an opportunity to examine the residual impact of the EACDRP intervention within the primary care setting, without research-driven funding and supervisory support, and thus inform the important question of sustainability.

It also provides an opportunity to document any influences that the EACDRP intervention may have had on government health policies and practices, including barriers that may hamper good long-term HT and DM care. This opportunity is what my PhD research is mainly about and is captured in chapter 5, 6 and 7.

Chapter 3: Research Objectives.

3.1. General Objective.

To assess the medium to long-term sustainability of a health system intervention to improve NCD services for HT and DM within primary care settings in SSA.

For this thesis, I defined Sustainability as the continued availability and readiness of services, in line with the concept introduced by WHO as Service Availability and Readiness Assessment (SARA) (35). Specifically, it was defined as the level of the physical availability of essential equipment and consumables required for the diagnosis and management of DM and HT combined with the level of clinical knowledge among the health workers that are expected to provide the service.

I defined Quality of Care and Patient Experience (QoCE) as the level to which real-life patients experienced adequate diagnosis and care activities at their health facility when they presented for DM and HT. This experience was determined through objective evidence that could be found for these activities.

For both of these concepts, specific indicators were defined which are listed in Chapter 4 in the Section on 'Outcome data collection and measurement'.

3.2. Research Questions.

1. *How sustainable has the improvement of HT and DM services been in terms of service readiness and utilisation since the end of EACDRP trial and which factors are associated with sustained intervention effects (in the absence of the funding and supervisory support that is typically associated with a research project)?*

Using a cross sectional survey of the EACDRP trial facilities from the former intervention arm, I assessed the current HT and DM services and looked at changes that occurred since the end of trial survey in 2016, using questionnaires and checklists, interviews with HWs, and a review of records. HT and DM service availability and service readiness (SAR) was defined as in the EACDRP trial and using a similar criterion for assessment. Specific objectives were to:

- Describe and compare current HT and DM care service availability and service readiness with that at the end of the EACDRP trial.
- Describe and compare current HW knowledge and practice
- Describe any changes at the national or district level in NCD policy, practice or guidelines, and the impact of these changes.
- Identify facilitators and barriers associated with sustainability (or substantial decline) of HT and DM services.

2. *How sustainable has the quality-of-care and patient experience been since the end of the HSDCP trial?*

Using a cross sectional survey of facilities from the former intervention arm facilities, I evaluated the quality-of-care and patient experience (QoCE) of a random sample of DM / HT patients currently registered at these HFs and compared these to findings from the end-line cross sectional evaluation of the EACDRP trial. Quality of care was defined as in the EACDRP trial from a HS perspective that is the degree to which patients were managed according to current guidelines. Specific objectives were to:

- Describe the current quality of care provided with that at the end of the trial.
- Describe the facilitators and barriers to or associated with a minimum level of sustainability (or substantial decline) of quality of HT and DM services.

3. *How sustainable is the EACDRP intervention in the future based on its the current sustainability capacity?*

Using a cross sectional study, I evaluated the sustainability capacity at all levels within the current practice setting against a known sustainability framework and using the Normalisation and Program Sustainability Assessment (PSAT) tools.

For purposes of this PhD, sustainability of the EACDRP intervention was defined through the presence of the components identified by Shediac-Rizkallah and Bone (32). I also assessed to what extent evidence could be found for future sustainability within current practice:

i) Sustained health outcomes e.g., service availability and readiness, quality of care and patient experience
ii) Continuation of health services e.g., program sustainability assessment among HWs and patients, HW normalisation
iii) Evidence of continued community ownership with regards to the intervention, e.g., functioning patient clubs

Specific objectives under research question no.3 were to

- Examine the current and future sustainability capacity of the intervention by assessing its strengths (or weaknesses) through the mean scores of each domain within the sustainability framework
- Assess the current extent and strength (or weakness) of normalisation among HWs in the former intervention HFs
- Examine the reliability and suitability of the normalisation and PSAT tool for use in assessing sustainability in this setting by determining Cronbach's alpha.

3.3. Outcome measurements.

I. Primary Outcomes.

i) Means scores for the level of HT and DM service readiness and availability in the former intervention arm facilities, and comparing it with the mean scores documented at the end of the EACDRP trial in 2016

ii) Proportion of HT and DM patients in the former intervention arm facilities currently receiving the minimum acceptable level of quality of care, and comparing it with the proportion documented at the end of the trial in 2016

iii) Mean overall (aggregate) scores for all sustainability domains combined, as relates to current or future sustainability capacity.

II. Secondary Outcomes.

i) Facilitators and barriers to sustainability with regards to a minimum level of HT and DM service readiness.

ii) Facilitators and barriers to sustainability with regards to a minimum level of HT and DM patient quality of care.

iii) Mean scores within each sustainability domain as relates to current or future sustainability capacity.

iv) The reliability of the intervention sustainability tool (PSAT) in assessing sustainability capacity in this setting.

Chapter 4: Methodology

4.1. Study setting.

Between 2013-2016, a cluster randomised trial of a HS intervention to improve HT and DM care was conducted in 38 primary care facilities in Uganda (the EACDRP trial). The intervention was also provided in the 6 referral facilities that served these 38 primary care units. The intervention package included: training of health workers; development of simple clinical guidelines and patient registers; provision of essential HT and DM care drugs; active outpatient screening; promotion of HT and DM awareness and screening in the community outreaches (**Table 2**). The intervention led to significant improvements in HT and DM management, overall service readiness and quality of care as described in section 1.5 of Chapter 1 (**Table *3***).
The current study was conducted between January and December 2020 in the two central districts of Uganda : (a) Wakiso district, which forms a crude horseshoe shape around the capital city of Kampala, and includes urban, rural and peri-urban areas with a population of 2.5 million (36);

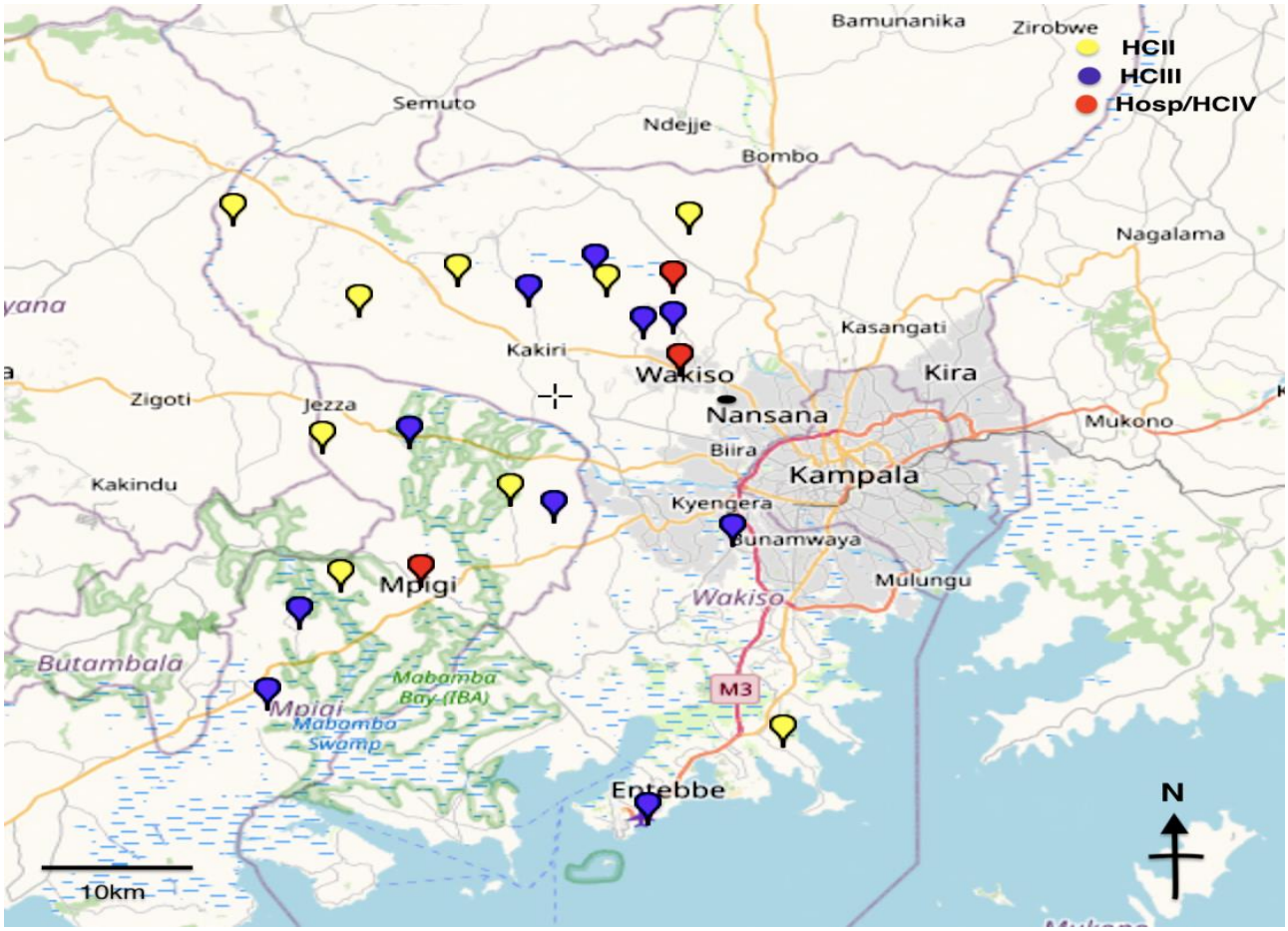

Figure 6 - Map showing the distribution of participating health facilities across Mpigi and Wakiso Districts in Uganda under the current PHD study (MeLoHanD) (Developed using GPS visualizer.com)

(b) Mpigi district, which lies just south west of Kampala along the shores of Lake Victoria, and has a population of 250,000 (36). It is largely a peri-urban and rural population mainly engaged in subsistence farming, fishing, and artisanship (Figure 1 & Figure 6).

4.1.1. Description of health facilities.

This study was conducted in all the original 19 lower-level facilities (10 HCIIIs and 9 HCIIs) from the intervention arm of the EACDRP trial and 3 of the 6 higher level referral facilities.

Previous randomisation strategy

Of the 38 Ugandan HFs (19 in each arm), 22 were randomised individually (singleton) while the remaining 16 rural HCIIIs and nearby HCIIs were randomised jointly as 8 pairs (Figure 6) to minimise likely contamination arising out of referral linkage and proximity (i.e., <5km) of some of the facilities, and because HCIIs are expected to refer complicated cases to nearby HCIIIs, if available.

Facilities were all enrolled and randomised one district at a time in a 1:1 ratio to either receive the HT and DM intervention package or continued standard of care (the control arm). To increase transparency and participant involvement, HFs were randomised in a public ceremony held in each district with a representative from each facility. Due to the nature of the intervention, it was not possible to mask intervention allocations to researchers or the participating HF staff after randomisation (1) (Appendix G).

In order, to avoid imbalance across treatment arms with respect to important characteristics, randomisation was stratified by district and further restricted through a covariate constrained randomisation scheme described by Ivers et al, 2012 (37) limiting the number of permissible random allocation sequences to those that would achieve good balance with respect to HF governance (public-run versus faith-based), and, in rural districts, the distance from hospitals/HCIVs (e.g., <60km versus ≥60km) (1) (Appendix G).

Hospitals or HCIVs in Uganda had performed substantially better than lower primary care facilities during an HT and DM service assessment conducted before the trial (4) and are also referral points for the wider catchment regardless of the intervention allocation. For this reason, hospitals/HCIVs were not originally randomised and received the intervention regardless. However, for the current study their performance over time was also assessed.

Current selection of health facilities

This study was conducted in 3 randomly selected higher-level facilities of the 6 referral units, and all the original 19 lower-level facilities (10 HCIIIs and 9 HCIIs) (Figure 6)

There were 7 facilities (4 HCIIIs, 3 HCIIs) in Mpigi and 12 facilities (6 HCIIIs, 6 HCIIs) in Wakiso district. Of these, only Wakiso district (Entebbe) has urban facilities (1 HCIIIs, 1 HCII) while the remaining 17 facilities (9 HCIIIs, 8HCIIs) were rural (**Table *5***).

Table 5 - Distribution of health facilities by district and facility level

Facility attribute		District				Total
		Mpigi		Wakiso		
		HCIIIs	*HCIIs*	*HCIIIs*	*HCIIs*	
Urban HFs	*Singleton*	-	-	1	1	2
Rural HFs	*Singleton*	2	1	3	3	9
	Paired	2	2	2	2	8
Referral facilities (HCIVs)		1 *(Peri-urban)*		2 *(1 Peri-urban, 1 rural)*		3
Total		8		14		22

As mentioned above, some facilities were also originally selected as HCIII-HCII pairs due to their proximity and to minimise contamination. All 2 urban facilities (1HCIIIs, 1HCII) were singleton or independently selected while among the 17 rural ones - 8 facilities selected as pairs (4HCIIIs, 4HCIIs) and 9 (5HCIIIs, 4HCIIs) as singletons (Figure 7). (**Table 5**)

Why only former intervention facilities were chosen?

This study was conducted only in facilities that had received the intervention during the trial (and not in former control facilities) because the research question around the sustainability of the achieved improvements could only be examined in these facilities. Whilst former control facilities had received intervention activities after the end of the trial for ethical reasons as well, the effectiveness of these had not been determined at the time, thus making a meaningful comparison at a later stage impossible. In addition, the end-of-trial roll out of the intervention to former control facilities had naturally been limited in terms of financial means and continued supervision.

This necessary bias of the current study associated with the focus on former intervention facilities implies that the generalisability of this PhD research is limited to the sustainability and durability of an optimised intervention. The effects of less intensive interventions might have waned faster.

Figure 7 - Kibumbiro HCII: example of a typical intervention HCII (singleton) in Uganda

4.1.2. Study design

This study was a comparison of two cross sectional surveys conducted at two-time points; that is at the EACDRP trial end in 2016 (or the new baseline) and currently (2020).

4.1.3. Field work and data collection

Pilot study (Jan 2020)

Prior to the start of current study, a pilot study was carried out in two independent HFs (an urban HCIII and a peri urban HCII) to train the study team and to test data collection tools and procedures. Findings from these pilot HFs were used to improve our procedures but were not included in the research data set of the study itself.

Operational findings from the pilot study that informed the study direction

Purpose of the pilot study:

- To test the effectiveness of the data collection tools to be used in the study.
- To enable the study team to get familiar with the questionnaires and other data collection tools e.g., tablet data entry before the beginning of the main study.
- To enable the study team to get familiar with the processes involved in the evaluation.

- To get a crude estimate of the average total time required for study assessment at each level.

Brief pilot work plan

Following introductory visits at the district health offices, pre - visits to the health facilities were made by the team to meet the HF in-charge for the purpose of introducing the team, informing the facility about the study purpose and activities and scheduling appointments for the pilot visit days. At this visit we also requested the HF in-charges to ensure that all the health workers were present over the proposed visit days as well as invite 20 randomly selected known patients of HT/DM.

Observations from the pilot study

Overall, there was a very positive response towards the study from both the HWs and the patients.

There was a marked reduction of time spent on each participant and health facility as the team got used to the study data collection tools and procedures.

The following additional data collection or operational tools were identified as needed

- Participant ID log
- Health Worker ID log
- MRC unit general laboratory request form
- MRC unit general chain of custody/sample delivery form
- Contact details form
- Referral letters

*Challenges identified during the pilot study (***Table *6**)

Table 6 - General challenges and recommendations from the pilot study

No.	Challenges	Actions/Recommendations
1.	• Some patient records lacked full contact details in the available registers, or these were out-dated • Men and DM patients were under-represented	• Need to use HF mobilisers at lower-level HFs. • Develop new SOPs to guide random selection and invitation of the 20 patients which seems to account for non-response or other contact difficulties • Need to have a good patient and HW register e.g., developed from the random sampling log • Consider revising SOP to stratify the sampling of men and DM patients
2.	HWs have 3 questionnaires in total – while most seem happy to answer these comfortably in one day, a few were not very keen	Consider splitting the questionnaires between the days at the HF if possible

3.	Team was not able to test the tablets in the field due to programming hitches	To do a team-led data entry of the completed paper questionnaires onto a more stable tablet version as part of post-pilot training
4.	Transport issues: e.g., switching drivers or midweek re-fuelling led to tardiness particularly when travelling to farther HFs	• Need to be assigned one driver for the week and proper driver handover. • Need to improve communication between team and administrators – sharing a biweekly or monthly travel timetable
5.	Some health facilities lack a private room we could use for patient interviews and examination	• Request for a private space and examine patient one by one
6.	HWs and patients expected study to provide drugs and clinical equipment.	• Clear information when making appointments for study visits that no donations would be given
7.	A few HWs appeared too busy to answer our questionnaires and some shied away from them	• Helping with some of the routine tasks at the HFs. • Giving an incentive in form of a soft drink or water • Applying the HW questionnaires one facility section at a time or soon after a hectic work period
8.	Very few HWs at some HFs	• Pre-visits very essential in making sure HWs turn up on the scheduled day as well as scheduling more than one visit day per HF • Early arrival at HF helps to find most of the HWs still around.
9.	Pilot data collection tool for facility inspection is quite lengthy and amount of time spent filling it is quite long	• As a team it was decided to split the team by the facility sections, so more sections were inspected at the same time to help reduce the time.
10.	BMI charts used had a range of 50-90 kg, however some patients were outside these ranges.	• For patients outside the given range, BMI was to be manually calculated
11.	Delayed essential field supplies not yet delivered	• Engage the procurement team early so that processes are faster

Further post-pilot recommendations following first supervisory field visit

i. To limit the respondents to be interviewed using the sustainability tool to individuals with sufficient institutional insight e.g., HF in-charges or focal persons, patient leaders, or patient-peer mobilisers

ii. To do another team training involving the most stable version of the tablet questionnaire.

iii. Sampling of patients - it was agreed that patients that are active or still in care at these facilities would be most appropriate to answer this QoCE question, rather than those lost to follow up or attending care elsewhere – need to sample those that are active or re-attendances by using a systematic random sampling in the available registers

iv. Main tool specific recommendations included:

- Overall study tool headers need to be standardised to include an introductory preamble
- Health worker normalization tool
    - adapt questionnaire to the study
    - include question on health worker involvement with intervention
- Intervention sustainability tool (PSAT)
    - adapt questionnaire to the study.
    - due to some noticeable difficulties in articulation of this tool - re-phrase and simplify or exemplify some terminologies used in each domain.
    - limit this tool to key informants e.g., patient leaders, health facility in charges/OPD heads, district/ MoH health officials and former study intervention officers.
- Routine supervision checklist
    - needs to be adapted to collect the information on the intervention component decay
    - Need to generate a question on the existence of patient clubs, their functionality, their management, and their challenges
    - less negative and more ambiguous or neutral question phrasing
    - Need to document any peculiar challenges at HCIII and HCII levels e.g., external threats – e.g., free nearby HT and DM services

Training of the study team (January to February 2020)

Training of the study team was performed in two parts:

(i) Initial training prior to the site initiation and pilot study (January 2020) – this involved training of all study team members on the study protocol, study tools and study procedures in preparation for the site initiation visit by the unit's study monitoring team. The site (or study) initiation visit involved inspection of the study site, checking of study tools and study equipment as well as the study team's capacity and training to ascertain its readiness to start the study. This training was conducted by the PI assisted by the unit's focal person responsible for research compliance.

(ii) Post-pilot training (February 2020) – following lessons learnt from the pilot study as well as amendments and refinement of some study tools, another training was carried out, focusing on GCP compliant data entry and verification of final study tools. This training was conducted by the data manager / REDCap® programmer with support from the PI.

Post-pilot fieldwork (February to March 2020 / September to December 2020)

Selection of study patients

At each facility, using either the NCD patient registers or other up-to-date DM or HT register where use of the registers had been abandoned or lost. Twenty eligible and patients active at that facility within a three-month period were randomly selected using either ordinary random tables or an excel random table formula sheet. To ensure adequate representation of men and patients with DM, the random selection was stratified by gender and type of disease.

All 20 eligible patients were invited over the course of the health facility visits without replacement. Efforts were made to contact those that did not respond on the visit days to find out the reasons for not attending.

Only patient leaders e.g., patient club leaders and peer patient mobilisers were invited and interviewed for the intervention sustainability questionnaire.

Selection of health workers

All consenting health workers working in the OPD section or in special HT and DM clinics were eligible for interview.

Outcome data collection and measurement

A team of 4-5 assessors was formed that included the PI (myself) and/or a study clinician, a study nurse and three field workers. One of the field workers doubled as a data management (quality assurance) assistant and liaised between the field team and the office-based data manager on any data capture queries on day-to-day basis. (**Table 7**)

The entire team was trained on REDCap® data capture and proper tablet use.

The team held weekly or biweekly feedback meetings regularly to quickly address any challenges with the field work and data collection.

All team members received human subject protection training (HSP) and good clinical practice (GCP) training prior to field work and data collection.(**Table *7***)

Table 7 - Training and qualifications of study team members

Study team member/role	Qualifications /profession	MeLoHanD Protocol trained	HSP/GCP trained	Previous field work experience with EACDRP trial	Previous field work experience on a clinical or field trial
Principal Investigator	Senior scientific officer /project leader	√	√	√	√
Study clinician	Clinical officer	√	√	√	√
Study nurse	Nursing officer	√	√	√	√
Field workers (2)*	Laboratory /Field technicians	√	√	X	√
Study clerk/ data QC field worker**	Social worker	√	√	√	√
Data manager/ REDCap® programmer	Programmer	√	√	X	√

Footnote: *Two full-fledged field workers

**QC – Quality control – as a data QC field worker she was responsible for the data quality checks in the field and data entry of paper-based facility assessment questionnaires. Also had previous experience in transcribing and coding qualitative interviews.

4.1.3.1. Study 1 - Evaluation of service readiness and service availability

A facility service availability and readiness assessment was done using a tool developed and used for the EACDRP trial and adapted from the WHO SARA tool (35) . The tool consists of two components: a) a facility inspection tool (through which a HF could achieve up to 60 points) and b) a health worker knowledge assessment (contributing up to 40 points)

The inspection of the facility and of available records was done on 5 main elements of 10 points each. These elements included:

i. Availability and functionality of essential equipment (e.g., blood pressure (BP) machine, weighing scale, stadiometer, glucometer/urine dipsticks, stethoscope, patient register book, HT/DM screening logbook, referral register book, health education record).

ii. Availability of drugs and other consumables (for the treatment of HT and DM and whether drugs were in line with guidelines and in sufficient stock).
iii. Quality of records on patients with HT and DM (guidelines, essential demographic data, clinical observations, information on diagnosis, treatment, referral and follow up).
iv. Healthcare utilisation at facility by patients with HT and DM (number of HT and DM patients, evidence for increase in utilisation over past year).
v. Prevention of HT and DM and their complications (evidence for and number of health education sessions given, evidence for active screening for HT or DM among those that presented with other conditions e.g., back pain: evidence of outreach activities).

Health worker knowledge was assessed by means of a supervised self-completed multi-choice questionnaire that was based on 3 clinical case scenarios on HT, DM, and HIV infection. For each scenario, the assessment also looked at five elements:

(1) Essential diagnostic steps (symptoms, signs, tests).
(2) Risk factors for each of these 3 diseases.
(3) Complications.
(4) Treatment regimens; and
(5) Guidelines for referral.

The HIV case scenario was included for comparison, as earlier knowledge tests had indicated that HWs in East Africa had generally good knowledge on HIV case management (4, 21). In Uganda, primary care facilities (HCIIIs and HCIIs) are expected to provide basic care for common chronic conditions including HIV infection and NCDs. In an earlier study (4), on the readiness of Ugandan health services for chronic disease care: I had found that primary care facilities were better equipped, trained and experienced in managing HIV infection than managing NCDs. It was therefore decided to evaluate DM and HT services in this PhD study in comparison to HIV care service readiness. Whereas also HIV programs are vertical and may not be very comparable to the HT AND DM intervention, there has been a recent push towards integration of the two programs in similar settings with much success and minimal disruption (INTE-AFRICA study) (38).

Each scenario was worth 10 points, so a HW could score a maximum of 30 points.

The inspection score from the SARA tool and the scores from the health worker clinical knowledge assessment were combined into a single aggregate facility performance score (FPS). The score from the SARA tool was converted to a percentage and scaled to a maximum of 60 points (e.g., a facility that scored 40 on the SARA would have achieved 40/50=0.80*60=48 points). Similarly, HW knowledge scores for each facility were totalled and converted to a percentage, then scaled to a maximum of 40 points. For example, if there were 5 HWs who accumulated a total of 132 points out of 150 (5 x 30) possible points (equivalent to 88%), the facility received a total of (40*0.88) = 35 points (rounded to the nearest whole number) for the knowledge assessment. The SARA and knowledge assessments points were then combined into the FPS with a maximum score of 100. Using the above example, the FPS would then be 48 + 35 = 83 out of a possible maximum of 100 points.

Scores for each of the elements were not individually weighted; however, in keeping with the method used during the original trial, physical service availability contributed up to 60% to the overall total facility performance score whilst health worker knowledge contributed 40%, reflecting the trialists' view at the time that physical service readiness was even more important than HW knowledge.

4.1.3.2. Study 2 - Evaluation of patients' quality of care and experience (QoCE)

This assessment was done based on interviews and examinations of consenting patients registered at the selected facilities. At each facility 4 HT and DM patients in 2016 and 10 HT and DM patients in 2020 (i.e., HT and/or DM) were identified - who had presented at the facility in the previous 3 months.

- These patients were identified through the facility register books or other available records and selected randomly.
- The patients' own medical records were reviewed along with records held at the facility.
- Based on the patients' own records, the facilities' records and the patient interviews, each patient received a care quality score on a 10-point scale.

The QoCE score (in **Table *10***) comprised questions assessing whether:

i) the patient was diagnosed correctly *(2 points).*
ii) treatment was provided *(2 points).*
iii) the patient received health education *(2 points).*
iv) the quality of reception and waiting time were acceptable *(2 points).*
v) the patient was managed according to guidelines *(2 points).*

For a patient to be classified as *adequately managed* he/she would need to score 7/10 or more regardless of whether the clinical condition of the patient was *effectively controlled*. (Note effective clinical control was not used as a criterion for '*adequate patient management*'. The rationale for this approach was that, whilst the intervention can be expected to improve the quality of the health services, this improvement may not immediately translate into an improvement of patients' health status, particularly if patients participating in the surveys had only been registered recently)
Each patient was given a quality of care and patient experience score, with a maximum score of 10 points.

4.1.3.3. Study 3 - Evaluation of normalization and intervention sustainability

Normalization strength.
Normalization has been described as the degree to which HWs have managed to routinely embed a new set of activities in already existing knowledge and practices (39). Normalization can be assessed by applying an instrument (the normalization tool) which was designed to get a better understanding of how to apply and integrate new technologies and complex interventions in health care. The tool asks questions about the implementation of the intervention and is administered to staff with different roles. The tool has 3 parts (A-C) (40). It has been previously validated (39, 41) and a modified version of this tool has been used to assess provider-initiated HIV counselling testing programs in South Africa (42).

Part A – comprises three brief multiple-choice questions about the respondent's background and their past and current involvement in the intervention.
Part B – comprises three general questions about how familiar the respondent currently feels with regards to the intervention, with a score of 0-10 (maximum score = 30)
Part C – comprises 20 statements regarding the normalization process as perceived by the

respondent, with possible responses each ranging from a score of 1 (strongly disagree) to 5 (strongly agree). The 20 statements are ordered under 4 domains, namely:

i. *Coherence (sense making)* – to what extent HWs perceive that the intervention is meaningful to them and their colleagues at the HF (4 statements).
ii. *Cognitive participation (buy in)* – to what extent HWs and their colleagues are engaged in the intervention and actively support it (4 statements).
iii. *Collective action (active implementation)* – to what extent HWs' individual and team efforts make the intervention work (7 statements).
iv. *Reflexive monitoring (appraisal)* – to what extent HWs have access to reports about the intervention and can use this feedback to appraise and improve the intervention (5 statements).

The maximum average score that a HF can achieve under each domain is 5. Across all 4 domains in part C, the maximum aggregate-average score is 20 (4 x 5). Each statement also allows for a lack of response such as a statement not being relevant to their role, not being relevant at the time or not being relevant to the intervention generally.

More details on this tool can be found at https://www.rds-se.nihr.ac.uk/wp-content/uploads/NoMAD-questionnaire-for-PPI-with-Logo.docx (40)

Intervention sustainability capacity

Programme sustainability capacity has been defined as *the ability to maintain programming and its benefits over time* (43-47). For this work, I used the program sustainability assessment tool (PSAT tool) to measure this ability. The tool has been validated for use in research and program settings for chronic diseases (43-45) and in Africa (46, 48).

This tool assesses the intervention's current capacity for sustainability across a range of specific organisational and contextual factors. Responses identify sustainability capacity and challenges under three main areas: Programme (Intervention), Organisation and Community (43, 44).

- *Programme (Intervention)* - this refers to the set of formal organised activities that one wants to sustain over time. Such activities could occur at the local, national, or international level and in a variety of settings.

- *Organisation* – this encompasses all the parent organisations or agencies in which the programme is housed. Depending on the programme, the organisation may refer to a national, or local department, a non-profit organisation, a hospital, etc.
- *Community* – this refers to the stakeholders who may benefit from or who may guide the program. This could include residents, organisational leaders, decision-makers, etc.

The tool covers eight domains, and each domain has 5 questions. Responses are scored from 1 (little or no extent) to 7 (to a great extent), giving a maximum score of 35 points per domain and a maximum average score (i.e., from the 5 questions) of 7 points per domain. These domains include:

I. *Environmental support:* having a supportive internal and external climate for the HT and DMHT and DM intervention e.g., in terms of resources, staffing and drug supplies
II. *Funding stability:* establishing a consistent financial base for the HT and DM intervention
III. *Partnerships:* cultivating connections between the HT and DM intervention and its stakeholders, and or interested or affected people or groups
IV. *Organisational capacity*: having the internal support and resources needed to effectively manage the HT and DM intervention and its activities
V. *Program evaluation*: assessing the HT and DM intervention to inform planning and document results
VI. *Program adaptation:* taking actions that adapt the HT and DM intervention to ensure its ongoing effectiveness
VII. *Communications:* strategic communication with stakeholders and the public about the HT and DM intervention
VIII. *Strategic planning:* using processes that guide the HT and DM intervention's direction, goals, and strategies

This questionnaire also allowed for lack of responses e.g., if participants responded that a question was "not applicable" to them or were not able to answer.

More details on the tool can be found at https://sustaintool.org (47) and http://creativecommons.org/licenses/by-nc/3.0/

4.1.4. Covid impact on field work and data collection

Following the global covid-19 pandemic, Uganda went into a full lockdown on 20th March 2020. The local institutional review board (IRB) and other oversight bodies put a halt to all studies involving human subjects while a review process was on-going and mandated that all studies develop study-specific covid risk management plans before they were allowed to continue as and when the situation would allow. The study team had only visited 8 out of the 22 HFs at this time. A risk management plan was quickly developed and submitted for approval. Approval was granted soon after partial lifting of the lockdown in early June 2020.

The PhD supervisory team recommended that I also develop a covid crisis workplan for the lockdown period to make up for any PhD time lost over a 3–6-month period April to September 2020

This work plan aimed:

- To continue with data collection activities to the extent allowed or possible during this time
- To change focus to other outputs not dependent on data collection
- To plan to engage staff already recruited on the PhD project to the extent allowed or possible during this time.

Non-patient-based activities were restarted in early June 2020 – these mainly involved pre-visits to the HFs to review the patient register and identify the 20 patients to be invited for interview eventually.

The supervisory team also advised that I start to plan for quick re-start and turnover of study activities when the lockdown is lifted in anticipation of a second wave as cases would rise soon after.

Patient-based activities were restarted towards the end of June after a 3-month halt. Study accrual progressed steadily and was completed in December 2020 through to the first quarter of 2021 for any re-visits.

In addition to this the following aspects were also either directly affected or by knock-on:

(i) Study participants (or patients) who were to be interviewed and examined as part of the study had not only missed their previous appointments but needed to be re-contacted and given new appointments which was a duplication of efforts and caused further delays of several weeks.

(ii) There were notably some restrictions to field work and vehicle transport e.g., the minimum number of people in a commercial vehicle was restricted to half the normal seat capacity which meant that for a study team of more than 3 people, two vehicles or two journeys would be needed or twice the duration in time. This similarly affected those study participants (patients) reliant on commercial transport as well. These restrictions went on for longer after the initial lock-down for about a year (in partial lockdown) - overall causing additional delays in data collection, data entry and cleaning, and overall data preparation.

(iii) The lock-down and later at-home office working arrangements caused an additional backlog with regards to data entry, data cleaning and data management, leading to further delays until one could begin analysis on a clean data set. This further delayed some activities for 6 months or longer depending on the affected section or required expertise.

(iv) Due to restrictions on travel to the UK, I could not attend some face-to-face modules which had also been suspended at the time.

However, even after the initial lock down, the various problems had a cumulative effect through knock-on effects that continued to delay and slow down the progress of my study beyond the 3-6 months of full lockdown. Additionally, towards the end of 2020 there was another wave of the covid epidemic with another shorter full lockdown of about 8 weeks but with lingering effects of a subsequent partial lock down that all together lasted over a year. I requested and was granted a 4.5-month extension for my PhD work, and this included an extension to my funding support.

4.2. Data analysis plan

4.2.1. Outcome measurements

Primary outcomes.

These included:

1. Mean score for the level of HT and DM service readiness and availability in the intervention arm facilities, and the difference from mean scores found at the end of the EACDRP trial in 2016

2. Proportion of HT and DM patients in the intervention arm facilities receiving the minimum acceptable level of quality of care and experience (QoCE), and the difference in proportions found at the end of 2016

3. Mean overall scores for all the sustainability domains combined (i.e., for normalization and intervention sustainability), as relates to current or future sustainability capacity.

Secondary outcomes.

These included:

1. Mean scores within each sustainability domain as relates to current or future sustainability capacity.

2. The reliability and suitability of the intervention sustainability tool (PSAT) in assessing sustainability capacity in this setting.

Explanatory or independent variables

These included:

1. The effect of the nature of facility e.g.
    a. Level of facility, i.e., HC II vs III
    b. District e.g., Mpigi vs Wakiso
    c. Whether paired or singleton
    d. Area (and/or distance from administrative centres) – rural, peri-urban and urban
    e. Staffing level e.g., more than 20% of staff below 2016 staffing norms. There was little difference in staffing levels between the two time points – this assessment was omitted due to this unity of effect.

2. The effect of the existence of patient clubs and with or without their functionality.

3. The effect of district level support e.g., differences in HT and DM associated supervision visits, stock-out rates

4. The effect of the presence or absence of other external or non-governmental support.

The primary analyses involved a comparison of proportions and mean (or median) scores between the two time points 2020 vs. 2016.

The mean HT and DM service readiness and quality of care (QoCE) scores, and the proportion of patients with acceptable quality of care (using the same definition as in 2016 of at least 7/10 points), was calculated.

Data analysis was performed using Stata® version 17.

4.2.2. Study 1. Evaluation of service readiness and service availability

Unit of analysis

The unit of analysis was the health facility.

Sample size calculation

The mean HF performance score in the intervention arm in 2016 was 80% (standard deviation (SD)=5%). Using a two-sample paired t-test and based on a one-sided hypothesis test in the 19 lower-level HFs, I had >85% power to detect an absolute decline of ≥5% in mean performance scores (e.g., from 80% to 75%), assuming a SD of 5% and a correlation between the paired observations of 0.01 or greater (**Table *8***).

Table 8 - Power to detect a difference in mean performance scores for service readiness in 19-lower-level HFs using a two-sample paired means t-test.

Mean HF performance score at end of trial (2016)	Mean HF performance score in current survey (2020)	Standard deviation (SD)	Power (%)
80%	75%	5%	**86%**
80%	70%	5%	**>99%**
80%	65%	5%	**>99%**
80%	75%	10%	**34%**
80%	70%	10%	**86%**
80%	65%	10%	**>99%**

Description of study population

I tabulated the characteristics of the facilities in the comparison groups i.e., 2020 vs 2016 (N, by proportions or means or medians) by district, facility level, facility pairing, and by some demographic characteristics of the patients (e.g., age, sex,) and health workers (e.g., occupation, intervention training, etc.)

HT and DM service readiness or the overall facility performance compared the intervention facilities in 2020 vs 2016 regarding:

a. Health facilities' performance on HT and DM prevention and care through physical inspection of HFs.

b. Clinicians' knowledge on 3 selected chronic diseases (HT, DM, HIV infection).

Primary outcome

The primary outcome for HT and DM service readiness was the aggregated facility performance score, FPS (0-100 points) and was comprised of two component outcomes i.e., the facility inspection score and the clinical knowledge score (Figure 8).

Component outcomes

The service readiness scoring system covers a range of characteristics of HF performance with respect to care and prevention of HT and DM. This scoring has been used previously in this setting within the EACDRP trial.

Each HF could obtain a maximum score of 100 points:

- up to 60 of these points were derived from an inspection of the facility including its records
- up to 40 points reflected the knowledge and skills of HWs with respect to selected HT and DM

Facility inspection score (0-60)

This was assessed using the following 5 sub-components. For each of them, a facility could score up to 10 points. However, the total facility inspection score was then weighted up to 60 points to reflect the original trialist's intentions.

1. Availability and functionality of essential equipment: sphygmomanometer, weighing scale, stadiometer, glucometers/urine dipsticks, stethoscope, patient register book, HT/DM screening logbook, referral register book, health education record. (10 actual points)

2. Availability of drugs and other consumables for the treatment and prevention of chronic diseases (and whether drugs are in line with guidelines and exist in sufficient quantities based on known presentation rates). (10 actual points)

3. Availability of guidelines on HT and DM and quality of records on patients with HT and DM (essential demographic data, clinical observations, information on diagnosis, treatment, referral and follow up) (10 actual points).

   Unlike the EACDRP trial, in the MeLoHanD comparison the availability of guidelines and quality of records were combined into one element. However, the same observations and attributes within the combined element were scored up to 10 actual points and assessed similarly at both time points."

4. Healthcare utilization at facility by patients with HT and DM (number of HT AND DM patients, evidence for increase in utilisation over past year) (10 actual points)

5. Prevention of HT and DM and their complications (evidence for and number of health education sessions given, evidence for screening of eligible patients for HT and DM who present with other conditions; evidence of outreach activities.) (10 actual points)

Clinical knowledge score (0-40)

Knowledge of clinicians was assessed with respect to:

1. Essential diagnostic steps (symptoms, signs, tests) for HT, DB & HIV
2. Risk factors for each chronic disease
3. Complications of these chronic diseases
4. Treatment regimens
5. Guidelines for referral

This is summarised in three specific component case studies as follows:

I. Case study on hypertension (10 actual points or 13.3 adjusted points)
II. Case study on diabetes (10 actual points or 13.3 adjusted points)
III. Case study on HIV (10 actual points or 13.3 adjusted points)

Each HW could score up to 30 points. Points from the HWs at each facility were then be combined into an overall score for that facility. The total was adjusted to the maximum possible score of 40 that this component contributed to the assessment of the HF. For example, if there were 5 HWs who accumulated a total of 132 points out of 150 (5 x 30) possible points (88%), the facility received a total of 35 points (rounded to the nearest whole number) for the knowledge assessment (i.e., 40 x 0.88).

Figure 8 - An illustration of the facility (aggregated) performance score and its two components

Scores for each of the elements were not individually weighted; however, in keeping with the method used during the original trial, physical service availability contributed up to 60% to the overall total facility performance score whilst health worker knowledge contributed 40%,

reflecting the trialists' view at the time that physical service readiness was even more important than HW knowledge.

4.2.3. Study 2. Evaluation of quality of patient care and experience

Unit of analysis

The unit of analysis were the patients within facilities.

Sample size calculation (patient assessment)

At the end of the EACDRP trial in 2016, 90% of patients in the intervention facilities were found to have an acceptable quality of care (1). The 2016 survey interviewed a random sample of 4 patients in each facility. Sample size calculations for the 2020 survey were based on methods for matched cluster randomised trials, with paired assessments of quality (i.e., 2016 and 2019) in each HF based on a one-sided hypothesis test.

With an average of at least 10 patients per HF in the 2020 survey, I had >85% power to detect an absolute decline of ≥30% in the proportion of patients with acceptable quality of care, assuming a coefficient of variation, k, between 0.25 and 0.30 (**Table *9***).

Table 9 - Numbers needed for different assumptions of power to demonstrate a difference in acceptable quality of HT and DM care, for different assumptions of patients per HF, cluster variation and effect sizes.

Number of HFs (cluster size)	Number of patients per HF [1]	Coefficient of variation (k)	Proportion (%) of patients with acceptable HT and DM care at end of trial (2016)	Proportion (%) of patients with acceptable HT and DM care currently (2020)	Power (%)
19	10	0.25	90%	65%	**81%**
	10	0.25	90%	60%	**93%**
	10	0.25	90%	55%	**98%**
	10	0.25	90%	50%	**>99%**
	10	0.30	90%	65%	**71%**
	10	0.30	90%	60%	**87%**
	10	0.30	90%	55%	**95%**
	10	0.30	90%	50%	**99%**

Footnote

[1]The average number of patients in each HF overall (including the 2016 survey) was estimated at 5.7

Description of study population

- At each facility 4 HT/DM patients had been sampled in 2016. In 2020, we sampled 10 HT and DM patients to increase the study power. These patients had presented at the facility during the previous 3 months.
- These patients were identified through the facility register books or other comprehensive and available record and selected at random. Identified patients were then tracked and invited for interview.
- Patients sampled in 2016 were not excluded as it was not possible to precisely identify them in 2020 and the re-sampling rate would probably be very low given that 3-4 times more patients were randomly sampled from each facility subsequently in 2020.
- The patients' own medical records were reviewed along with records held at the facility.

Assessment of participant's responses

- Based on the patients' own records, the facilities' records and the patient interviews, each patient received a quality-of-care score on a 10-point scale (Table 10).
- The data collection was done by an experienced clinician and a nurse both of whom had done this assessment in a similar evaluation survey during the EACDRP trial previously. Both were trained during the EACDRP trial as well as the two training sessions for the MeLoHanD project.
- Additionally, within the study tool there was a check question (Q62 in Annex 4) on the overall QoCE assessment (Q61 in Annex 4) to help provide congruence to the summary responses. At the end of each day the QC field worker reviewed the study tool for consistency in responses."

The QoCE score comprised questions assessing whether:

i) the patient was diagnosed correctly (2 points)
ii) treatment was provided (2 points)
iii) the patient received health education (2 points)
iv) the quality of reception and waiting time were acceptable (2 points)
v) the patient was managed according to guidelines (2 points)

For a patient to be classified as adequately managed he/she would need to score 7/10 or more. Only the summary scores from Annex 4 were used for the QoCE analysis.

I tabulated the demographic characteristics of the patients in the 2020 survey and those in 2016, by facility level, district, and other facility-level characteristics.

Table 10 - Summary table of patient quality-of-care and experience (QoCE).

Item	Possible score (circle)	Possible points (circle)	Total points achieved
1. Patient has been diagnosed correctly	No Partial evidence [1] Correctly diagnosed, supporting evidence was recorded	0 1 2	
2. Treatment provided	No evidence Partial evidence [1] Treatment provided with sufficient drugs and/or guidance provided until next visit	0 1 2	
3. Patient received health education	No evidence Patient is aware of symptoms, risks, and complications Patient is also aware of recommended lifestyle changes	0 1 2	
4. Quality of reception and waiting time	Patient had to wait for more than 2 hours Patient had to wait less than 2 hours Patient had to wait but received support or health education during waiting time	0 1 2	
5. Management according to Guidelines	Patient is not being managed according to guidelines Patient is being partially managed acc. to guidelines Patient is being fully managed acc. to guidelines	0 1 2	
	Total points achieved		**!__! !__!**
	Patient adequately managed. **Yes 1 No 2**		**!__!**

Footnote

[1]Evidence from available records not clear or insufficient to ascertain the correct diagnosis or treatment

4.2.4. Statistical methods for study 1 and study 2

Data were collected by a team of 4-5 assessors that included a study clinician or study nurse and three field workers, mainly via hand-held tablets using REDCap® version 7.6.3. Data from REDCap were actively synced or uploaded on to the study servers at the end of each day. Facility inspection data were collected on paper checklists and double entered in REDCap. All

data entry from paper sources was overseen by a senior data manager and REDCap programmer.

All analyses were conducted in Stata 17.0. Continuous variables were summarised as means and standard deviations (SD), or medians and interquartile ranges (IQR). Categorical variables were summarised with frequency counts and percentages. Characteristics of health workers and patients surveyed in 2020 and 2016 were compared using the Pearson chi-squared statistic with the second-order correction of Rao and Scott to account for the clustered design.

Analysis of facility performance (FPS) and service quality (QoCE)

The aggregate FPS was the primary outcome used to assess the impact of the lack of research-driven support on service availability and readiness assessment. The analysis used methods designed for pair-matched cluster randomised trials, with each HF in 2020 being treated as paired with its observation in 2016. First, the mean aggregate FPS was calculated for each HF in 2016 and in 2020, and log transformed due to skewness of the data and because the assumptions for a paired t-test would not be met by possible non-random variation of pair-wise differences of observations within each HF cluster. Then, the difference in log mean scores between 2020 and 2016 was calculated for each HF, and a paired t-test was performed on the pair-wise differences. A similar analysis was done for each component of the FPS: the facility inspection score and the health worker knowledge score.

The association between the aggregate FPS in 2020 and factors that may have influenced service quality was explored using linear regression. These factors included the functionality of patient clubs, whether the HFs had external support such as extra drug supplies from a non-governmental organisation (NGO) or community-based organisation (CBO), HF level, area (rural, peri-urban, or urban, district (Mpigi or Wakiso), and pairing at randomisation) (**Table *11***).

Initial models evaluated each factor individually, adjusted for the FPS in 2016. All variables that were associated with the 2020 score at $p<0.20$ after adjusting for the 2016 score were included in a multivariable model (the 'fully adjusted' model); those that remained associated at $p<0.20$ in the fully adjusted model were retained.

The QoCE score, and the proportion of adequately managed patients (QoCE ≥7), was used to assess the impact of the lack of research-driven support on the quality of patient care, using the same analysis approach as for the FPS. First, the mean QoCE score and the prevalence of

adequately managed patients in each HF in 2016, and in 2020, was calculated and log transformed due to skewness of the data and because the assumptions underlying the use of a paired t-test would not be met if possible non-random variation occurred with regards to pair-wise differences of observations within HF clusters. Then, the difference in log mean scores, and in log prevalence, between 2020 and 2016 was calculated for each clinic, and a paired t-test was performed on the pair-wise differences.

The association between QoCE scores and factors that may have influenced quality of care was explored in an individual-level analysis using a Tobit regression with random effects to account for the correlation of multiple observations within clinic. These factors included the patients' age, gender, the functionality of patient clubs, whether the HFs had external support such as extra drug supplies from a non-governmental organisation (NGO) or community-based organisation (CBO), HF level, area (rural, peri-urban, or urban, district (Mpigi or Wakiso), and pairing at randomisation)(**Table *11***). Since the QoCE score is bounded by a maximum of 10, ordinary linear regression can lead to biased standard errors. Therefore, Tobit regression is used to reduce the bias in the estimation of standard errors when the outcome is censored (bounded). (49) Initial regression models evaluated each factor individually, adjusted for assessment year (2016 or 2020). All variables that were associated with the QoCE score at $p<0.20$ after adjusting for the assessment year were included in a multivariable model; those that remained associated at $p<0.20$ in the fully adjusted model were retained.

Table 11 - Definition of exploratory or independent variables on facility performance (FPS) and service quality (QoCE)

Exploratory variables	**Question or definition**	**Final measurement**
Age[1]	Date of birth or best midyear or midmonth estimate by DD/MM/YYYY	Age/10 (to increase the coefficient size to at least 3 decimal places)
Gender[1]	Male or Female	Male or Female
Patient club functionality	Aggregated scores of functionality attributes e.g., +/- existence of a patient club, +/-elected club leadership, +/-regular meetings, +/-member contributions, +/-financial records, +/- annual general meetings	Highly functional or Moderately functional or Lowly or non-functional

External support (excludes patient club support)	Any external support e.g., drugs received from an NGO or CBO that excluded the patient club	Yes or No
Facility level	Original attribute of the public facility level of care	HCII, HCIII or HCIV/Hospital
Area	Geographical location of the health facility as at the 2010 national census	Urban or Peri-urban, or Rural
District	Parent district of health facility	Mpigi or Wakiso
Pairing at randomisation	Whether selected as a referral, paired or singleton facility – effects of referral or pairing linkages e.g., easier up- and back-referrals, shared drugs, shared support supervision,	Referral or Paired or singleton

Footnote:
[1]Age and Gender were only included for the service quality assessment (QoCE).

4.2.5. Study 3. Evaluation of sustainability capacity - normalization and intervention sustainability

Unit of analysis

This was individuals (HWs or patients) within the health facility. The normalization and sustainability data were not collected in 2016 so the analysis used data collected in 2020 only.

Sample size calculation

There were 91 HWs who participated in the normalization tool, and 110 individuals (patients, health workers and district supervisors) who participated in the intervention sustainability assessment (**Table *12***).

Table 12 - Distribution of the observed and sub-sampled participants

Groups	Observed overall	Sub-sampled for PSAT
Health workers	91[1]	35[2]
District/ MoH supervisors	11[3]	11[3]
Patients	332	64[2]
	434	**110**

Footnotes
[1]*All 91 HWs that were interviewed for the normalization tool*
[2]*Only patient leaders or HW focal persons (not all patients or HWs) were interviewed for the intervention sustainability (PSAT)*
[3]*Includes 3 former intervention supervisors*

Explanation for subsample for the PSAT

Following lessons learned from the pilot study experience regarding time needed and complexity of the intervention sustainability questionnaire, the number to be interviewed on the intervention sustainability questionnaire (PSAT) was limited to improve tool precision and include only key patient and health worker informants at each health facility rather than all the patients and health workers. This, therefore, included only patient leaders e.g., patient club leaders or patient-peer mobilisers for the patient interviews and only HF focal persons and/or facility in-charges were interviewed for the health worker interviews.

Sampling assumptions for normalization strength

Assuming a design effect of 2 to allow for the clustering of HW responses within facilities and a SD of 1.0, with 91 HWs there would be >90% power to demonstrate whether the mean normalization score overall, or for each domain would be >0.5 higher than 3.5 which is the halfway score rounded up to the next 0.5 (or a hypothesised reference value below the desired target score of ≥4 for good domain strength). Hence, adequate domain strength was defined as a score of ≥4 of a possible 5.

Sampling assumptions for intervention sustainability capacity

With 110 individuals surveyed, assuming a design effect of 2 and a SD of 1.0, I had >80% power to demonstrate a similar difference of >0.4 higher than 4.5 which is the halfway score rounded up to the next 0.5 (or a hypothesized value below the desired target value of ≥5 for good domain strength). Hence, adequate domain strength was defined as a score of ≥5 of a possible 7.

Description of study population

I tabulated the demographic characteristics of the individuals participating in the survey, by facility level, district, and other facility-level characteristics.

Primary outcome

Mean total overall score or the proportion of adequate strength scores e.g., ≥ 4 for normalization strength or ≥ 5 for the intervention sustainability strength.

Secondary outcomes

Mean score within each domain or the proportion of adequate domain strength scores e.g., ≥ 4 for normalization strength or ≥ 5 for the intervention sustainability strength.

Primary analysis assessed both mean summary scores and proportions of adequate domain strength by the health facility level.

The mean score for sustainability overall (i.e., normalization strength or intervention sustainability strength, and within each domain, was compared with the hypothesised mean value.

Within the pre-defined domains, mean and aggregate scores were determined at domain and facility level for both assessments.

The analyses were performed using the statistical package in Stata® version 17.

Graphic or spider-web chart comparisons of domain means or medians by HF level were presented.

The reliability of the normalization and intervention sustainability (PSAT) tools in assessing sustainability capacity in this setting

Reliability

Reliability as a measure of internal consistency was assessed by measuring to what extent each component domain score and the overall total domain (normalization or sustainability) score measure the same thing.

For example, if the overall total domain score is 4 - then how well did each of the component domain score in predicting the overall total domain score correctly and this is calculated using *Cronbach's alpha*, which tests the tool for internal consistency of all component domains. A value of ≥0.8 defined as high, 0.6-0.8 as moderate and >0.6 low consistency. If alpha is high, this may mean many redundant questions asking the same thing. Conversely, a low alpha may mean that there aren't enough questions on the tool.

4.3. Data management

Data entry

Standardised questionnaires and record forms were used, most of which had also been used for the EACDRP trial. Data was mainly collected using hand-held Huawei Mate® tablets with REDCap® version 7.6.3, actively synced or uploaded on to the study servers at the end of each day.

Quality assurance

Paper-based questionnaires were mainly used for facility-based performance interviews only. These were transcribed and double entered onto a REDCap® version database while electronic devices were uploaded on to the database servers directly at the end of day. Where paper-based questionnaires were used they were routinely checked for logical and range errors by the team leader or the responsible QC field worker in the field, and by the data manager using the REDCap® automated software. All data entry was overseen by a senior data manager and certified REDCap® programmer.

4.4. Official Approval & Ethical Considerations.

Official approval

Approval of the study activities was obtained from the ministry of health (MoH) and in collaboration with MoH district health teams, building on the goodwill and linkages already established with the EACDRP.

Ethical clearance

Ethical Approval was obtained from the ethical review committee of LSHTM (LEO) (17914) and from the Uganda Virus Research Institute (UVRI) Research and Ethics Committee (GC/127/19/09/743). The study also got clearance by the Uganda National Council for Science and Technology (UNCST) (HS 2714).

The study team was trained in human subject protection (HSP) and good clinical practice (GCP) before start of data collection.

Consent

General formal permission to interview patients and health workers was obtained from both the MoH supervisors and respective district health teams.

Written informed consent was obtained from all HWs and patients who were interviewed.

Confidentiality.

Data collected from or about study participants and health workers was treated with strict confidentiality. Names of study participants were recorded so that they could be traced for follow up if found ill or insufficiently managed, but these records and their contact information were not attached to or stored with other clinical and personal data. Whilst names of HWs were also recorded, observations on knowledge and skills of specific HWs was recorded anonymously. Heads of HFs and individual HWs were duly informed that the study was not being conducted to evaluate them as individuals, but to investigate the impact and sustainability of the prior intervention from a HS perspective.

Some key informant interviews or meetings were also voice recorded only with exceptional consent from the key informants as to whether they agreed to be recorded or be specifically quoted. Voice recordings were later transcribed anonymously but the original audio files were kept in encrypted 7z-zip® folders on the unit servers.

Treatment of patients.

The study team did not actively treat patients, but patients previously screened and diagnosed with HT and DM during the EACDRP trial continued to receive treatment according to available algorithms developed from national treatment and referral guidelines and in line with the standard of care currently in place for HT and DM in the country. Any individual patient that was identified during the assessment as not appropriately managed according to guidelines was discussed with the HW in charge of the HF or respective outpatient section, and improvements or referral to a higher level of care were suggested as necessary. Occasionally, urgent, or complicated cases that required emergency attention were transported by study vehicle to the nearest referral unit or hospital.

Chapter 5: Research Paper 1

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	389984	**Title**	Dr
First Name(s)	David		
Surname/Family Name	Katende		
Thesis Title	Investigating the medium to long term sustainability of an intervention to improve care for hypertension and diabetes within the primary health care setting in Uganda (MeLoHanD)		
Primary Supervisor	Prof. Heiner Grosskurth		

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

*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?	BMC Health Services Research
Please list the paper's authors in the intended authorship order:	Katende, David; Kasamba, Ivan; Sekitoleko, Isaac1; Nakuya, Kevin; Kusiika, Caleb; Buyinza, Allan; Mubiru, Michael Charles; Mutungi, Gerald; Nyirenda, Moffat; Grosskurth, Heiner; Baisley, Kathy

[redacted] 4/2/13

[redacted] 4/02/13

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 designed the study and wrote the protocol with input from Heiner Grosskurth (HG) Moffat Nyirenda (MN) and Kathy Baisley (KB); I performed the analysis with support from KB and inputs from Isaac Sekitoleko (IS) and Ivan Kasamba (IK); I wrote the first draft and responded to co-author comments and revisions; I submitted the paper for publication

SECTION E

Student Signature	David Katende [redacted]
Date	4/02/2023

Supervisor Signature	Heiner Grosskurth [redacted]
Date	4/02/2023

TITLE Medium-to-long term sustainability of a health systems intervention to improve service readiness and quality of non-communicable disease (NCD) patient care and experience at primary care settings in Uganda

RUNNING TITLE Health services evaluation for NCDs

ARTICLE TYPE Original article

TARGET JOURNALS

AUTHORS Katende, David[1 2]; Kasamba, Ivan[2]; Sekitoleko, Isaac[1 2]; Nakuya, Kevin[2]; Kusilika, Caleb[2]; Buyinza, Allan[2]; Mubiru, Michael Charles[2]; Mutungi, Gerald[3]; Nyirenda, Moffat[1 2]; Grosskurth, Heiner[1]; Baisley, Kathy[1]

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WORD COUNT **379** (abstract)
7005 (main article: without abstract, acknowledgements, references, tables, and figures)

NUMBER OF TABLES 8

NUMBER OF FIGURES 1

NUMBER OF WEB-BASED APPENDICES ('Additional material') 0

KEYWORDS sustainability, evaluation, chronic diseases, NCDS, health systems, primary care, sub-Saharan Africa, Uganda, intervention trial, long term, medium term, patient clubs, adherence clubs.

CITATION (FULL TEXT IN APPENDIX G)

Katende, D., Kasamba, I., Sekitoleko, I. et al. Medium-to-long term sustainability of a health systems intervention to improve service readiness and quality of non-communicable disease (NCD) patient care and experience at primary care settings in Uganda. BMC Health Serv Res 23, 1022 (2023).
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Abstract

Background

With the double burden of rising chronic non-communicable diseases (NCDs) and persistent infectious diseases facing sub-Saharan Africa, integrated health service delivery strategies among resource-poor countries are needed.

Our study explored the post-trial sustainability of a health system intervention to improve NCD care, introduced during a cluster randomised trial between 2013 and 2016 in Uganda, focusing on hypertension (HT) and type-2 diabetes mellitus (DM) services.

In 2020, 19 of 38 primary care health facilities (HFs) that constituted the trial's original intervention arm until 2016 and 3 of 6 referral HFs that also received the intervention then, were evaluated on i) their facility performance (FPS) through health worker knowledge, and service availability and readiness (SAR), and ii) the quality-of-patient-care-and-experience (QoCE) received.

Methods

Cross-sectional data from the original trial (2016) and our study (2020) were compared. FPS included a clinical knowledge test with 222 health workers: 131 (2016) and 91 (2020) and a five-element SAR assessment of all 22 HFs. QoCE assessment was performed among 420 patients: 88 (2016) and 332 (2020). Using a pair-matched approach, FPS and QoCE summary scores were compared. Linear and random effects Tobit regression models were also analysed.

Results

The mean aggregate facility performance (FPS) in 2020 was lower than in 2016: 70.2 (95%CI= 66.0-74.5) vs. 74.8 (95%CI=71.3-78.3) respectively, with no significant difference (p=0.18). Mean scores declined in 4 of 5 SAR elements.

Overall FPS was negatively affected by rural or urban HF location relative to peri-urban HFs (p<0.01). FPS was not independently predicted but patient club functionality showed weak association (p=0.09).

QoCE declined slightly to 8.7 (95%CI=8.4-9.1) in 2020 vs 9.5 (95%CI=9.1-9.9) in 2016 (p=0.02) while the proportion of patients receiving adequate quality care also declined slightly to 88.2% from 98.5% respectively, with no statistical difference (p=0.20). Only the parent district weakly predicted QoCE (p=0.05).

Conclusions

Four years after the end of research-related support, overall facility performance had declined as expected because of the interrupted supplies and a decline in regular supervision. However, both service availability and readiness and quality of HT/DM care were surprisingly well preserved.

Sustainability of an NCD intervention in similar settings may remain achievable despite the funding instability following a trial's end but organisational measures to prepare for the post-trial phase should be taken early on in the intervention process.

Introduction

Non-communicable diseases (NCDs) were predicted to account for over 70% of all disease burden in developing countries in 2020 as compared to just under 50% in 1990 (2). The current burden of NCDs accounts for 71% of all global deaths (41 million people) each year (3). Annually, 15 million NCD deaths occur between 30 and 69 years of age and over 85% of these "premature" deaths occur in low- and middle-income countries (LMICs) including Uganda (3). In sub-Saharan Africa, between 1990 and 2017 the proportion of total disability adjusted life years (DALYs) attributable to NCDs increased from 19 to 30% of the total burden (3). Therefore, health systems (HS) in these countries face the need to undergo a transition from services largely fashioned on managing communicable diseases like malaria, HIV/AIDS, or tuberculosis (TB) to services that must become able to address both these infections and the increasing burden of NCDs. Due to the urgency of care, the double burden on the already limited available resources means that curative services often get prioritised over preventative ones. Additionally, in LMICs, many NCDs including most cases of hypertension remain undetected due to the lack of active screening efforts (20, 50).

In Uganda, the prevalence of one or more modifiable NCD risk factors is over 94% indicating that NCDs may be largely preventable (51). Despite the call to global action taken by the UN General Assembly resolution on NCDs control and prevention in 2011 (52), there is still limited domestic and global investment in addressing NCDs. Furthermore, the required response to NCDs among the poorest countries requires the introduction of integrated health service delivery strategies (53).

In 2016, we concluded a large cluster randomised trial to improve NCD care for hypertension (HT) and type-2 diabetes (DM) at primary care facilities in Uganda and Tanzania (the UK-MRC funded East African Chronic Disease Programme, EACDRP) (1). The trial demonstrated significant improvements in NCD service readiness, with large differences between intervention and control facilities in the availability of functional basic equipment and healthcare worker knowledge. For example, in Uganda, the mean performance score in the intervention facilities was nearly double that in the control (74% vs 43%) and similarly 95% of these intervention facilities provided good quality NCD care according to national guidelines compared to only 8% in the control arm (1).

A comprehensive definition of sustainability of a health services intervention includes three components: (i) continued benefits to those who received the services when the interventions started and to new participants after the supporting funds were discontinued, (ii) continued implementation of intervention activities through a responsible organisation following discontinuation of financial support and (iii) community empowerment to improve their health by continuing intervention activities after its end (32). Several efforts were made to ensure that NCD services were sustained after the EACDRP trial. These included close involvement of the ministerial and local governance structure in study activities, handover of important intervention resources (e.g., documents, equipment and up to 9 months' buffer supply of NCD drugs at the end of the trial). The study also encouraged a patient-led initiative to form patient clubs which promoted peer support and contributions to a small-scale communal fund to assist patients with their treatment, by procuring drugs or supplies with a high stock out rate, e.g., bendrofluazide, metformin or glucose test strips over periods when the usual freely provided health facility (HF) supplies were interrupted.

The EACDRP created an excellent platform to assess medium-to-long term sustainability (which we defined as a period of 2 to 5 years after the end of research funding support) of a successful health system NCD intervention on the management of HT and DM within primary care settings in Uganda, the **MeLoHanD** study. We used this platform to re-evaluate health worker (HW) knowledge, and HT and DM service availability and readiness of HFs, and the quality of care experienced by patients at these HFs, at about 4 years after the research-related funding support had ended.

Methods

Study setting

Between 2013-2016, a cluster randomised trial of a health system intervention was conducted to improve NCD care in 38 primary care facilities and 6 referral facilities in Uganda (the EACDRP trial) (1)(Figure 2, Figure 1*Figure 1*). The intervention package included the following components: training of health workers; provision of simple clinical management algorithms and patient registers in line with national guidelines; provision of essential NCD care drugs; active outpatient screening; promotion of NCD awareness and screening in the community

outreaches, and regular support supervision visits to monitor the intervention conducted jointly by district and project staff.

At the end of the research support in 2016, an evaluation was conducted to assess HF service readiness and quality of patient care that the intervention project had achieved (1). This involved a detailed inspection of each of the intervention and control facilities, a written test of HWs' knowledge at each facility, and a survey of a random sample of 4 NCD patients from each facility. The surveys used standardised tools and questionnaires.

Fieldwork for the current MeLoHanD study was conducted between January and December 2020 in all 19 former intervention facilities and 3 referral facilities, in two central districts of Uganda: (a) Wakiso district, which forms a horseshoe shape around the capital city of Kampala with an urban, peri-urban, and rural population of 2.5 million (36); (b) Mpigi district, which lies just southwest of Kampala along the shores of Lake Victoria and has a population of 250,000 (36). The population is largely peri-urban and rural which is mainly engaged in subsistence farming, fishing, and artisanship.

Description of health facility levels in Uganda

The primary health care system of Uganda is tiered along the politico-administrative organisation of the country (Table 1) and is overseen by the district health office, led by an experienced medical doctor, who co-ordinates resource distribution and staff deployment (54) to health centres (HC) II, III, IV and district hospitals (**Error! Reference source not found.***Figure 1*). Several districts form a region which is served by a hospital that can provide specialist care. HCIIs and HCIIIs which may include some private-not-for-profit health facilities are expected to diagnose and manage uncomplicated chronic disease cases including DM, HT, asthma, and HIV infection. HCIIs should also be able to diagnose DM, but usually refer DM patients to a HCIII or higher level facilities (55).

Randomisation strategy applied during the original trial

Of the 38 Ugandan lower-level HFs (19 in each arm), 22 were randomised individually (as singletons) while the remaining 16 HCIIIs and nearby HCIIs (within a 10km radius) were randomised jointly as 8 pairs, to minimise potential contamination owing to their proximity. In Uganda, hospitals and HCIVs are referral HFs for lower-level HFs in their catchment area. To ensure consistent care delivery to any patient referred to them from an intervention facility, all the 6 referral HFs (hospitals/HCIVs) in the project area therefore received the intervention

without randomisation (37). For each community in our study, the categories used for urban, peri-urban, or rural localisation followed the classification used by the Uganda's 2010 national population census (56) and by the Uganda Demographic and Health Survey, 2011 (57).

Study design

Our follow-up evaluation study (MeLoHanD) was a comparison of data from two cross-sectional surveys conducted at two-time points: the end of the EACDRP trial in 2016 and 4 years after the end of the trial, in 2020. We could thus evaluate the durability or sustainability of the service availability and readiness at former intervention HFs, as well as the health service-centred quality of care and patient experience (QoCE) over the 4 years without research-driven support. The MeLoHanD study was conducted in 3 randomly selected higher-level facilities (HCIVs) of the 6 referral units, and all the 19 lower-level facilities (10 HCIIIs and 9 HCIIs) that constituted the original intervention arm of the EACDRP trial described in the section above.

Of the 3 randomly selected HCIVs, 1 HCIV (peri-urban) was selected from Mpigi district while 2 HCIVs (1 peri-urban, 1 rural) were selected from Wakiso district. There were 7 lower-level facilities (4 HCIIIs, 3 HCIIs) from Mpigi and 12 lower-level facilities (6 HCIIIs, 6 HCIIs) from Wakiso district. Of these, only Wakiso district (Entebbe) had urban facilities (1 HCIII, 1 HCII) while the remaining 17 facilities (9 HCIIIs, 8HCIIs) were rural (**Table 2**).

A pilot study to test study tools and prepare the study team for their field work was done in two health facilities (an urban HCIII and a peri-urban HCII) prior to this evaluation. Findings from these pilot HFs were not included in the analysis for the MeLoHanD study.

To evaluate *service availability and readiness*, each HF was inspected using a modified WHO Service Availability and Readiness Assessment (SARA) tool (35). In addition, a clinical knowledge assessment was administered to all health workers present at the HF on the survey days. This is a validated knowledge test that has been used previously in East Africa (4, 21).

Selection of participants for the MeLoHanD study

For the *quality of care and experience* (*QoCE)* assessment, patients were interviewed using a previously used tool as well as any available patient records to check consistency in responses. Twenty active patients who had been in care for at least 3 months at each HF were randomly selected from all HT and DM patients on the patient register. The study team made a pre-survey visit to each HF to confirm the survey days, prepare the HF staff, get the contacts of the

identified individuals, and invite them on the survey days. We applied a restricted random selection approach to ensure adequate balance of men and women, and of HT and DM patients. Men and DM patients were found to be heavily under-represented in the pilot study.

All 20 selected patients were invited to visit the HF for participation in the survey. A transport refund was given to those that presented on the survey day. Efforts were made to contact those that did not present on the scheduled days to encourage their participation. We aimed to establish reasons for non-participation. Defaulters were not replaced. To ensure adequate statistical power for the study four times more patients were sampled in 2020 than in 2016. All assessment tools were identical to the versions used for the evaluation of the EACDRP intervention in 2016.

Assessment of service availability and readiness (SAR)

The modified SARA tool assessed five aspects of service delivery elements (listed below). A HF could obtain up to 10 points for each element, so that a maximum of 50 points could be achieved.

i. Availability and functionality of essential equipment (e.g., blood pressure (BP) machine, weighing scale, stadiometer, glucometer/urine dipsticks, stethoscope, patient register book, HT/DM screening logbook, referral register book, health education record).
ii. Availability of drugs and other consumables (for the treatment of HT and DM and whether drugs were in line with guidelines and in sufficient stock).
iii. Quality of records on patients with NCDs (guidelines, essential demographic data, clinical observations, information on diagnosis, treatment, referral and follow up).
iv. Healthcare utilisation at facility by patients with NCDs (number of HT and DM patients, evidence for increase in utilisation over past year).
v. Prevention of NCDs and their complications (evidence for and number of health education sessions given, evidence for active screening for HT or DM among those that presented with other conditions e.g., back pain evidence of outreach activities).

Details of the adapted SAR tool used are available from (**Supplementary table 2**).

Health worker knowledge was assessed by means of a supervised self-completed multi-choice questionnaire that was based on 3 clinical case scenarios on HT, DM, and HIV infection. For each scenario, the assessment also looked at five elements: 1) essential diagnostic steps

(symptoms, signs, tests); 2) risk factors for each of these 3 disease; 3) complications; 4) treatment regimens; and 5) guidelines for referral. The HIV case scenario was included for comparison, as earlier knowledge tests had indicated that HWs in East Africa had generally good knowledge on HIV case management (4, 21). Each scenario was worth 10 points, so a HW could score a maximum of 30 points.

The inspection score from the SARA tool and the scores from the health worker clinical knowledge assessment were combined into a single aggregate facility performance score (FPS). The score from the SARA tool was converted to a percentage and scaled to a maximum of 60 points (e.g., a facility that scored 40 on the SARA would have achieved 40/50=0.80*60=48 points). Similarly, HW knowledge scores for each facility were totalled and converted to a percentage, then scaled to a maximum of 40 points. For example, if there were 5 HWs who accumulated a total of 132 points out of 150 (5 x 30) possible points (equivalent to 88%), the facility received a total of (40*0.88) = 35 points (rounded to the nearest whole number) for the knowledge assessment. The SARA and knowledge assessments points were then combined into the FPS with a maximum score of 100. Using the above example, the FPS would then be 48 + 35 = 83 out of a possible maximum of 100 points.

Additional details on health worker characteristics are available from **Supplementary table 1**.

Assessment of quality of patient care and experience (QoCE)

The QoCE assessment comprised five questions assessing whether: 1) the patient was diagnosed correctly; 2) treatment was provided; 3) the patient received health education; 4) the quality of reception and waiting time were acceptable; and 5) the patient was managed according to national guidelines (**Table 3**). The observations were summarised into a QoCE score. Each question could result in up to 2 points, for a maximum score of 10. The patient was considered to be adequately managed if their QoCE score was ≥7/10.

Statistical methods

Data were collected by a team comprising a study clinician or study nurse and 3 field workers, mainly via hand-held tablets using REDCap® version 7.6.3. Data from REDCap® were checked in the field by the clinician or the nurse and were then actively synced or uploaded on to study servers at the end of each day. Facility inspection data were collected on paper checklists and double entered in REDCap®. All data entry from paper sources was overseen by a senior data

manager and REDCap® programmer. If necessary, queries were raised and communicated to the field team for verification.

All analyses were conducted in Stata 17.0. Continuous variables were summarised as means and standard deviations (SD), or medians and interquartile ranges (IQR). Categorical variables were summarised with frequency counts and percentages. Characteristics of health workers and patients surveyed in 2020 and 2016 were compared using the Pearson chi-squared statistic with the second-order correction of Rao and Scott to account for the clustered design.

The aggregate FPS was the primary outcome used to assess the impact of the lack of research-driven support on service availability and readiness assessment in 2020. The analysis used methods designed for pair-matched cluster randomised trials, with each HF in 2020 being treated as paired with its observation from 2016. First, the mean aggregate FPS was calculated for each HF in 2016 and in 2020, and log transformed. Then, the difference in log mean scores between 2020 and 2016 was calculated for each HF, and a paired t-test was performed on the pair-wise differences. A similar analysis was done for each component of the FPS: the facility inspection score and the health worker knowledge score.

The association between the aggregate FPS in 2020 and factors that may have influenced service quality was explored using linear regression. These factors included the functionality of patient clubs, whether the HFs had external support such as extra drug supplies from a non-governmental organisation (NGO) or community-based organisation (CBO), HF level, area (rural, peri-urban, or urban, district (Mpigi or Wakiso), and pairing at randomisation before the start of the original trial). Initial models evaluated each factor individually and adjusted for the FPS in 2016. All variables that were associated with the 2020 score at $p<0.20$ after adjusting for the 2016 score were included in a multivariable model (the 'fully adjusted' model).

The QoCE score, and proportion of adequately managed patients (QoCE ≥7), was used to assess the impact of the lack of research-driven support on the quality of patient care in 2020, using the same analysis approach as for the FPS. First, the mean QoCE score and the prevalence of adequately managed patients in each HF in 2016, and in 2020, was calculated and log transformed. Then, the difference in log mean scores, and in log prevalence, between 2020 and 2016 was calculated for each HF, and a paired t-test was performed on the pair-wise differences.

The association between QoCE scores in 2020 and factors that may have influenced quality of care was explored in an individual-level analysis using a Tobit regression with random effects to

account for the correlation of multiple observations within HF. Since the QoCE score is bounded by a maximum of 10, ordinary linear regression can lead to biased standard errors. Therefore, Tobit regression is used to reduce the bias in the estimation of standard errors when the outcome is censored (bounded) (49). These factors included the patients' age, gender, the functionality of patient clubs, whether the HFs had external support such as extra drug supplies from a non-governmental organisation (NGO) or community-based organisation (CBO), HF level, area (rural, peri-urban, or urban, district (Mpigi or Wakiso), and pairing at randomisation). Initial regression models evaluated each factor individually and adjusted for the facility-level mean QoCE score in 2016 a priori. All variables that were associated with the QoCE score in 2020 at $p<0.20$ after adjusting for the mean score in 2016 were included in a multivariable model.

Results

Service availability and readiness

All 22 health facilities were inspected using the SARA tool. A total of 91 HWs from the 22 facilities were assessed on the clinical knowledge test, compared with 131 from the EACDRP trial in 2016. The lower number in 2020 was due to COVID restrictions and absenteeism. 60 HWs (66%) surveyed had also completed the test in 2016. The age distribution across the two years was similar with a mean (SD) age of 37.0 (7.9) in 2020 compared with 36.6 (9.6) in 2016 (p=0.01). A slightly lower proportion of respondents in 2020 were female than in 2016 (65% vs 70%, respectively, p=0.11), and a larger proportion were clinicians 27% in 2020 vs 17% in 2016), although the difference was not statistically significant (p=0.29). Most respondents were either nurses, midwives, or nursing aides (67% in 2020 and 76% in 2016). In 2020, 47% of HWs were from HCIIIs and 28% were from HCIIs, compared with 60% and 18% in 2016, respectively, while 25% of HWs in 2020 and 22% in 2016 were from HCIVs (p<0.01) (**Table *5***, **Supplementary table 1**).

The mean aggregate FPS from the facility inspection and clinical knowledge assessments in 2020 was lower than in 2016: 70.2 (95%CI= 66.0-74.5) compared with 74.8 (95%CI=71.3-78.3), respectively (**Table 4**). However, there was no evidence of a significant difference (p=0.18).

In evaluating the separate components of the FPS score, across the 5 elements of the modified SARA tool for facility inspection, we observed a decline in mean scores of 4 of the components,

ranging from 2 to 5 points: the *availability of essential equipment, essential drugs, utilisation of NCD treatment services* and *preventive services* (**Table 4 Table *6***). The *utilisation of NCD services for HT and DM* was most adversely impacted, with a mean score of 3.0 (95%CI 1.8, 4.2) in 2020 compared with 8.0 (95%CI=7.3, 8.7) in 2016 (p<0.001). In contrast, the mean score for the *quality of records* showed an improvement: 9.8 (95%CI= 9.5, 10.0) in 2020 vs 9.1 (95%CI=8.7, 9.5) in 2016 (p=0.001).

Mean health worker knowledge scores were slightly higher in 2020 than 2016: 26.8 (95%CI=26.1, 27.5) vs 26.0 (95%CI=25.3, 26.7), although the difference was not significant (p=0.11) (**Table *5***). There was some evidence that mean knowledge scores for HIV were higher in 2020 than in 2016 (8.5 vs 8.2, respectively; p=0.08), but no evidence that knowledge scores differed for the other disease areas or across HF levels (**Table *5***).

The FPS in 2020 was inversely associated with FPS in 2016, with mean FPS in 2020 decreasing by 0.4 points (95%CI -0.8, 0.1; p<0.01) for every point increase in the 2016 score. After adjusting for the FPS in 2016, there was strong evidence that the FPS in 2020 was associated with location of the HF (p<0.01) (**Table *6***). The mean FPS was 10.9 points lower in HFs located in rural areas (95%CI= -19.9, -1.9) and 20.6 points lower in those located in urban (95% CI -32.8, -8.4) compared with peri-urban areas. There was borderline association with a HF's patient club functionality (p=0.05) with moderate and low functionality associated with a mean FPS that was 5.6 (95%CI= -13.3, 2.0) and 6.8 (95%CI= -14.1, 0.5) points lower, respectively, than patient clubs with high functionality. There was some evidence of an association between FPS and facility level (p=0.08), with mean FPS scores 1.1 points higher (95%CI=-0.6, 18.5) in HCIIIs than in HCIIs and 8.9 points higher (95%CI= -0.6, 18.5) in HCIVs than in HCIIs. There was also weak evidence that the FPS was lower in Mpigi than in Wakiso (-4.6, 95%CI= -10.7, -1.6, p=0.11). There was no evidence of an association with post-trial external support received (e.g., from NGOs) (p=0.22) or pairing at randomisation (0.19) (**Table *6***).

In the final adjusted model, after adjusting for patient club functionality, facility level, HF area, district and pairing at randomisation, the mean FPS in 2020 decreased by 0.6 points (95% CI -0.9, -0.2) for every point increase in the 2016 score (p<0.01). None of the other factors was found to be an independent predictor of FPS but club functionality showed a weak association (p=0.09) (**Table *6***).

Quality of patient care and experience

QoCE assessments were available from interviews with 332 patients in 2020 and 88 patients from 2016. The patients in 2020 were older than in 2016 (mean (95%CI) =60.1 (58.5, 61.8) vs 55.9 (53.6, 58.1)), respectively (p<0.01) but the sex distribution was similar across both groups (71% female in 2020 vs 65% in 2016, p=0.22). Patient distribution across HF levels was not different (p=0.86). More than half of patients (53%) in 2020 said they were employed compared to 29% in 2016 respectively while 40% in 2020 considered themselves to be homemakers compared to 47% in 2016. Only 7% were either unemployed or retired or reported belonging to other categories in 2020 compared to about a quarter (24%) in 2016 (p<0.01).

There was good evidence that the mean QoCE score was lower in 2020 than in 2016 (8.72 vs 9.45, respectively, p=0.02) (**Table *7***). The proportion of *adequately managed patients* was also lower in 2020 (88.2% vs 95.5%), but the difference was not significant (p=0.20). When stratified by HF level, the largest decrease in QoCE scores was seen in HCIIs (a mean decrease of 0.91 points, 95% CI= -1.82, -0.003).

There was no evidence that mean QoCE scores in 2016 were associated with QoCE scores in 2020 (p=0.71). After adjusting for QoCE scores in 2016, there was some evidence that scores in 2020 were associated with patient gender, external support (excluding patient club support), district, and patient club functionality (**Table *8***). Mean QoCE scores in 2020 were 0.43 points higher (95%CI=-0.08, 0.95; p=0.10) in women than men, 1.35 points higher (95%CI= -0.28, 2.41; p=0.02) in HFs with external support than those without, and 1.04 points higher (95%CI= -0.09, 2.17; p=0.08) in Wakiso than Mpigi district. Mean QoCE scores in 2020 were lower in HFs with low patient club functionality compared with those with high functionality (-0.92, 95%CI=-2.19, 0.36; p=0.05). After adjusting for QoCE scores in 2016, gender, patient club functionality, external support, facility level, area, and district, only parent district remained an independent predictor of QoCE scores in 2020, with HFs in Wakiso having scores 1.21 points higher (95%CI=0.25, 2.18; p=0.02) than Mpigi (**Table *8***).

Discussion

We defined facility performance as having two inputs i) health worker clinical knowledge and ii) the facility inspection with five constituent elements of service availability and readiness. Overall, health worker knowledge was well preserved, and knowledge scores were similar across all facility levels whether by subject matter or the 3 disease case scenario questions. This

indicates that over the post-trial period of 4 years, despite any decay or shortcomings in support supervision or motivation or even underutilisation of the facility; the NCD case management competence of HWs were largely sustained. Only 66% of HWs interviewed in 2020 took part in the assessment in 2016 which suggests that NCD related knowledge among new staff members was also adequate. This finding was also reinforced by a similar finding on adequate quality of care and experience which remained unchanged over this same period. Health worker knowledge is usually measured as a pre- and post-training assessment we have had the benefit of assessing it at least 4 years after the intervention. Interestingly, most studies in SSA that have assessed task shifting with nurse-led NCD management, have shown good knowledge retention in using a qualitative framework approach (58) or the bundled education and support with text (BEST) method (19). However, our study like others in Kenya and South Africa (17, 18), also demonstrates that a protocol-driven or clinical knowledge test approach based on national guidelines is essentially comparable.

Despite the decline in most of the elements of service availability and readiness over the period 2016-2020, there was no evidence of difference in overall facility performance owing to the strong performance of HWs on the clinical knowledge test. Of the five constituent elements of SAR only the quality of records was preserved while the utilisation of NCD services and evidence of preventive activities declined most strongly. The availability of essential drugs and to a lesser extent the availability of essential equipment and consumables also declined, but less steeply. This suggests that the support obtained from functional patient clubs may have alleviated the performance decline to some extent, through the replenishment of consumables, repair or replacement of simple equipment and the direct purchase of essential medicines. However, with regards to the availability of essential medicines, the worst performing HFs only scored <2 points out of possible 10 in 2020 (not shown), indicating that some HFs were more severely impacted by inconsistent drug supplies than others, and also had little to no patient club support.

The utilisation of primary care services at public facilities usually reflects the availability of essential medicines and other consumables (59-61), and therefore the observed decline in utilisation was expected. This decline is most likely also a result of a reduction in screening efforts, consistent with our finding that preventive activities in 2020 occurred much less frequently than in 2016. This in turn implies that only a few new NCD cases were actively detected and put into NCD care.

The association of FPS with patient club functionality (p=0.05) and facility level (p=0.08) was borderline. District location (Mpigi vs Wakiso) (p=0.19) and the peri-urban vs rural or urban location of a health facility (0.23) did not affect service availability and readiness. None of them predicted facility performance independently despite a weak association with patient club functionality (0.09). However, adjusting for 2016 scores, rural and urban HFs mean scores in 2020 were 11 and 21 points lower than peri-urban HFs (p<0.01) respectively, perhaps a chance finding. Our findings are reminiscent of a recent study from southern Nigeria which found that service readiness increased with the presence of some power sources (electricity, generators, batteries and solar), but was lower among lower-level units that did not have this support. Travel time to headquarters and rural facilities significantly also reduced indices of equipment availability (62). We did not assess the effect of electricity or power sources on facility performance in this study. However, lower-level facilities in Uganda have at least one power source from either solar panels or public electricity (63). The availability and functionality of the solar equipment or electricity system lies in the docket of the parent district; however, district location was not found to affect facility performance but was found to be an independent predictor of service quality instead.

Our findings also differ from the Nigerian study with regards to the urban health facility location, which in Uganda we speculate may be due to an intervening local administrative level at the municipality or local town council that usually distorts the district office's direct influence. A district health officer or their team may not exercise the same direct supervisory oversight and authority over those units within a semi-autonomous local municipality as those outside because these usually report to the local municipality health officer instead. This gap often leads to poor district support in terms of consistent supervisory oversight and timely medical supplies or replenishments especially where the municipality or local authority administration is weak. Public health facilities in urban areas are often poorly utilised as urban-dwelling patients have more health care options such as services from commercial drug shops and private clinics (64). Public HFs in Uganda are also generally shunned because of inconsistent drug supplies, health worker absenteeism and poor overall supervision (65).

The weak association of FPS with HF level in the initial models where higher-level units performed up to 9-points better than HCIIs (or HCIIIs) can be partly explained by the fact that these facilities are referral clinics and have more consistent drug supplies. They also usually have stronger patient clubs.

The quality of patient care and experience showed a statistically significant decline between 2016 and 2020 ($p<0.02$). The proportion of patients receiving adequate quality of care in line with national guidelines also declined but not significantly so ($p=0.24$). A U-shaped relationship between service quality and patient volume has been previously described by a service quality assessment in Ethiopia which indicated that service quality increases until a peak patient volume of 90 patients per day and then decreases (66). Whereas we did not measure patient volume directly as related to service quality we did measure service utilisation under facility performance which had dropped in 2020 to less than half of that observed in 2016 (8 vs 3-points; $p>0.001$). It can be argued that service utilisation in 2020 was only about half of that seen when the intervention had reached its peak optimisation in 2016. This might explain our mixed findings; we would speculate that indeed some HFs had in fact optimised, and also reached their patient volume thresholds with a subsequent dip in service quality thereafter. Whilst other HFs might still be optimising or re-optimising service quality below their patient volume thresholds currently.

The quality of patient care was strongly associated with parent district ($p=0.02$) Wakiso district was found to have 1.2-point higher increase in mean QoCE than Mpigi, this association appeared to stronger after controlling for all other factors. Wakiso district geographically encircles the capital city of Uganda, Kampala, and as such benefits from the better road network that radiates from the capital city in a variety of directions. This has the double effect of ensuring quicker and more regular replenishment of essential medical supplies to most of Wakiso district as well as more regular support supervision due to easier access to remote district HFs. However, this could also be a chance finding as logistical support to NCD services did not seem to differ that much between the two districts.

Regarding provider or HS quality of care studies on NCDs in SSA, one study in Lesotho within HIV clinics (67) found that about a third of patients did not have records on NCD outcomes. The main barriers to care were equipment shortage or disrepair and staff shortage which affected the organisational structure for NCD care while inadequate screening for NCDs, poor scheduling and inadequate patient education affected treatment processes (67). This is not very different from what we found regarding the challenges to facility performance on very similar 4 of the 5 elements of service readiness. However, in our study one element i.e., the quality of records was adequately preserved over 4 years.

Strengths

The EACDRP intervention project had provided a strong and effective NCD service intervention with fully optimised elements against which it was easy to study potential changes in service readiness or service quality over time. For example, record keeping had been optimised in intervention HFs during the trial, data quality was high in both consecutive surveys. This applied to both routine data collection tools and records e.g., patient registers.

Identical and standardised study tools were used at both time points. To avoid observed bias, care was taken to ensure that observed data collection in 2020 did not involve any staff member from the original intervention (implementation) team. Also, instead, we recruited staff from the original evaluation team, and this helped to ensure comparability of the data sets generated at the two time points. The restricted sampling technique used for the QoCE assessment, allowed us to sample up to 20 eligible patients who were invited without replacement for defaulting, and also to ensure appropriate representation of men and women and patient groups (DM and HT). This also helped increase the power of the study.
Lastly, most post-intervention evaluations in a research or programmatic setting are usually done after 2 or 5 years, the 2020 survey was conducted about 4 years after the end of the intervention trial. This interval was sufficiently long to study mid- to long-term sustainability and durability of intervention effects.

Limitations

We were not able to collect data on service readiness and quality of care at any point of time between 2016 and 2020. We, therefore, could not assess whether the observed declines had occurred earlier or later, and whether the decline followed a linear pattern or occurred at certain points in time. Because there were no major changes in policy, infrastructure, or human resource or staff attrition in the assessed intervention facilities over this period; we assume the deterioration occurred slowly.
We also cannot ascertain whether any effect of the intervention may have in fact optimised after 2016, and whether any positive effects observed in 2020 reflected that subsequent

optimisation rather than intervention durability. However, the 4-year gap between assessments is likely to be a long enough period to hone out only the durable post-trial effects.

As this study focused on evaluating sustainability in facilities that received the intervention, we did not evaluate the former control facilities for comparison; therefore, it is possible that our findings were a result of other external influences that might have alleviated a possible decline of SAR and/or QoCE, rather than of the durability of the intervention. However, there were no major changes in health policy, health facility management or community initiatives during this period, and we are not aware of any other (e.g., NGO-related) health service efforts to strengthen health service performance, neither among the former intervention nor the former control facilities. Although all primary care centres in Uganda participate in ongoing efforts of the national NCD control programme to strengthen the response to NCDs, the effect of these efforts has been limited: for example, the proportion of health workers trained "during the last year" was 23% in 2020 and 39% in 2016, and there was little difference in having "received any NCD training" (68% in 2020 vs. 65% in 2016).

Our sample size of health workers and patients in 2016 was fixed; therefore, our ability to increase the power of the study was limited. However, we increased the number of participants in the 2020 survey so that we had reasonable power (>80%) to detect important changes in service readiness or quality of care.

Both health workers and patients who participated in the MeLoHanD study represent clusters of participants: it can be assumed that individuals from the same HF were likely to be more similar with regards to the variables that we determined in this study than a random selection of independent individuals. We accounted for this clustered design in the statistical analysis. However, there were some notable differences in the study populations between the two surveys e.g., there were fewer health workers at HCIIs in 2016 than in 2020 (18% vs 28%) and more at HCIIIs (60% vs 47%) which could mean that HCIIs were over-represented or HCIIIs were under-represented in the 2020 health worker sample. This could be partly explained by the fewer number of health workers that were available for survey in 2020 due to COVID restrictions or related absenteeism. In spite of this, there was generally a more equitable spread in 2020.

Conclusions

The clinical knowledge of HWs was sustained over 4 years after the end of the intervention project. This suggests that within similar primary care settings in LMICs, training effects resulting from the original intervention are likely to be maintained for some extended period, even as service availability and readiness decline in the absence of funding support. Nevertheless, we recommend that refresher training of health workers should be routinely provided within a public health care system.

As expected, overall facility performance was negatively affected because of the interrupted supplies and a decline in regular supervision. Some intervention components declined more strongly in urban or rural than peri-urban settings; and we speculate that this depended on administrative impediments and supervision. Lastly, the availability of functioning patient clubs seemed to have a positive effect with regards to service availability and readiness.

Surprisingly, although the overall quality of care received and experienced by HT and DM patients had declined, the proportion of those receiving adequate care according to national guidelines had not substantially changed even 4 years after the end of funding support to the intervention. District oversight was important to maintaining service quality.

More research in similar primary care settings is needed to clarify the role of well-functioning patient clubs for the sustainability of NCD care: what is their mean time-to-full optimisation and how and when do they begin to affect the continuity of NCD or other chronic care services in the absence of any funding support.

Sustainability or durability of an NCD intervention in similar primary care settings may remain achievable despite the funding instability and logistical challenges that follow withdrawal of research or programme support. Early during an intervention trial, health system managers and researchers should jointly plan how to sustain the intervention beyond the end of the project if the trial demonstrates its effectiveness.

List of abbreviations

CBO	Community Based Organisation
CI	Confidence Interval (usually 95%)
DHO	District Health Office(r)
DM	Diabetes mellitus
EACDRP	EACDRP – East African Chronic Disease Research Project
FPS	Facility Performance Score(s)

HC(s)	Health Centre(s) Is, IIs, IIIs, IVs, termed HCs of level 1, 2, 3, 4)
HF(s)	Health Facility (Health Facilities)
HIV	Human Immuno-deficiency Virus
HS	Health system(s)
HT	Hypertension
HW(s)	Health worker(s) / Healthcare worker(s)
IQR	Interquartile range
LSHTM	London School of Hygiene and Tropical Medicine
LMICs	Low- and middle- income countries
MeLoHanD	Medium to Long term sustainability to improve management of Hypertension and Diabetes within the primary care setting in Uganda
MoH	Ministry of Health (Uganda)
MRC	Medical Research Council
NCD	Non-communicable disease(s)
NGO	Non-governmental Organisation
UVRI	Uganda Virus Research Institute
SAR(A)	Service Availability and Readiness Assessment
SSA	Sub-Saharan Africa
SD	Standard deviation
QoC(E)	Quality of Care (and Experience)

Declarations

Ethics approval and consent to participate

Approvals

Our study was approved by the Research and Ethics Committee of the Uganda Virus Research Institute (GC/127/19/09/743), the Uganda National Council for Science and Technology (HS 2714) and the Ethics Committee of the London School of Hygiene and Tropical Medicine (17914).

Informed consent

Participants read or were read to the appropriate participant information and consent form (ICF) to acquaint themselves with what the current study entailed and what was required of them to participate. Both verbal and written informed consent was obtained from all participants in this study. This was documented on the ICF by the participant's own signature. If the participant was not able to read or write, a thumb print was obtained from them instead, in

the presence of a competent independent witness. The witness also under-wrote and signed on that participant's behalf. All study consent procedures were approved by the Research and Ethics Committee of the Uganda Virus Research Institute and the Ethics Committee of the London School of Hygiene and Tropical Medicine.

Research conduct and compliance

Research on human subjects or material or data in this study was conducted in compliance the Declaration of Helsinki and followed Human Subject Protection (HSP) principles and Good Clinical Practice (GCP) guidelines. All study methods were carried out in accordance with relevant guidelines and regulations and approved by both the Research and Ethics Committee of the Uganda Virus Research Institute and the Ethics Committee of the London School of Hygiene and Tropical Medicine. All study staff were also HSP and GCP trained.

Patients with uncontrolled NCDs detected during the survey were jointly discussed with the healthcare provider at their respective facility to ensure that they receive adequate care.

Consent for publication

Not applicable as no identifiable data is presented in the current study.

Availability of data and materials

The datasets that support these findings are available from London School of Hygiene and Tropical Medicine (LSHTM) and MRC/UVRI and LSHTM Uganda Research Unit (MUL), but restrictions apply to the availability of these data, which were used under licence for the current study, and so are not publicly available. However, data are available from the authors (David Katende) upon reasonable request and with permission of both LSHTM and MUL.

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Competing interests

The authors declare that they have no conflicts of interest.

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Author's contributions

DK, HG, KB, and MN designed the study; DK, KN, CK and AB conducted the fieldwork; KN and MCM oversaw the data management; DK performed the analysis with support from KB; GM provided input to the study design and fieldwork; MCM, IK and IS contributed to the analysis; DK wrote the manuscript; KB, HG and MN contributed to the manuscript. All authors approved the final version of the manuscript.

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Tables and figures - Medium-to-long term sustainability of a health systems intervention to improve service readiness and quality of non-communicable disease (NCD) patient care and experience at primary care settings in Uganda

Table 1 - Description of the Levels of Public Health Service Delivery in Uganda

Health Facility Level[Ψ]	Political or Administrative Level	Catchment Target Population	Main Function or Infrastructural Requirement	Facility head/Supervisor* title and/or their educational background
Regional Hospital	Region or several districts	>2 million	General and specialist services e.g.,	Medical director (e.g., MD+MPH)
District Health Office	District	500,000 to 2 million	Resource distribution, staffing	DHO-er (e.g., MD+MPH)
District Hospital/HCIV	District or constituency	100,000 to 500,000	50-100 in-patient beds, general theatre,	Medical director (e.g., MD+/-MPH)
HCIII	Sub-county	30,000	10-20 in-patient beds, maternity unit, a simple	Non-MD clinician or Mid-wife
HCII	Parish or several villages	5,000 to 10,000	1–2 day-care beds, first line emergency and out-	Nurse
HCI	Village	1,000-5,000	Mobile outreach post	Nursing assistant or Health visitor

[Ψ]**HC- Health Centre; *MD - Medical Doctor; MPH - Master's course in public health**

Tables

Table 2 - Distribution of health facilities by district and facility level

Facility attribute		District				Total
		Mpigi		Wakiso		
		HCIIIs	*HCIIs*	*HCIIIs*	*HCIIs*	
Urban HFs	*Singleton*	-	-	1	1	2
Rural HFs	*Singleton*	2	1	3	3	9
	Paired	2	2	2	2	8
Referral facilities (HCIVs)		1 *(Peri-urban)*		2 *(1 Peri-urban, 1 rural)*		3
Total		8		14		22

Table 3 - Data collection sheet to assess quality of patient care and experience (QoCE)

Item	Possible score (circle)	Possible points (circle)	Total points achieved
1. Patient has been diagnosed correctly	No Partial evidence * Correctly diagnosed, supporting evidence was recorded	0 1 2	
2. Treatment provided	No evidence Partial evidence* Treatment provided with sufficient drugs and/or guidance provided until next visit	0 1 2	
3. Patient received health education	No evidence Patient is aware of symptoms, risks, and complications Patient is also aware of recommended lifestyle changes	0 1 2	
4. Quality of reception and waiting time	Patient had to wait for more than 2 hours Patient had to wait less than 2 hours Patient had to wait but received support or health education during waiting time	0 1 2	
5. Management according to guidelines	Patient is not being managed according to guidelines Patient is being partially managed acc. to guidelines Patient is being fully managed acc. to guidelines	0 1 2	
	Total points achieved		**!__! !__!**
	Patient adequately managed. **Yes 1 No 2**		**!__!**

Footnote

*- Evidence from available records not clear or insufficient to ascertain the correct diagnosis or treatment

Table 4 - Summary of facility performance scores (FPS) and five elements of service availability and readiness (SAR)

	Mean score (95% CI)	
	2016	2020
Overall		
		P=0.18[1]
Overall FPS aggregate (inclusive of knowledge assessment scores)[2]	74.8 (71.3-78.3)	70.2 (66.0-74.5)
Individual elements[3]		
		P<0.001
Availability & functionality of essential equipment /consumables	7.59 (7.27, 7.91)	5.56 (4.98, 6.14)
		P<0.001
Availability of essential drugs and other consumables	8.28 (6.57, 9.99)	3.71 (2.46, 4.97)
		P=0.001
Quality of records on case management of HT and DM	9.09 (8.68, 9.50)	9.77 (9.54, 10.01)
		P<0.001
Utilisation of health facility by HT & DM patients	8.00 (7.33, 8.67)	3.00 (1.82, 4.18)
		P<0.001
Evidence of preventive activities for HT & DM	7.18 (6.56, 7.80)	3.77 (2.87-4.67)

Footnote

[1]p-values obtained from paired t-test of difference in log-transformed mean in each HF.

[2]Includes both scaled-up health worker knowledge assessment (max. 40 points) and SAR scores (max. 60 points) out of a maximum 100 points.

[3]Score out of 10 points

Table 5 - Summary of health worker knowledge assessment

Health worker knowledge assessment	2016 mean (95% CI)	2020 mean (95% CI)	P-value*
Overall & by health facility level (out of 30 maximally possible points)			
Overall	***N=131***	***N=91***	0.11
	26.0 (25.3-26.7)	26.8 (26.1-27.5)	
HCIIs	***N=24***	***N=25***	0.43
	25.1 (23.7-26.5)	25.9 (24.6-27.1)	
HCIIIs	***N=78***	***N=43***	0.22
	26.8 (26.0-27.6)	27.5 (26.5-28.4)	
HCIVs	***N=28***	***N=23***	0.49
	26.1 (21.9-30.2)	27.3 (25.1-29.5)	
By disease component (out of 10 maximally possible points)			
Hypertension	9.1 (8.8, 9.4)	9.3 (9.1, 9.6)	0.22
Diabetes	8.8 (8.4, 9.1)	8.9 (8.6, 9.2)	0.42
HIV	8.2 (7.9, 8.4)	8.5 (8.2, 8.8)	0.08

Footnote

*- p-values obtained from paired t-test of difference in log-transformed mean in each HF

Table 6 – Unadjusted and adjusted analysis of the effect of independent factors on facility performance (FPS)

Variable	Level	Model 1 Coefficient, (95% CI)	Model 2[1] Coefficient, (95%CI)	Model 3[2] Coefficient, (95%CI)
Mean FPS score in 2016		P<0.01 -0.45 (-0.77, 0.12)	P<0.01 -0.45 (-0.77, -0.12)	P<0.01 -0.55 (-0.89, -0.21)
Patient club functionality		P=0.26	P=0.05	P=0.09
	High	ref	ref	ref
	Moderate	-4.98 (-14.30, 4.34)	-5.62 (-13.25, 2.00)	-6.30 (-14.96, 2.35)
	Low or none	-5.11 (-13.94, 3.72)	-6.82 (-14.12, 0.47)	-4.96 (-12.97, 3.06)
Other external support received by HF[3]		P=0.44	P=0.22	-
	No	ref	ref	-
	Yes	2.74 (-4.52, 10.01)	3.43 (-2.75, 9.62)	-
Facility level		P=0.70	P=0.08	P=0.81
	HCIIs	ref	ref	ref
	HCIIIs	-2.69 (-10.34, 4.95)	1.12 (-5.64, 7.89)	-0.93 (-8.33, 6.47)
	HCIVs	4.56 (-6.54, 15.66)	8.90 (-0.65, 18.46)	3.02 (-13.55, 17.93)
Area		P=0.10	P<0.01	P=0.23
	Peri-urban	ref	ref	ref
	Rural	-5.84 (-18.02, 6.34)	-10.90 (-19.90, -1.91)	-6.22 (-24.65, 12.21)
	Urban	-13.02 (-29.36,	-20.59 (-32.76, -8.42)	-12.91 (-37.36, 11.54)
District		P=0.15	P=0.11	P=0.19
	Mpigi	ref	ref	ref
	Wakiso	-5.13 (-12.28, 2.02)	-4.57 (-10.73, 1.59)	-3.03 (-9.54, 3.48)
Pairing at randomisation		P=0.31	P=0.19	P=0.60
	Singleton	ref	ref	ref
	Paired or Referral	3.53 (-3.53, 10.59)	3.59 (-2.44, 9.62)	-1.21 (-5.58, 7.99)

Footnote

[1] - Adjusted for baseline FPS scores in 2016

[2] - Adjusted for baseline FPS, patient club functionality, facility level, area, district and pairing at randomisation

[3]- Post trial external support includes any supplementary drugs or other support that a HF received between 2016-20 from an NGO or CBO excluding its patient club.

Table 7 – Summary of patient quality of care and experience (QoCE) assessment

Variable		2016 N=88	2020 N=332	p-value[1]
Gender[2]				
	Women	56 (65)	237 (71)	0.22
	Men	30 (35)	95 (29)	
Age				
	Mean (95%CI)	55.9 (53.6, 58.2)	60.1 (58.5, 61.7)	<0.01
Health facility level				
	HCIIs	40 (45)	145 (44)	<0.01
	HCIIIs	36 (41)	134 (40)	
	HCIVs	12 (14)	53 (16)	
Occupation				
	Employed	26 (29)	176 (53)	<0.01
	Homemaker	41 (47)	132 (40)	
	Unemployed/Retired/Other	21 (24)	24 (7)	
Overall QoCE score				
	Mean score (95% CI)	9.45 (9.05-9.86)	8.72 (8.36-9.08)	0.02
	Proportion adequately	95.5%	89.2%	0.24
QoCE score by health facility level				
HCIIs	*Mean score (95% CI)*	9.78 (9.48-10.07)	8.87 (8.15-9.58)	0.05
	Proportion adequately	100%	88.0%	0.34
HCIIIs	*Mean score (95% CI)*	9.12 (8.31-9.94)	8.41 (8.05-8.76)	0.14
	Proportion adequately	90.0%	87.0%	0.74
HCIVs	*Mean score (95% CI)*	9.58 (9.12-10.04)	9.30 (8.70-9.89)	0.61
	Proportion adequately	100%	96.4%	0.64

[1]P-values from paired t-test of log-transformed facility-level summaries (mean score or proportion of adequately managed patients)

[2]- 2 patients missing gender in 2026

Table 8 - Unadjusted and adjusted analysis of the effect of independent factors on quality of patient care and experience (QoCE) using Tobit regression

Variable	Model 1 Coefficient (95%CI)	Model 2[1] Coefficient (95%CI)	Model 3[2] Coefficient (95%CI)
Mean QoCE score in 2016	P=0.71 0.13 (-0.53, 0.78)	P=0.71 0.13 (-0.53, 0.78)	P=0.75 0.08 (-0.42, 0.58)
Age	P=0.48 -0.07 (-0.25, 0.12)	P=0.49 -0.07 (-0.25, 0.12)	–
Sex	P=0.10	P=0.10	P=0.13
Male	Ref	Ref	Ref
Female	0.43 (-0.08, 0.95)	0.43 (-0.08, 0.95)	0.40 (-0.12, 0.91)
Patient club functionality	P=0.05	P=0.05	P=0.87
High	Ref	ref	Ref
Moderate	0.71 (-0.62, 2.04)	0.68 (-0.65, 2.02)	0.31 (-0.88, 1.51)
Low or none	-0.90 (-2.18, 0.37)	-0.92 (-2.19, 0.36)	0.09 (-1.26, 1.43)
External support[3]	P=0.02	P=0.02	P=0.20
No	Ref	ref	Ref
Yes	1.32 (0.25, 2.39)	1.35 (0.28, 2.41)	0.77 (-0.38, 1.92)
Facility level	P=0.15	P=0.15	P=0.64
HC II	Ref	Ref	Ref
HC III	-0.94 (-2.12, 0.23)	-0.99 (-2.24, 0.25)	-0.53 (-1.61, 0.56)
HC IV	0.52 (-1.15, 2.20)	0.51 (-1.17, 2.19)	-0.34 (-2.62, 1.94)
Area	P=0.13	P=0.13	P=0.37
Peri-urban	Ref	Ref	Ref
Rural	-1.40 (-3.28, 0.47)	-1.42 (-3.28, 0.45)	-1.28 (-4.00, 1.45)
Urban	-2.84 (-5.54, -0.14)	-2.88 (-5.57, -0.19)	-2.60 (-6.37, 1.18)
District	P=0.09	P=0.08	P=0.02
Mpigi	Ref	Ref	Ref
Wakiso	1.03 (-0.10, 2.16)	1.04 (-0.09, 2.17)	1.21 (0.25, 2.18)
Pairing at randomisation	P=0.64	P=0.66	–
Singleton	Ref	Ref	
Paired or Referral	-0.28 (-1.45, 0.90)	-0.26 (-1.44, 0.91)	

Footnote:

[1]Adjusted for mean QoCE score in 2016.

[2]Adjusted for mean QoCE score in 2016, sex, club functionality, external support, facility level, area, and district.

[3]Post trial external support includes any supplementary drugs or other support that a HF received between 2016-20 from an NGO or CBO excluding its patient club.

Figures

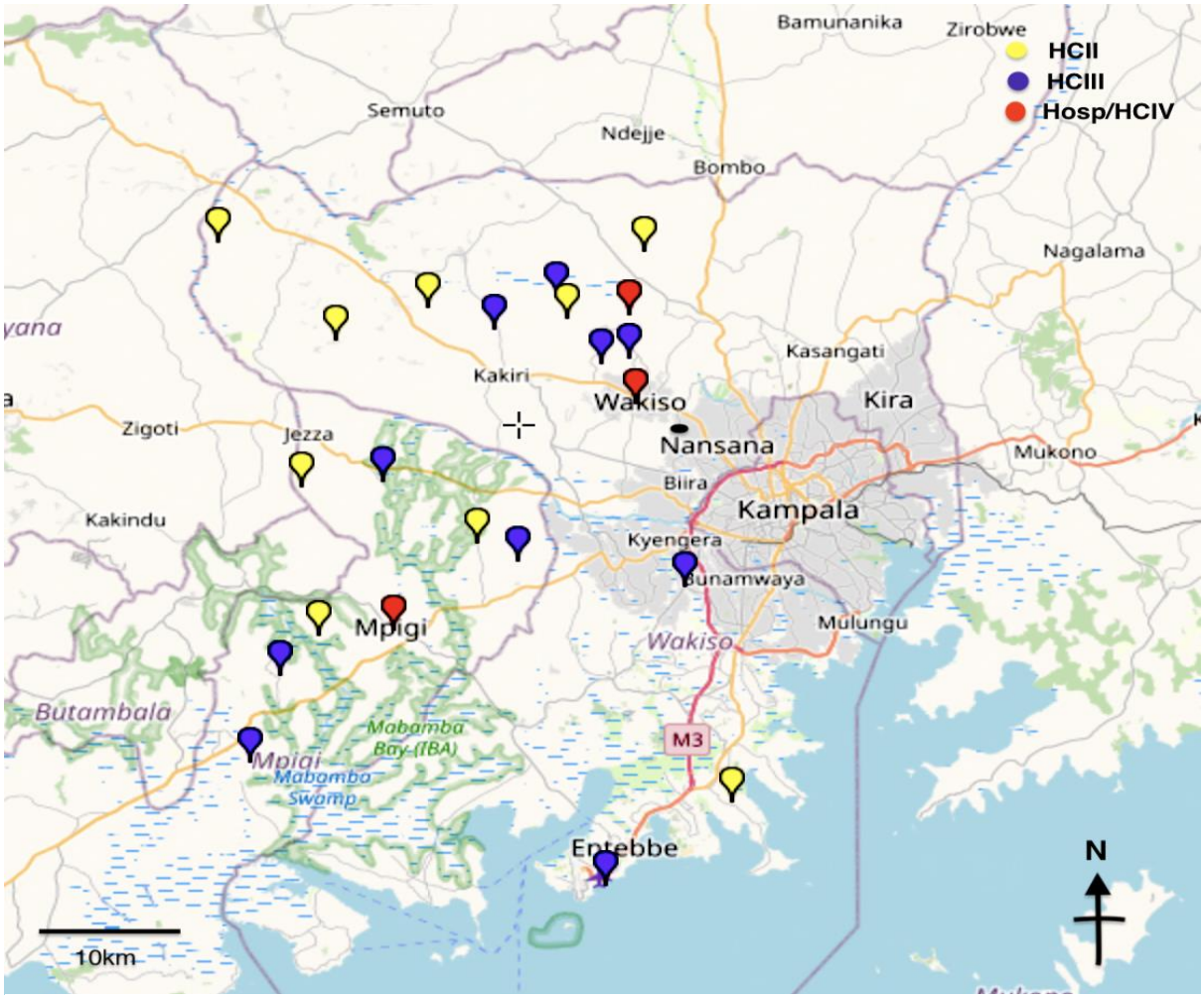

Figure 1 - Map showing the distribution of participating health facilities across Mpigi and Wakiso Districts in Uganda (Developed using GPS visualizer.com)

Supplementary tables

Supplementary table 1 - Health worker survey – characteristics of HWs in 2016 and 2020

Variable		2016 n (%) (N=131)	2020 n (%) (N=91)	p-value[1]
Gender	Female	92 (70)	59 (65)	0.11
	Male	31 (24)	32 (35)	
	*Missing**	*8 (6)*	*0 (0)*	
Age	Mean (SD)	36.6 (9.6)	37.0 (7.9)	0.01
Facility type/level	HC II	28 (18)	25 (28)	<0.01
	HC III	79 (60)	43 (47)	
	HCIV	24 (22)	23 (25)	
Cadre	Clinicians MO or CO	23 (18)	25 (27)	0.29
	Nurse or Midwife	66 (50)	40 (44)	
	Nursing assistant /aide	34 (26)	23 (26)	
	Other	8 (6)	3 (3)	
Experience with patients: In last three months, how many patients have you seen with:				
Hypertension	*None*	3 (2)	0 (0)	0.23
	1-5 patients	32 (25)	18 (20)	
	>5 patients	96 (73)	73 (80)	
Diabetes	*None*	28 (21)	11 (12)	0.20
	1-5 patients	59 (38)	37 (41)	
	>5 patients	54 (41)	43 (47)	
Chronic heart failure	*None*	107 (82)	79 (87)	0.48
	1-5 patients	20 (15)	11 (12)	
	>5 patients	4 (3)	1 (1)	
HIV	*None*	8 (6)	5 (6)	< 0.01
	1-5 patients	47 (36)	14 (15)	
	>5 patients	76 (58)	72 (79)	
COPD	*None*	102 (78)	68 (75)	0.30
	1-5 patients	24 (18)	22 (24)	
	>5 patients	5 (4)	1 (1)	
Asthma	*None*	35 (27)	20 (22)	0.50
	1-5 patients	90 (69)	64 (70)	
	>5 patients	6 (4)	7 (8)	
Epilepsy	*None*	40 (31)	16 (18)	0.01
	1-5 patients	71 (54)	48 (53)	
	>5 patients	20 (15)	27 (29)	
Level of comfort: How comfortable are you with patients with				
Hypertension	*Very comfortable*	40 (31)	28 (31)	0.96
	OK, but need more training	89 (68)	62 (68)	
	Very uncomfortable	2 (2)	1 (1)	
Diabetes	*Very comfortable*	33 (25)	18 (20)	0.37
	OK, but need more training	92 (70)	71 (78)	
	Very uncomfortable	6 (5)	2 (2)	
Chronic heart failure	*Very comfortable*	2 (2)	2 (2)	0.34
	OK, but need more training	84 (64)	66 (73)	
	Very uncomfortable	45 (34)	23 (25)	
HIV	*Very comfortable*	50 (38)	30 (33)	0.65
	OK, but need more training	77 (59)	59 (65)	

	Very uncomfortable	4 (3)	2 (2)	
COPD	*Very comfortable*	7 (5)	2 (2)	0.21
	OK, but need more training	80 (61)	65 (72)	
	Very uncomfortable	44 (34)	24 (26)	
Asthma	*Very comfortable*	42 (32)	24 (26)	0.20
	OK, but need more training	81 (62)	65 (72)	
	Very uncomfortable	8 (6)	2 (2)	
Epilepsy	*Very comfortable*	18 (14)	16 (17)	0.64
	OK, but need more training	98 (75)	67 (74)	
	Very uncomfortable	15 (11)	8 (9)	
Necessary equipment: Do you have the necessary equipment to manage				
Hypertension	*Yes, I have all*	103 (79)	53 (58)	< 0.01
	No, I lack some equipment	25 (19)	38 (42)	
	I don't know	3 (2)	0 (0)	
Diabetes	*Yes, I have all*	85 (65)	21 (23)	<0.01
	No, I lack some equipment	42 (32)	70 (77)	
	I don't know	4 (3)	0 (0)	
HIV	*Yes, I have all*	79 (60)	53 (58)	0.55
	No, I lack some equipment	48 (37)	37 (41)	
	I don't know	4 (3)	1 (1)	
Necessary drugs: Do you have the necessary drugs to manage				
Hypertension	*Yes, I have all*	96 (73)	19 (21)	< 0.01
	No, I lack the drugs	31 (24)	72 (79)	
	I don't know	4 (3)	0 (0)	
Diabetes	*Yes, I have all*	76 (58)	16 (18)	<0.01
	No, I lack the drugs	51 (39)	75 (82)	
	I don't know	4 (3)	0 (0)	
HIV	*Yes, I have all*	99 (75)	55 (60)	0.04
	No, I lack the drugs	30 (23)	35 (39)	
	I don't know	2 (2)	1 (1)	
Support supervision and training: When last did you have detailed advice or training through				
For hypertension or diabetes:				
a facility supervisor	*Within last year*	69 (53)	30 (33)	< 0.01
	Before last year	22 (17)	35 (39)	
	Never	29 (22)	15 (16)	
	I am in charge at this facility	11 (8)	11 (12)	
district health management or other department	*Within last year*	58 (44)	18 (20)	< 0.01
	Before last year	25 (19)	29 (32)	
	Never	48 (37)	44 (48)	
a training course	*Within last year*	51 (39)	21 (23)	< 0.01
	before last year	34 (26)	41 (45)	
	Never	46 (35)	29 (32)	
For HIV:				
a facility supervisor	*Within last year*	62 (48)	45 (49)	0.92
	Before last year	33 (25)	20 (22)	
	Never	24 (18)	16 (18)	
	I am in charge at this facility	12 (9)	10 (11)	
district health management or other department	*Within last year*	72 (55)	37 (41)	0.04
	Before last year	28 (21)	33 (36)	
	Never	31 (24)	21 (23)	

a training course	*Within last year*	40 (31)	27 (30)	0.88
	before last year	59 (45)	39 (43)	
	Never	32 (24)	25 (27)	

[1]Pvalue from Pearson chi-squared statistic with the second-order correction of Rao and Scott to account for the clustered design

Supplementary table 2 - Facility inspection - distribution of the constituents of the elements of service availability and readiness (SAR)

Element of service availability and readiness (SAR)		2016 n (%) (N=22)	2020 n (%) (N=22)	p-value[1]
1. Availability of basic equipment				
BP machine	*missing from OPD*	0 (0)	1 (5)	1.00
	1 available not working	1 (5)	0 (0)	
	1 available and working	12 (55)	11 (50)	
	2 or more machines available and working	9 (40)	10 (45)	
BP Cuffs	*cuffs missing*	0 (0)	1 (5)	0.20
	standard size only	5 (23)	9 (40)	
	At least 2 cuff sizes	17 (77)	12 (55)	
Adult weight scale	*available not working*	0 (0)	2 (9)	**<0.01**
	available and working	0 (0)	8 (36)	
	evidence of use from records	22 (100)	12 (55)	
Adult size stethoscope	*missing from OPD*	10 (45)	11 (50)	0.61
	1 available not working	4 (18)	1 (5)	
	1 available and working	7 (32)	8 (36)	
	2 or more machines available and working	1 (5)	2 (9)	
Stadiometer	*missing from OPD*	0 (0)	1 (5)	**<0.01**
	available and working	1 (5)	17 (77)	
	evidence of use from records	21 (95)	4 (18)	
Glucometers for HCIVs & HCIIIs[1]	*missing from OPD*	0 (0)	1 (8)	0.10
	available and working	4 (31)	0 (0)	
	evidence of use from records	9 (69)	12 (92)	
Blood glucose strips for HCIVs/HCIIIs[2]	*missing from OPD*	0 (0)	1 (8)	**0.02**
	some strips available	0 (0)	5 (38)	
	supply for at least one month	13 (100)	7 (54)	
Urine glucose strips for HCIIs[3]	*missing from OPD*	0 (0)	16 (72)	**<0.01**
	have at least 30 tests	0 (0)	5 (23)	
	have more than 30 tests	22 (100)	1 (5)	
Patient register	*available but not used*	0 (0)	1 (5)	0.22
	available and used but not up-to-date	6 (27)	10 (45)	
	available and up-to-date	16 73)	11 (50)	
HT / DM screening logbook	*missing form OPD*	0 (0)	3 (13)	**<0.01**
	available but not used	0 (0)	1 (5)	
	available evidence of some use	1 (5)	12 (55)	
	available, evidence of good use	21 (95)	6 (27)	
Referral register	*missing form OPD*	8 (36)	13 (59)	0.27
	available but not used	1 (5)	1 (5)	
	available, used but incorrectly	3 (14)	4 (18)	
	available and used correctly	10 (45)	18 (4)	

2. Availability of essential drugs				
Essential drugs for HT				
HCIVs and HCIIIs[2]	*1st line drugs available*	4 (31)	8 (61)	0.39
	2nd line drugs also available	7 (54)	4 (31)	
	3rd line drugs also available	2 (15)	1 (8)	
HCIIs[3]	*missing 1st line drugs*	0 (0)	2 (22)	0.27
	1st line drugs available for <1 month	1 (13)	3 (33)	
	1st line drugs available for 1-3 month	6 (74)	3 (33)	
	1st line drugs available for >3months	1 (13)	1 (12)	
Essential drugs for DM				
HCIVs and HCIII[2]	*1st line drugs available*	12 (92)	10 (77)	0.59
	2nd line drugs also available	1 (8)	3 (23)	
HCIIs[3]	*missing 1st line drugs*	0 (0)	5 (56)	**0.03**
	1st line drugs available	9 (100)	4 (55)	
3. Quality of records				
NCD register[4]	*names recorded*	22 (100)	22 (100)	1.00
	age and sex recorded	22 (100)	22 (100)	1.00
	residence recorded	16 (73)	21 (95)	0.10
	initial treatment recorded	22 (100)	21 (95)	1.00
NCD follow-up record[4]	*age and sex recorded*	19 (86)	22 (100)	1.00
	bp/blood glucose level recorded at last visit	22 (100)	22 (100)	1.00
	risk factors recorded	14 (64)	19 (86)	0.16
Referral register book	*missing from OPD*	8 (36)	13 (59)	0.24
	available not used	1 (5)	1 (5)	
	available and used but incorrectly	3 (14)	4 (18)	
	available and used correctly	10 (45)	4 (18)	
Health education record book	*missing from OPD*	1 (5)	10 (45)	0.20
	available no evidence	0 (0)	5 (23)	
	available, evidence of some use	12 (55)	5 (23)	
	evidence of regular use	2 (9)	2 (9)	
	ncd-related health education given	7 (31)	0 (0)	
4. Utilisation of the health facility				
Number of newly registered patients over last 3 months				
with HT at HCIIIs & HCIVs[2]	*1-20 patients*	0 (0)	9 (69)	**<0.01**
	21-40 patients	3 (23)	1 (8)	
	>40 patients	10 (77)	3 (3)	
with HT at HCIIs[3]	*1-10 patients*	0 (0)	8 (89)	**<0.01**
	11-20 patients	0 (0)	1 (11)	
	>20 patients	9 (100)	0 (0)	
with DM at HCIIIs & HCIVs[2]	*no patients registered*	0 (0)	0 (0)	**<0.01**
	1- 4 patients	2 (15)	9 (70)	
	5-10 patients	1 (8)	2 (15)	
	>10 patients	10 (77)	2 (15)	
with DM at HCIIs[3]	*no patients registered*	1 (11)	7 (78)	**0.01**
	1- 2 patients	2 (22)	2 (22)	
	3-5 patients	4 (45)	0 (0)	

	>5 patients	2 (22)	0 (0)	
Evidence of utilisation over last one year				
for HCIIIs & HCIVs[2]	*none or <10% increase*	2 (15)	8 (61)	**0.05**
	increase of 10-100%	8 (62)	4 (31)	
	increase of >100%	3 (23)	1 (8)	
for HCIIs[3]	*none or <10% increase*	2 (22)	7 (78)	**<0.05**
	increase of 10-100%	3 (33)	2 (22)	
	increase of >100%	4 (45)	0 (0)	
5. Preventive activities				
Health education session provided in waiting area	*no evidence*	1 (5)	4 (18)	0.25
	at least one session verbally reported	11 (50)	6 27)	
	at least one session recorded	2 (9)	6 27)	
	1-4 per month	6 (27)	4 (18)	
	more than 1 per week	2 (9)	2 (9)	
Screening session for HT or DM conducted	*no evidence*	0 (0)	3 (14)	**<0.01**
	at least one screening session verbally reported	0 (0)	3 (14)	
	at least one screening session recorded	0 (0)	9 (41)	
	10-50 patients screened	8 (36)	7 (32)	
	>50 patients screened	14 (64)	0 (0)	
Outreach activities	*None*	3 (14)	20 (91)	**<0.01**
	1-2 per month	1 (5)	1 (5)	
	more than 2 per month	18 (81)	1 (5)	

Footnote

[1]P-value from Fisher's statistic with the second-order correction of Rao and Scott to account for the clustered design

[2]Only applied to HCIIIs and HCIVs

[3]Only applied to HCIIs

[4]Applied to all health facilities

Chapter 6: Research Paper 2

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	389984	**Title**	Dr
First Name(s)	David		
Surname/Family Name	Katende		
Thesis Title	Investigating the medium to long term sustainability of an intervention to improve care for hypertension and diabetes within the primary health care setting in Uganda (MeLoHanD)		
Primary Supervisor	Prof. Heiner Grosskurth		

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

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SECTION C – Prepared for publication, but not yet published

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Where is the work intended to be published?	BMC Health Services Research
Please list the paper's authors in the intended authorship order:	Katende, David; Nalweyiso, Norah; Nabulime, Gertrude; Mubiru, Michael Charles; Sekitoleko, Isaac; Baisley, Kathy; Nyirenda, Moffat; Grosskurth, Heiner

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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 designed the study and wrote the protocol with input from Heiner Grosskurth (HG) Moffat Nyirenda (MN) and Kathy Baisley (KB); I performed the analysis with support from KB and inputs from Isaac Sekitoleko (IS); I wrote the first draft and responded to co-author comments and revisions; I submitted the paper for publication

SECTION E

Student Signature	David Katende [redacted]
Date	4/02/2023

Supervisor Signature	Heiner Grosskurth [redacted]
Date	4/02/2013

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Abstract

Introduction

Interventions for non-communicable diseases are increasingly implemented and evaluated in sub-Saharan Africa, but little is known about their medium- to long-term sustainability beyond the end of research funding.

A cluster randomised trial conducted between 2013 and 2016 in Uganda and Tanzania showed that an intervention package to improve hypertension (HT) and type-2 diabetes mellitus (DM) care was highly effective in increasing service readiness and quality of care.

The present study assesses the sustainability of the intervention 4 years after the trial in Uganda.

Methods

The study was conducted in 2020 in 22 primary care health facilities (HFs) (3 referrals and 19 lower-level units) that had received the intervention package until trial end (2016), to assess their current capacity and practice to sustain ongoing intervention activities for HT and DM care. Through a cross-sectional survey, 4 pre-defined domains *(i.e., cognitive participation, coherence, collective action, and reflexive monitoring)* were examined with regard to health worker (HW) normalization and 8 pre-defined domains for intervention sustainability *(i.e., organisational capacity, local environment, funding stability, partnerships, communication, evaluation, adaptation, and strategic planning)*, using the normalisation tool and the program sustainability tool (PSAT). Summary scores were assessed by domains and facility level.

Results

Overall normalization strength was adequate at 4.0 (IQR: 3.8, 4.2) of a possible 5 with no evidence of association with HF level (p=0.40); *cognitive participation* (buy-in) and *reflexive monitoring* (appraisal) were strongest at >4 across all HF levels. All HF levels were weak (<4) on *collective action* (teamwork) and *coherence* (sense-making). Only collective action differed by level (p<0.002).

Overall intervention sustainability was suboptimal at 3.1 [IQR: 1.9, 4.1] of a possible 7 with weak scores on *funding stability* (2.0), supportive *partnerships* (2.2), and *strategic planning* (2.6). Domain differences by HF level were significant for *environmental support* (p=0.02) and *capacity in organisation* (p=0.01). Adequate strength at a cut-off mean of ≥5 did not differ by HF level for any domain.

Conclusions

Four years after their introduction, practice-dependent intervention elements e.g., local organisational context, HW knowledge or dedication were sustained, but external elements e.g., new funding support or attracting new partners to sustain intervention efforts were not. Whenever new interventions are introduced into an existing health service, their long-term sustainability including the required financial support should be ensured. The quality of services should be upheld by providing routine in-service training with dedicated support supervision.

Introduction

Sub-Saharan Africa (SSA) is facing a rapidly increasing burden of non-communicable diseases (NCDs) whilst the prevalence of infectious diseases such as malaria, HIV/AIDS and tuberculosis remains substantial (25, 26). In Uganda, the prevalence of hypertension (HT) and diabetes mellitus (DM) has been estimated at 26% and 1%, respectively (22) whereas prevalence in the central districts of Wakiso and Mpigi lies between 19-26% and 2-4% respectively (20). The increasing NCD burden has created a demand to incorporate NCD care into health services which in sub-Saharan Africa (SSA) and many other low- and middle-income settings have until recently been structured to mainly manage acute or infectious conditions (4). Thus, many NCDs go unnoticed and are poorly managed (20, 50).

To address this double challenge, the UN General Assembly issued a resolution on NCDs control and prevention in 2011 stated as "*Resolution 3. Recognize the primary role and responsibility of Governments in responding to the challenge of non-communicable diseases and the essential need for the efforts and engagement of all sectors of society to generate effective responses for the prevention and control of non-communicable diseases;..*" (68) Subsequently, WHO and many governments in low-and-middle-income countries introduced new policies and took initiatives to address the NCD problem including measures to improve NCD care services at primary care level (69). To facilitate these efforts, several research projects have been launched, including health service-based interventions to improve NCD care, including in SSA (16). These intervention projects were set at different levels, including hospitals, primary care settings, and in the community, and usually a variety of components including capacity building or task shifting. The effectiveness and fidelity of such research-embedded interventions have been previously reported (16, 29), however little is known about their medium to long term sustainability or effectiveness, e.g., 2 to 5 years after the end of research funding. However, it will be crucial to understand whether newly introduced interventions for chronic NCD care can be sustained in the long term, and how best this can be achieved.

From 2013 to 2016, we conducted a large cluster randomised controlled trial to evaluate the effectiveness of an intervention package that aimed to improve NCD care at primary care facilities in Uganda and Tanzania, with a focus on HT and DM (the health systems and chronic disease project, EACDRP, ISRCTN27340385). The EACDRP trial showed that the intervention was highly effective in improving NCD service readiness at intervention facilities across different levels of primary care, with

large and significant differences between intervention and control facilities in the availability of functional basic equipment and consumables and in healthcare worker knowledge. The intervention was also highly effective in improving quality of care, measured by the proportion of NCD patients who were treated according to national guidelines. For example, in Uganda, the mean performance score in intervention facilities was nearly double that in control facilities, and 95% of the intervention facilities provided NCD care according to guidelines compared to only 8% in the control arm (1).

Efforts were also made to ensure that the newly introduced NCD services were sustained after the end of the trial. These included close involvement of the ministerial and local governance structure in study activities throughout the study and handover of important intervention resources (e.g., documents, equipment and up to 9 months of a buffer supply of NCD drugs to overcome potential shortfalls in the national drug supply system). The study also encouraged patient-led initiatives to form patient clubs. These clubs promoted peer support and monetary contributions to a communal fund to procure drugs and other supplies with a high stock out rate, e.g., metformin or glucose test strips. These supplies were issued when the freely provided supplies from the public health system were insufficient.

The EACDRP trial created an excellent platform to assess the medium- to long-term sustainability of a successful health system NCD intervention within primary care settings in Uganda, the **MeLoHanD** study. A comprehensive definition of sustainability of a health intervention includes three components: (i) continued benefits to those who received the health services when the intervention started and extension of benefits to new participants who presented after the supporting funds have been discontinued, (ii) continued implementation of intervention activities by the public health system in which the research had been embedded e.g., a local or national organisation and, (iii) community empowerment to support the continuation of intervention activities after the end of research funding (32).

As part of the MeLoHanD study, we have previously reported the post-trial effects on service availability and readiness and the HF-based quality-of-patient care and experience (70). We found that supervised aspects of HF performance e.g., the availability of guidelines and records, HW knowledge as well as quality-of-patient care and experience were well sustained. However, logistical aspects of facility performance e.g., the availability of essential drugs and consumables had declined (70).

We also used the MeLoHanD study as an opportunity to assess *HW normalization*, i.e. the degree to which the intervention became incorporated into routine practice (34), and prospective *intervention programme sustainability*, i.e., the degree to which the health system is likely to sustain the intervention efforts in future (43). This paper presents the results of that assessment of current HW normalization and of the capacity for future intervention sustainability within the MeLoHanD study.

Methods

Operational details of the previous trial

The EACDRP trial intervention package included: training of HWs; development of simple clinical guidelines and patient registers; provision of essential NCD care drugs and equipment; active HT/DM case finding among general outpatients (screening); promotion of NCD awareness and screening during community outreaches (1).

At the end of the study in 2016, the HF service readiness and quality of patient care were evaluated (1). This was done through detailed inspection of each of the intervention and control facilities, including a survey of HWs' knowledge, and a survey of a random sample of 4 HT and DM patients from each facility. Both assessments used standardised tools and questionnaires (1).

Study setting

In contrast to the earlier EACDRP trial which had been conducted in Tanzania and Uganda, the current study (MeLoHanD) was conducted between January and December 2020 in Uganda only, in the same two central districts: (a) Wakiso district, which forms a horseshoe shape around the capital city of Kampala and includes urban, peri-urban, and rural areas with a population of 2.5 million; (b) Mpigi district, which lies just southwest of Kampala along the shores of Lake Victoria and has a population of 250,000 (*Figure 1*). The population of Mpigi is largely a peri-urban and rural mainly engaged in subsistence farming, fishing, and artisanship.

Study design

This study involved a cross-sectional survey conducted in 2020 using structured self-administered but supervised interviews of HWs, patients, patient-leaders, and health managers. It evaluated the current degree to which HW *normalization* had been achieved using the normalization tool; and the current capacity for intervention *sustainability* using a validated programme sustainability assessment tool (PSAT) (34, 43, 44, 47, 71).

Description of health facility levels in Uganda

The primary health care system of Uganda is tiered along the politico-administrative organisation of the country (**Table *1***) and is overseen by the district health office, led by an experienced medical doctor (MD) who co-ordinates resource distribution and staff deployment (54) to health centres II, III, IV and district hospitals (**Table *1***). Several districts form a region which is served by a regional hospital that can provide specialist care. HCIIs and HCIIIs, which may include some private-not-for-profit health facilities, are expected to diagnose, and manage uncomplicated NCD cases including diabetes, hypertension, asthma, and HIV infection. HCIIs should also be able to diagnose DM, but usually refer DM patients to HCIIIs or higher level facilities (55).

Selection of health facilities

This study was conducted in 3 randomly selected higher-level facilities of the originally 6 referral units that participated in the trial, and in all the original 19 lower-level facilities (10 HCIIIs and 9 HCIIs) from the intervention arm of the trial.

There were 7 facilities (4 HCIIIs, 3 HCIIs) in Mpigi and 12 facilities (6 HCIIIs, 6 HCIIs) in Wakiso district. Of these, only Wakiso district (Entebbe) had urban facilities (1 HCIIIs, 1 HCIIs) while the remaining 17 facilities (9 HCIIIs, 8HCIIs) were rural (**Table *2***).

Some HFs had originally been randomised as HCIIIs-HCIIs pairs due to their proximity and to minimise contamination whilst others had been independently randomised (defined here as 'singleton'). The 2 urban HFs (1HCIIIs, 1HCIIs) were singleton while among the 17 rural HFs - 8 had been selected as pairs (4HCIIIs, 4HCIIs) and 9 (5HCIIIs, 4HCIIs) as singletons (**Table *2***).

Prior to the start of current study, a pilot study was carried out in two independent HFs (an urban HCIII and a peri urban HCII) to train the study team and to test data collection tools and procedures. Findings from these pilot HFs were used to improve our procedures but were not included in the research dataset of the study itself.

Selection of participants.

All HWs present at the facility on the study visit days were interviewed using the HW normalization tool. On this occasion HWs also took part in the evaluation of service availability and readiness assessment mentioned above and published elsewhere (70).

For the intervention sustainability (PSAT) tool, following experience from the pilot study; only the focal persons at HFs (e.g., HF in-charges, or OPD / NCD clinic heads) rather than all HWs, and likewise only patient leaders (e.g., patient clubs' leaders or mobilisers) instead of all patients were selected. Health managers at the district and Uganda Ministry of Health (MoH) were also included as well as former intervention officers.

Data collection and measurement

Interviews were conducted by three trained field workers that had not participated in the previous EACDRP evaluation. They were supervised by an experienced clinician or research nurse.
Data was collected via hand-held tablets using REDCap® version 7.6.3 and actively synced or uploaded on to backup servers at the end of each day. All data entry was overseen by a senior data manager who was also the REDCap programmer.

Normalization tool

Normalization has been described as the degree to which HWs have managed to routinely embed a new set of activities in already existing knowledge and practices (39). Normalization can be assessed by applying an instrument (the normalization tool) which was designed to get a better understanding of how to apply and integrate new technologies and complex interventions in health care. The tool asks questions about the implementation of the intervention and is administered to staff with different roles. The tool has 3 parts (A-C) (40). It has been previously validated (39, 41) and a modified version of this tool and constructs have been used to assess provider-initiated HIV counselling and testing programs in South Africa (42).

Part A – comprises three brief multiple-choice questions about the respondent's background and their past and current involvement in the intervention.
Part B – comprises three general questions about how familiar the respondent currently feels with regard to the intervention, with a score of 0-10 (maximum score = 30)
Part C – comprises 20 statements regarding the normalization process as perceived by the respondent, with possible responses each ranging from a score of 1 (strongly disagree) to 5 (strongly agree). The 20 statements are ordered under 4 domains, namely:

1. *Coherence (sense making)* – to what extent HWs perceive that the intervention is meaningful to them and their colleagues at the HF (4 statements).

2. *Cognitive participation (buy in)* – to what extent HWs and their colleagues are engaged in the intervention and actively support it (4 statements).
3. *Collective action (active implementation or teamwork)* – to what extent HWs' individual and team efforts make the intervention work (7 statements).
4. *Reflexive monitoring (appraisal)* – to what extent HWs have access to reports about the intervention and can use this feedback to appraise and improve the intervention (5 statements).

The maximum average score that a HF can achieve under each domain is 5. Across all 4 domains in part C, the maximum aggregate-average score is 20 (4 x 5). Each statement also allows for a lack of response such as a statement not being relevant to their role, not being relevant at the time or not being relevant to the intervention generally.

More details on this tool can be found at https://www.rds-se.nihr.ac.uk/wp-content/uploads/NoMAD-questionnaire-for-PPI-with-Logo.docx *(40)*

Intervention sustainability tool

Programme sustainability capacity has been defined as *the ability to maintain programming and its benefits over time* (43-47). For this work, we used the program sustainability assessment tool (PSAT) to measure this ability. The tool has been validated for use in research and programme settings for chronic diseases (43-45) and in Africa (46, 48).

This tool assesses the intervention's current capacity for sustainability across a range of specific organisational and contextual factors. Responses identify sustainability capacity and challenges under three main areas: Programme (Intervention), Organisation and Community (43, 44).

- *Programme (Intervention)* - this refers to the set of formal organised activities that one wants to sustain over time. Such activities could occur at the local, national, or international level and in a variety of settings.
- *Organisation* – this encompasses all the parent organisations or agencies in which the programme is housed. Depending on the programme, the organisation may refer to a national, or local department, a non-profit organisation, a hospital, etc.
- *Community* – this refers to the stakeholders who may benefit from or who may guide the program. This could include residents, organisational leaders, decision-makers, etc.

The tool covers eight domains, and each domain has 5 questions. Responses are scored from 1 (little or no extent) to 7 (to a great extent), giving a maximum score of 35 points per domain and a maximum average score (i.e., from the 5 questions) of 7 points per domain. These domains include:

IX. *Environmental support:* having a supportive internal and external climate for the HT and DM intervention e.g., in terms of resources, staffing and drug supplies

X. *Funding stability:* establishing a consistent financial base for the HT and DM intervention

XI. *Partnerships:* cultivating connections between the HT and DM intervention and its stakeholders, and or interested or affected people or groups

XII. *Organisational capacity*: having the internal support and resources needed to effectively manage the HT and DM intervention and its activities

XIII. *Program evaluation*: assessing the HT and DM intervention to inform planning and document results

XIV. *Program adaptation:* taking actions that adapt the HT and DM intervention to ensure its ongoing effectiveness

XV. *Communications:* strategic communication with stakeholders and the public about the HT and DM intervention

XVI. *Strategic planning:* using processes that guide the HT and DM intervention's direction, goals, and strategies

This questionnaire also allowed for lack of responses e.g., if participants responded that a question was "not applicable" to them or were not able to answer.

More details on the tool can be found at https://sustaintool.org (47) and http://creativecommons.org/licenses/by-nc/3.0/

Data Analysis

Units of analysis: These include HWs, patients, patient-leaders, health managers at HFs, at the district health office and at the MoH as well as former intervention officers. The normalization and sustainability capacity data were not previously collected in 2016, so this analysis was done for the 2020 data only.

Sample size: We interviewed all 91 HWs present on the survey dates to determine normalization strength, and 110 individuals (patients, HWs and district/MoH supervisors) to measure intervention sustainability (**Table *3***). For the sustainability tool (PSAT) and learning from the pilot study, the groups

were sub-sampled to only include those directly involved in the day-to-day management of the intervention such as HF managers and/or focal persons (i.e., intervention team leaders at the HFs), and patient leaders (such as patient club leaders or community members of the HF management team) to improve tool precision.

For the normalisation assessment, assuming a design effect of 2 to allow for the clustering of HW responses within facilities and a standard deviation (SD) of 1.0, a sample of 91 HWs provided >90% power to demonstrate whether the mean normalization score overall, or for each domain would be >0.5 higher than 3.5 which is the halfway score rounded up to the next 0.5 (or a hypothesised reference value below the desired target score of ≥4 for good domain strength). Adequate domain strength was defined as a score of ≥4 of a possible 5.

For the intervention sustainability assessment, with 110 individuals surveyed, and assuming a design effect of 2 and a SD of 1.0, we had >80% power to demonstrate a similar difference of >0.4 higher than 4.5 which is the halfway score rounded up to the next 0.5 (or a hypothesized value below the desired target value of ≥5 for good domain strength). Hence, adequate domain strength was defined as a score of ≥5 of a possible 7.

Within the pre-defined domains, mean and aggregate scores were determined at domain and facility level for both assessments.

The analyses were performed using the statistical package in Stata® version 17.
Graphic or spider-web chart comparisons of domain means or medians by HF level are presented. Finally, both tools were tested for the internal consistency of all component domains in measuring the outcome using Cronbach's alpha with a value of ≥0.8 defined as high, 0.6-0.8 as moderate and <0.6 as low consistency.

Results

Assessment of normalization strength

All 91 HWs present on the survey days for the clinical knowledge test in the MeLoHanD study in 2020 (70) were also interviewed for this analysis. This represented 70% of the 131 HWs expected as only 95

HWs were contacted to be met over the 2-3 survey visit days and of which 4 indicated they had transferred out of the HF. Most of the 36 HWs we could not meet, did not attend due to COVID-19 restrictions on HF staffing and travel or absenteeism at the time. Of the 91 HWs, 59 (65%) were female, and 27 (30%) were doctors or clinical officers while 64 (70%) were nursing staff or aides. The median age was 36 (IQR: 31,46). Eighty-two (90%) had been trained during the intervention roll-out from 2014 – 2016 but 23 (25%) of these were not currently involved in NCD case management. Almost all HWs that had not received formal NCD training (8/9) during the original trial reported that they did currently provide NCD care (**Table *4***).

Overall, at HCIIIs and HCIIs there were more female than male HWs, but this was not the case at HCIVs. This gender imbalance was not statistically significant (p=0.10). However, the type of HW (p<0.001) and their intervention training attribute (p=0.02) differed significantly across HF levels. HCIIIs and HCIVs had more clinicians while HCIIs had none. HCIVs had fewer *trained and involved* staff than lower-level HFs (i.e., 35% vs 71% at HCIIIs and 80% at HCIIs). Interestingly, HCIVs had also the highest proportion of HWs *trained but not involved* (i.e., 52% vs 16% at HCIIIs or HCIIs). Age, *perceptions about the intervention*, and *whether NCD care was a normal part of their work now or in the future* did not show statistical differences across HF levels.

Overall, the median aggregate score for normalization was 4 out of a possible maximum of 5 (IQR: 3.8, 4.2) with no evidence of association with HF level (p=0.40). Assessing the four domains with a maximum median score of 5, normalization strength was highest (>4) for *cognitive participation* and *reflexive monitoring* across all HF levels. With respect to *cognitive participation* more than 90% of all HFs had achieved an adequate level (≥4). All HF levels were weak (<4) on *collective action* and *coherence*; with HCIIs faring strongest on *collective action* at 3.9 (IQR: 3.6, 4.0) while HCIVs were strongest on *coherence* at 3.8 (IQR: 3.5, 4.0) (Figure 2 & **Table *5***).
Only *collective action* was substantially stronger at HCIIs than at HCIIIs and HCIVs (p=0.002), although still only 44% of HCIIs achieved adequate strength (≥4).

Internal consistency of the normalization tool

In assessing the internal consistency of the normalization tool, each of the four component domains' mean scores were included as assumed equal maximal contributors to the overall normalization strength (or aggregate mean score). Using a standardised Cronbach's test of agreement, the tool

demonstrated fair internal consistency for normalization strength overall (Cronbach's α=0.59) (**Table *6***). Without reflexive monitoring, the internal consistency of the tool was weakened (Cronbach's α=0.37) while without coherence it just slightly improved (Cronbach's α=0.62). The other two domains did not appear to affect it much.

Assessment of intervention sustainability capacity

One hundred ten interviews were analysed. Interviewees included 35 (32%) HW focal persons, 64 (58%) patient leaders and 11 (10%) district/MoH leaders or former intervention officers (**Table *3***). Thirty-seven (34%) of those interviewed were from urban/peri-urban facilities while 77 (66%) were from rural facilities. Thirty-three (30%) interviews were conducted at HCIIs, 57 (52%) at HCIIIs and 20 (18%) at HCIV or district level or higher.

The overall median domain score was 3.1 [IQR (1.9,4.4)] out of a maximal score of 7; HCIIs showed the lowest overall median capacity at 2.2 [IQR (1.8,3.5)] while HCIVs scored highest at 4.1 [IQR (3.0,4.6)], with HCIIIs just in-between at 3.1 [IQR (1.9,4.3)] (**Table *7***).

Sustainability capacity was highly dependent on facility level (p=0.02), with HCIVs scoring higher than HCIIIs which in turn scored higher than HCIIs in nearly all domains. HCIVs demonstrated particularly high scores (>4) in *environmental support*, *capacity in organisation*, *evaluation,* and *adaptation*, and moderate scores for *communication* and *strategic planning.* HCIIIs were strongest at *communication* (3.9) but of moderate strength (3.1-3.5) at *environmental support*, *capacity in organisation*, *evaluation,* and *adaptation.* HCIIs were mostly weak (<3) with regard to all domains. The ability to foster *partnerships* and *funding stability* was poor at all facility levels. Evidence for domain differences by facility level was statistically significant for *environmental support* (p=0.02) and *capacity in organisation* (p=0.01) and borderline for *funding stability* (p=0.05), *communication* (p=0.07) and *strategic planning* (p=0.08) (**Table *7***)(*Figure 3*).

Using a mean score of 5 as cut off, overall adequate sustainability was highest for *evaluation* (38%) and adaptation (37%), and lowest for *funding stability* (11%) across all HF levels. There was no evidence of a significant difference across facility levels (p=0.35). *Strategic planning* was proportionately stronger at higher levels (i.e., HCIVs (30%), HCIIIs (44%)) than at HCIIs (21%) while *funding stability* was weakest overall with HCIIs and HCIIIs at 12% each and HCIVs at 5% (**Table *8***).

Internal consistency of the intervention sustainability tool

In assessing the internal consistency of the intervention sustainability tool, each of the eight component domains' mean scores were included as assumed equal maximal contributors to the overall intervention sustainability capacity (or aggregate mean score). Using Cronbach's test of agreement, the tool demonstrated very good internal consistency for sustainability (Cronbach's α=0.94) (**Table *9***). All component domains affected the internal consistency of the tool similarly (Table 9).

Discussion

With regard to HW normalization, our study showed that there was generally good or adequate normalization strength (a median score of 4 (IQR; 3.9, 4.3) out of a maximum of 5) at all facility levels. This suggests that some aspects of the EACDRP intervention were well sustained, such that they were now embedded within routine practice. Normalisation scores were particularly high with respect to reflexive monitoring and cognitive participation.

All facility levels showed good strength on cognitive participation which suggests that HWs internalised the intervention's aims and processes. Evidence for reflexive monitoring was also strong suggesting an ability among HWs to consciously adapt their work to the dwindling support after the end of the trial. The domains of coherence (indicating intervention sense-making) and collective action (indicating ability to work as a team) were weak overall, but unexpectedly more so for higher level units which are usually less affected by absenteeism or the lack of mentors (6, 72). This might be explained by the fact that larger HW staffing levels (73) (74) may allow for a less rigorous duty schedule and less supervisory oversight or even a reduced opportunity to supervise or be directly supervised by an experienced focal person. In contrast, HCIIs showed greater strength in collective action than higher level HFs. The reason for this, is unclear but the observation may reflect that the necessity to act in a united fashion is particularly strong among small teams.

Most of the respondents (74%) had been previously trained or were fully involved in the post-intervention phase, but this was much less the case at HCIVs than at lower-level HFs (HCIIs & HCIIIs-84% vs HCIVs-44% - **Table *4***). This may have contributed to the differences observed on collective action and coherence.

HCIIIs and HCIVs had more clinicians while HCIIs had none which is as expected per current MoH staffing norms. Compared to lower-level HFs, HCIVs had fewer staff who had been trained on NCDs during the trial (e.g., 35% vs 71% – 80% *'trained and involved staff'* – **Table *4***). This was expected

because at referral HFs, only staff directly involved in NCD care at the time of the intervention trial had received the training, for logistical reasons. Most health workers, regardless of HF level, reported either being very familiar with this NCD care intervention (70%) and largely felt it was already part of their normal work (81%) or that it would become so soon (89%).

Whilst we observed evidence for normalization that survived the end of the trial by 4 years, it was also obvious that for some domains, normalization strength was low, suggesting that it may have substantially declined since the end of research-related support in 2016.

It is important to note that normalization is not irreversible, and good practices can be de-normalized over time (34). Normalization domains are not independent of each other but have dynamic relationships with each other and other domains within the normalization framework of an intervention, such as the organisational context, local context or social norms (34). Furthermore, normalisation may occur during the course of an intervention project onto some but not all newly introduced activities and procedures (16).

A South African study that examined implementation factors around provider-initiated HIV testing and counselling (PITC) after 2 years of embedding using the normalisation process model found that normalization was promoted by strong senior leadership, implementation support, appropriate accountability mechanisms, an intervention design that adapted to needs and practices, positive staff and patient perceptions, and a responsive organisational context (42). However, challenges were found in operational weaknesses, patient communication gaps and inadequate training (42). This is not very different from our findings which showed that HW coherence (sense-making) and collective action as the main weakness at all levels while reflexive monitoring (or intervention appraisal) and cognitive participation (HW buy-in) were the strengths. Similarly, another recent South African study on PITC implementation found that the main facilitator was the participation of all healthcare workers although they also faced barriers such as a lack of workspace and under-appreciation (75). Another study that explored how solar electrification to off-grid rural primary health care facilities in Ghana and Uganda could improve the availability of maternal and child health services using normalization process theory constructs found that implementation with improved outcomes was associated with stakeholder engagement activities to promote internalization (buy-in or sense-making), provision of materials and information to encourage participation, and establishment of relationships to support integration (or teamwork). Barriers to achieving outcomes were also largely operational such as drug stockouts, lack of transportation and poor amenities.

On intervention sustainability, we found that the overall sustainability capacity was low (median 3.1 (IQR 1.9,4.4) out of a maximum of 7). Higher level units performed better than lower-level ones. Their main strengths lay in communication, evaluation, adaptation and to a lesser extent the local environment or organisational capacity. In contrast, lower-level HFs performed rather weakly with respect to funding stability, forging partnerships, and strategic planning. The disparities between facility levels were particularly high for organisational capacity, evaluation, and strategic planning. This is likely due to differences in organisational capacity that affect strategic management (76, 77) and supervisory support at the different facility levels (78). The decline in measures of sustainability over the years since the end of the EACDRP trial is likely to be a result of many factors, not only the discontinuation of funding support. These processes have been captured by Chambers et al., in a dynamic sustainability framework, that emphasizes an ongoing dynamism from implementation to continuation or institutionalisation, and from efficacy to effectiveness, with ongoing adaptation from learning and problem solving (33). More importantly, the framework recognises the fact that as an intervention moves from testing to continuation with little support supervision, a 'program drift' occurs (i.e., a decrease in yield or benefit due to deviations from the protocols in operationalised manuals as the intervention is delivered in the 'real world') and a 'voltage drop' becomes inevitable (i.e., an expected decrease in yield from efficacy to effectiveness into real world use) (33). Obviously, some domains were better sustained than others. This applies in particular to domains that depended less on funding support and more on good organisation and management, or on staff qualities such as knowledge, confidence, and dedication. There was a paucity of findings within the NCD context in sub-Saharan Africa. However, our observations are similar to those from an NCD programme study in Malaysia, which also applied the PSAT (79). In that study, seven of the eight domains achieved an average score of ≥ 4: again, with the highest mean scores for communications (4.5) and organizational capacity (4.4). The lowest score was documented for funding stability (3.8) (79). It is also important to note that as one US study found; participants' reported PSAT scores about perceived sustainability capacity did not directly align with previously reported perceptions about PSAT domain importance or modifiability and so it might be important to identify potential barriers and enablers influencing program (or intervention) sustainability during the planning phase (80). A Spanish study that implemented a school-based, peer-led, social-marketing intervention that encouraged healthy diet and physical activity, in low socioeconomic adolescents and examined change in PSAT over time at two periods during intervention implementation: end of the first year and end of the second year found

that strategic planning (4.43 +/- 1.98) and funding stability (4.38 +/- 1) were considered deficient domains, and at the end of the second year, these domains had improved by 1.67 points (p =0.043) and 0.59 points (p = 0.159), respectively. The funding stability increase was not significant, and the sustainability capacity final score was 5.93 +/- 1.13. The sustainability capacity assessment earlier on in the intervention had allowed its improvement and perhaps even in the long term.

It is unclear whether the modest sustainability capacity that our study found will continue to be maintained in the long term. It will be important to identify ways in which the HFs can maintain or newly establish partnerships. Developing solutions to the lack of funding support will also be essential. The creation of patient clubs might be one option. The organisation of patients into an active and functional club directly impacts funding stability because essential drugs or other critical supplies would become available when freely provided supplies are low. Similar organisational or logistical benefits have been demonstrated with patient adherence clubs in HIV chronic care clinics (81) (82). Additionally, the organisational structure of clinics and the patient management at HFs can benefit from patient leaders or peer supporters (81).

During the EACDRP intervention, deliberate efforts had been made to encourage sustainability through full engagement of MoH and district leadership in the design and revision of the programme, and by organising regular support supervision to HFs. This engagement, even though to varying extents, has largely continued even with other subsequent research projects.

Strengths

This study is one of few studies examining factors associated with HW normalization and intervention sustainability among NCD services in SSA. We attempted to use a quantitative approach to answer a qualitative question: how well an NCD service intervention programme was sustained according to the perceptions of primary stakeholders such as HWs, health facility and programme managers, patient leaders, and patients. This approach helped us to quantify the various contributory domains as well as to identify areas of strength or weakness that may be amenable to renewed intervention.

This study used standardised and previously validated tools to explore aspects of normalization and intervention sustainability. Overall, validity testing for both the normalization tool and PSAT showed fair (α=0.6) to very good-to-excellent (α=0.9) reliability respectively. From a qualitative viewpoint, this means that we can have confidence in the findings as a true reflection of the perceptions of this study population.

Limitations

This study was a one-time point cross-sectional assessment as a similar assessment was not done in 2016. Due to lack of this temporal comparison, there is reason to wonder about reverse causality – does current sustainability capacity say more about future capacity (post-intervention) or the previous intervention's residual capacity? However, the post-intervention period lasted about 4 years which should provide adequate time for honing out of any temporary benefits attributable to the previous intervention. Any benefits still present are probably genuinely institutionalised and should continue to do so well into the future.

Response to scalar score-based questions is usually subjective and prone to respondents choosing the middle ground or null (i.e., between the extreme scores) or a regression to the mean. Additionally, respondents may choose what is perceived as socially desirable or acceptable to them. These were both minimised by allowing for a lack of responses (e.g., if participants responded that a question was 'not applicable' or that they did not know the answer). Also, most respondents whether HWs or patients had interacted with the intervention for long which minimised the chance of difference between what they observed and what really prevails (83) (84).

Impact of the COVID-19 epidemic: The COVID-19 outbreak in Uganda represented a challenge to our study. The immediate effect was protraction of the study duration as field activities and data collection had to be suspended for about 4 months. Restrictions on travel and work lasted even longer so that fewer than expected HWs could be interviewed. However, due to the longevity of the intervention we believe that the possible effect of this on the variation of HWs' responses was small as the majority of HWs (78%) had been based at their health facilities for 3 years or longer.

Conclusions

About 6 years after the introduction of a multi-faceted NCD health service intervention in Uganda, and 4 years after the end of active research-related funding support, we found that the intervention was still normalized among health workers, at least to some extent. This was particularly the case with cognitive participation and reflexive monitoring at small and mid-level primary care facilities. Higher level primary care units need more supervisory support to improve cognitive participation and to foster teamwork (collective action). In particular lower-level primary care units need support enabling

them to strengthen the domain of coherence (sense-making) through improving their organisational capacity and long-term strategic planning. All primary care levels will need to strengthen their evaluation and appraisal capacities to maintain optimal reflexive monitoring.

Regarding intervention sustainability, we found that low and mid-level primary care units generally scored sub-optimally (or <4) on all 8 domains. Higher level primary care units were weak on funding and with respect to supportive partnerships with other stakeholders. Overall, good funding stability, effective partnerships and long-term strategic planning are needed to ensure continuity in services and logistics at all levels.

Future overall sustainability capacity may be enhanced by maintaining and strengthening supervisory support (e.g., in-service support supervision) and organisational capacity, a better communication strategy and adaptation in the absence of adequate or reliable funding. More studies are needed to understand exactly how and when each of these domains come into play in different settings during the life-course of an intervention and its post-implementation period.

List of abbreviations

CD(s)	Chronic Disease(s)
DM	Diabetes Mellitus
EACDRP	EACDRP – East African Chronic Disease Research Project
GCP	Good Clinical Practice
HC	Health Centre (Is, IIs, IIIs, IVs or 1, 2, 3, 4 levels)
HF(s)	Health Facilities
HIV	Human Immuno-deficiency Virus
HSP	Human Subject Protection
HT	Hypertension
HW(s)	Health Workers / Healthcare Workers
ICF	Information and Consent Form
IQR	Interquartile Range
LSHTM	London School of Hygiene and Tropical Medicine
MeLoHanD	Medium to Long term sustainability to improve management of Hypertension and Diabetes within the primary care setting in Uganda
MoH	Ministry of Health (Uganda)
MRC	Medical Research Council

MUL	MRC/UVRI and LSHTM Uganda Unit (MUL)
NCD(s)	Non-communicable Diseases
OPD	Out-patient Department
PSAT	Program Sustainability Assessment Tool
UVRI	Uganda Virus Research Institute
SSA	Sub-Saharan Africa
SD	Standard deviation
WHO	World Health Organization

Declarations

Ethics approval and consent to participate

Approvals

The study was approved by the Research and Ethics Committee of the Uganda Virus Research Institute (GC/127/19/09/743), the Uganda National Council for Science and Technology (HS 2714) and the Ethics Committee of the London School of Hygiene and Tropical Medicine (17914).

Informed consent

Participants read or were read to the appropriate participant information and consent form (ICF) to acquaint themselves with what the current study entailed and what was required of them to participate. Both verbal and written informed consent was obtained from all participants in this study. This was documented on the ICF by the participant's own signature, or thumbprint obtained from those not able to read or write in the presence of a competent independent witness. The witness also underwrote and signed on that participant's behalf.

Research conduct and compliance

Research on human subjects or material or data in this study was conducted in compliance the Declaration of Helsinki and followed Good Clinical Practice (GCP) guidelines. All study staff were also GCP trained.

Patients with uncontrolled NCDs detected during the outcome assessment at health facilities were jointly discussed with the healthcare provider at their respective facility to ensure that they receive adequate care.

Consent for publication

Not applicable as no identifiable data is presented in the current study.

Availability of data and materials

The datasets that support these findings are available from London School of Hygiene and Tropical Medicine (LSHTM) and MRC/UVRI and LSHTM Uganda Research Unit (MUL), but restrictions apply to the availability of these data, which were used under licence for the current study, and so are not publicly available. However, data are available from the authors (David Katende) upon reasonable request and with permission of both LSHTM and MUL. Contact person: Ayoub Kakande Email: Ayoub.Kakande@mrcuganda.org

Contributors

DK, HG, KB, and MN designed the study; DK, NN, GN and KN conducted the fieldwork; KN and MCM oversaw the data management; DK and KB performed the analyses; MCM and IS contributed to the analysis; DK wrote the manuscript; KB, HG and MN contributed to the manuscript. All authors approved the final version of the manuscript.

Competing interests

The authors declare that they have no conflicts of interest.

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Tables and figures - Sustainability capacity and health worker normalisation of a successful non-communicable disease (NCD) health systems intervention within primary care settings in Uganda: a quantitative approach to a qualitative question

Tables

Table 1 - Description of the Levels of Public Health Service Delivery in Uganda

Health Facility Level[Ψ]	Political or Administrative Level	Catchment Target Population	Main Function or Infrastructural Requirement	Facility head/Supervisor* title and/or their educational background
Regional Hospital	Region or several districts	>2 million	General and specialist services e.g.,	Medical director (e.g., MD+MPH)
District Health Office	District	500,000 to 2 million	Resource distribution, staffing	DHO-er (e.g., MD+MPH)
District Hospital/HCIV	District or constituency	100,000 to 500,000	50-100 in-patient beds, general theatre,	Medical director (e.g., MD+/-MPH)
HCIII	Sub-county	30,000	10-20 in-patient beds, maternity unit, a simple	Non-MD clinician or Mid-wife
HCII	Parish or several villages	5,000 to 10,000	1–2 day-care beds, first line emergency and out-	Nurse
HCI	Village	1,000-5,000	Mobile outreach post	Nursing assistant or Health visitor

[Ψ]HC- Health Centre; *MD - Medical Doctor; MPH - Master's course in public health
(Adapted from Readiness of Ugandan health services for the management of outpatients with chronic diseases, Katende et al, 2015)

Table 2 - Distribution of health facilities by district and facility level

Facility attribute		District				Total
		Mpigi		Wakiso		
		HCIIIs	*HCIIs*	*HCIIIs*	*HCIIs*	
Urban HFs	*Singleton*	-	-	1	1	2
Rural HFs	*Singleton*	2	1	3	3	9
	Paired	2	2	2	2	8
Referral facilities (HCIVs)		1 *(Peri-urban)*		2 *(1 Peri-urban, 1 rural)*		3
Total		8		14		22

Table 3 - Distribution of the observed and sub-sampled participants

Groups	Observed overall	Sub-sampled for PSAT
Health workers	91[1]	35[2]
District/ MoH supervisors	11[3]	11[3]
Patients	332	64[2]
	434	**110**

Footnotes

[1]All 91 HWs that were interviewed for the normalization tool

[2]Only patient leaders or HW focal persons (not all patients or HWs) were interviewed for the intervention sustainability (PSAT)

[3]Includes 3 former intervention supervisors

Table 4 - Population characteristics of 91 health workers by health facility level and perceptions regarding their engagement in NCD care

Population characteristic	Category	HCIIS (25)	HCIIIS (43)	HCIV (23)	Overall, N=91	P-value[2]
Age	*Median (IQR)*	37 (33-39)	37 (31-44)	34 (28-40)	36 (31-42)	0.36[3]
Sex	*Women (%)*	18 (72%)	31 (72%)	10 (43%)	59 (65%)	0.10
	Men (%)	7 (18%)	12 (18%)	13 (57%)	32 (35%)	
Duration of posting at HF	*3 yrs. or less*	5 (20%)	5 (12%)	3 (13%)	13 (14%)	0.60
	>3yrs	20 (86%)	38 (89%)	20 (87%)	78 (86%)	
HW type	*MO/CO*	0 (%)	13 (30%)	14 (61%)	27 (30%)	**<0.001**
	Nurse/Mw	14 (56%)	18 (42%)	6 (26%)	38 (42%)	
	Other	11 (44%)	12 (30%)	3 (13%)	26 (28%)	
Intervention training and current involvement[1]	*Trained and involved*	20 (80%)	31 (72%)	8 (35%)	59 (65%)	**0.02**
	involved not trained	1 (4%)	5 (12%)	2 (9%)	8 (9%)	
	not involved but trained	4 (16%)	7 (16%)	12 (52%)	23 (25%)	
	not involved not trained	0 (0%)	0 (0%)	1 (4%)	1 (1%)	
Feeling about intervention	*new to somewhat 0-6*	5 (20%)	14 (33%)	8 (35%)	27 (30%)	0.45
	very familiar =>7	20 (80%)	29 (67%)	15 (65%)	64 (70%)	
	Median scores (IQR)	10 (8-10)	8 (6-10)	8 (6-10)	9 (6-10)	0.13[3]
"NCD care is now normal part of work"	*not at all to somewhat 0-6*	3 (12%)	10 (23%)	4 (17%)	17 (19%)	0.51
	completely =>7	22 (88%)	33 (77%)	19 (83%)	74 (81%)	
	Median scores (IQR)	10 (9-10)	10 (8-10)	9 (7-10)	10 (8-10)	0.24[3]
"NCD care will become a normal part of work"	*not at all to somewhat 0-6*	2 (8%)	6 (14%)	2 (9%)	10 (11%)	0.69
	completely =>7	23 (92%)	37 (86%)	21 (91%)	81 (89%)	
	Median scores (IQR)	10 (10-10)	10 (9-10)	10 (9-10)	10 (9-10)	0.45[3]

Footnote

[1] *'Involved'* - means they were actively involved in NCD care at the time of this survey

[2]Design-based chi-test of difference between the facility levels

[3†] Kruskal-Wallis's equality-of-populations rank test

Table 5 - Normalization strength by proportions and medians across domains by health facility level, as reported by 91 HWs, using the normalization tool

Normalization domain	Adequate strength *(Yes≥4/No<4)* [1]	HCIIS (25)	HCIIIS (43)	HCIV (23)	Overall domain score, N=91	p-value[2]
Coherence	*No / NA*	16 (64%)	29 (67%)	15 (65%)	60 (66%)	0.96
	Yes	9 (36%)	14 (33%)	8 (35%)	31 (34%)	
	Median scores (IQR)	3.5 (3.3, 4.3)	3.5 (3.0, 4.0)	3.8 (3.5, 4.0)	3.5 (3.0, 4.0)	0.22[3]
Cognitive participation	*No / NA*	1 (4%)	1(2%)	0 (0%)	2 (2%)	0.64
	Yes	24(96%)	42 (98%)	23 (100%	89 (98%)	
	Median scores (IQR)	4.8 (4.3, 5.0)	4.8 (4.3, 5.0)	4.3 (4.5, 5.0)	4.8 (4.3, 5.0)	0.89[3]
Collective action	*No / NA*	14 (56%)	39 (91%)	20 (87%)	73(80%)	**0.002**
	Yes	11 (44%)	4 (9%)	3 (13%)	13 (20%)	
	Median scores (IQR)	3.9 (3.6, 4.0)	3.4 (3.1, 3.7)	3.3 (3, 3.9)	3.6 (3.1, 4.0)	**0.002**[3]
Reflexive monitoring	*No / NA*	2 (8%)	8 (19%)	3 (13%)	13 (14%)	0.48
	Yes	23 (92%)	35 (81%)	20 (87%)	78 (86%)	
	Median scores (IQR)	4.2 (4.0, 4.4)	4.2 (4.0, 4.6)	4.3 (4.0, 4.6)	4.2 (4.0, 4.6)	0.93[3]
Overall facility score, N=91	*No / NA*	13 (52%)	22 (51%)	11 (48%)	46 (51%)	0.95
	Yes	12 (48%)	21 (49%)	12 (52%)	45 (49%)	
	Median scores (IQR)	4.0 (3.9, 4.3)	4.0 (3.7, 4.2)	4.0 (3.0, 4.2)	4.0 (3.8, 4.2)	0.40[3]

Footnotes

[1]Assessing domain strength using mean score cut offs Yes≥4 vs No<4

[2]Design-based chi-test of difference between the facility levels

[3†] Kruskal-Wallis's equality-of-populations rank test

IQR – Interquartile range

N/A – "not applicable or relevant" or "not answered"

Table 6 - Internal consistency of all four component domains with normalization strength based on responses from 91 HWs using the normalization tool

Domain/Theme	No. of domains[1]	Average inter-domain co-variance (standardised)	Cronbach's alpha
Coherence	3	0.35	0.62
Cognitive participation	3	0.28	0.54
Collective action	3	0.25	0.51
Reflexive monitoring	3	0.16	0.37
Normalization strength	**4**	**0.26**	**0.59**

Footnote

[1]Assessment excludes the component domain indicated except for the theme "normalisation strength" which includes all 4 domains

Table 7 - Median scores for the 8 domains of intervention sustainability, based on responses from 110 respondents to the PSAT

Health facility level	Overall facility median score (IQR)	Sustainability capacity domain (median score (IQR))							
		Environmental support	Funding stability	Partnerships	Organisational capacity	Evaluation	Adaptation	Communication	Strategic planning
HCIIs (33)	**2.2 (1.8, 3.5)**	2.7 (2.0, 3.8)	1.6 (1.3, 2.6)	2.0 (1.6, 3.2)	2.2 (1.4, 3.7)	2.5 (1.8, 4.8)	2.4 (1.8, 4.4)	2.7 (1.8, 4.7)	1.9 (1.5, 3.6)
HCIIIs (57)	**3.1 (1.9, 4.3)**	3.4 (2.0, 4.6)	2.1 (1.0, 3.0)	2.2 (1.6, 3.8)	3.3 (1.6, 4.6)	3.4 (1.8, 5.2)	3.5 (2.1, 5.4)	3.9 (2.2, 5.5)	3.0 (1.6, 5.5)
HCIVs/higher (20)	**4.1 (3.0, 4.6)**	4.4 (3.2, 5)	2.7 (1.8, 3.9)	2.5 (1.7, 4.5)	4.4 (3.7, 5.2)	4.6 (3.5, 5.6)	4.3 (3.1, 5.1)	4.0 (3.1, 5.4)	4.0 (2.2, 5.1)
Overall domain score (110)	**3.1 (1.9, 4.4)**	**3.2 (2.0, 4.8)**	**2.0 (1.3, 3.0)**	**2.2 (1.6, 3.8)**	**3.3 (1.7, 4.6)**	**3.4 (2.0, 5.0)**	**3.2 (2.0, 5.2)**	**3.6 (2.2, 5.4)**	**2.6 (1.6, 5.0)**
p-value[1]	**0.02**	**0.04**	**0.05**	0.38	**0.01**	0.10	0.19	0.07	0.08

Footnote

[1]Kruskal-Wallis's equality-of-populations rank test

HC - Health centre levels II, III, IV

PSAT – Program sustainability tool

Table 8 - Intervention sustainability by domain and health facility level, based on responses from 110 respondents to the PSAT

Health facility level	Adequate strength[1] Yes /No (≥5)/ (<5)		Sustainability capacity domain (N=110)							
		Environmental support	Funding stability	Partnerships	Organisational capacity	Evaluation	Adaptation	Communication	Strategic planning	Overall facility strength
HCIIs (33)	*No / NA*	27 (82%)	29 (88%)	30 (76%)	28 (85%)	23 (70%)	23 (70%)	25 (76%)	26 (79%)	29 (88%)
	Yes	6 (18%)	4 (12%)	3 (24%)	5 (15%)	10 (30%)	10 (30%)	8 (24%)	7 (21%)	4 (12%)
HCIIIs (57)	*No / NA*	43 (75%)	50 (88%)	43 (75%)	43 (75%)	33 (58%)	32 (56%)	36 (63%)	32(56%)	49 (86%)
	Yes	14 (25%)	7 (12%)	14 (25%)	14 (25%)	24 (42%)	25 (43%)	21 (37%)	25 (44%)	8 (14%)
HCIVs/ higher (20)	*No / NA*	13 (65%)	19 (95%)	16 (80%)	12 (60%)	12 (60%)	14 (70%)	13 (65%)	14 (70%)	17 (85%)
	Yes	7 (35%)	1 (5%)	4 (20%)	8 (40%)	8 (40%)	6 (30%)	7 (35%)	6 (30%)	3 (15%)
Overall domain strength (110)	*No / NA*	83 (75%)	98 (89%)	89 (81%)	83 (75%)	68 (62%)	69 (63%)	74 (67%)	72 (65%)	95 (86%)
	Yes	27 (25%)	12 (11%)	21 (19%)	27 (25%)	42 (38%)	41 (37%)	36 (33%)	38 (35%)	15 (14%)
p-value[2]		0.35	0.69	0.30	0.19	0.58	0.47	0.49	0.20	0.35

Footnotes

[1]Assessing adequate domain strength using mean score cut-offs Yes≥5 / No<5

[2]Design-based chi-test of difference between the health facility levels

HC - Health centre levels II, III, IV

PSAT – Program sustainability tool

N/A – "not applicable" or "not answered"

Table 9 – Internal consistency of all 8 component domains with intervention sustainability, based on responses from 110 respondents to the PSAT

Theme	No. of domains[1]	Average inter-domain co-variance (standardised)	Cronbach's alpha
Environmental support	7	0.68	0.94
Funding stability	7	0.68	0.94
Partnerships	7	0.68	0.94
Organisational capacity	7	0.65	0.93
Evaluation	7	0.65	0.93
Adaptation	7	0.68	0.94
Communication	7	0.66	0.93
Strategic planning	7	0.65	0.93
Intervention sustainability	**8**	**0.67**	**0.94**

Footnote

[1]Assessment excludes the component domain indicated except for the theme "intervention sustainability" which includes all 8 domain

PSAT – Program sustainability tool

Figures

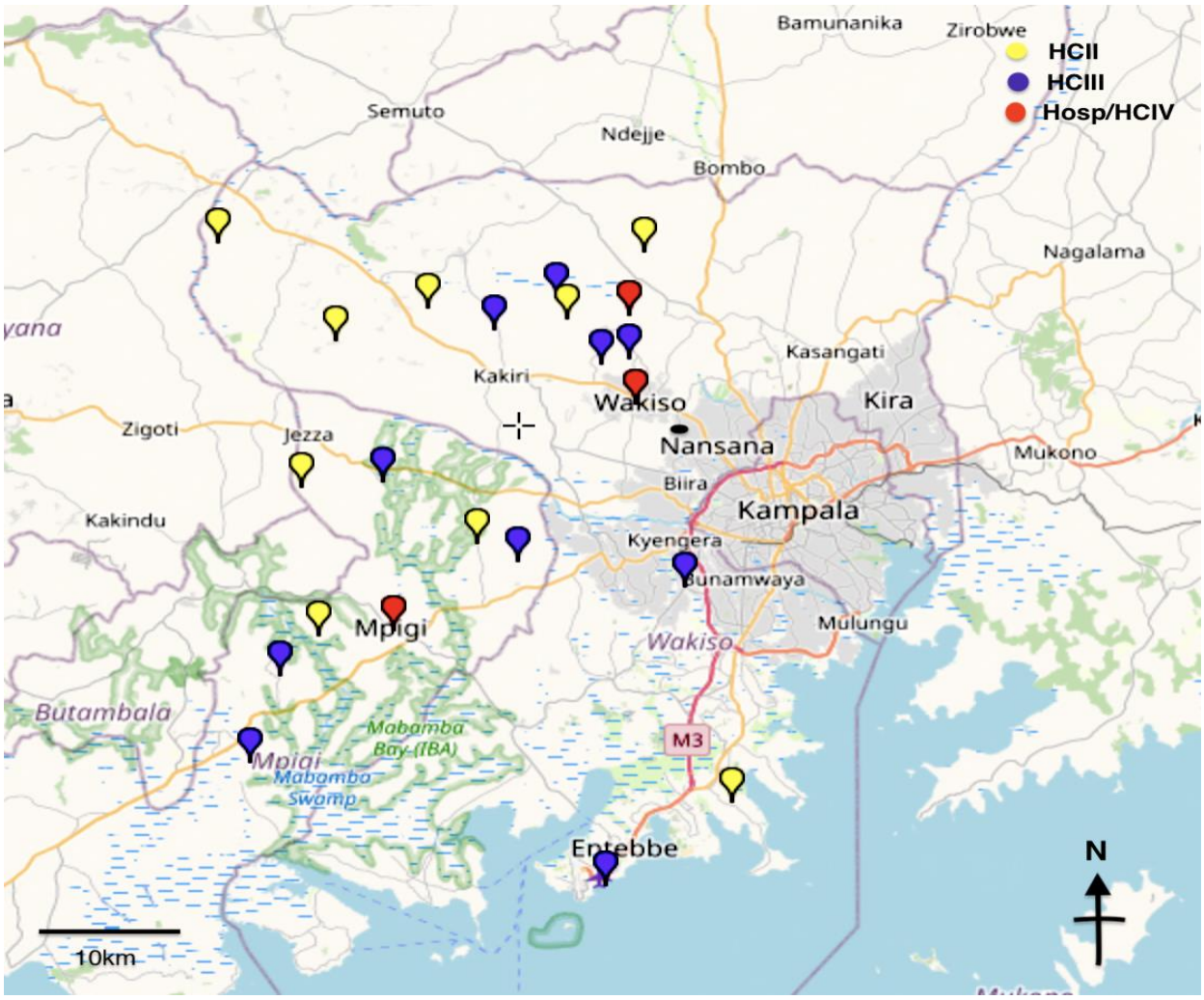

Figure 1 - Map showing the distribution of participating health facilities across Mpigi and Wakiso Districts in Uganda (developed using GPS visualizer.com)

Footnote

HC - Health centre levels II, III, IV

Hosp - Hospital

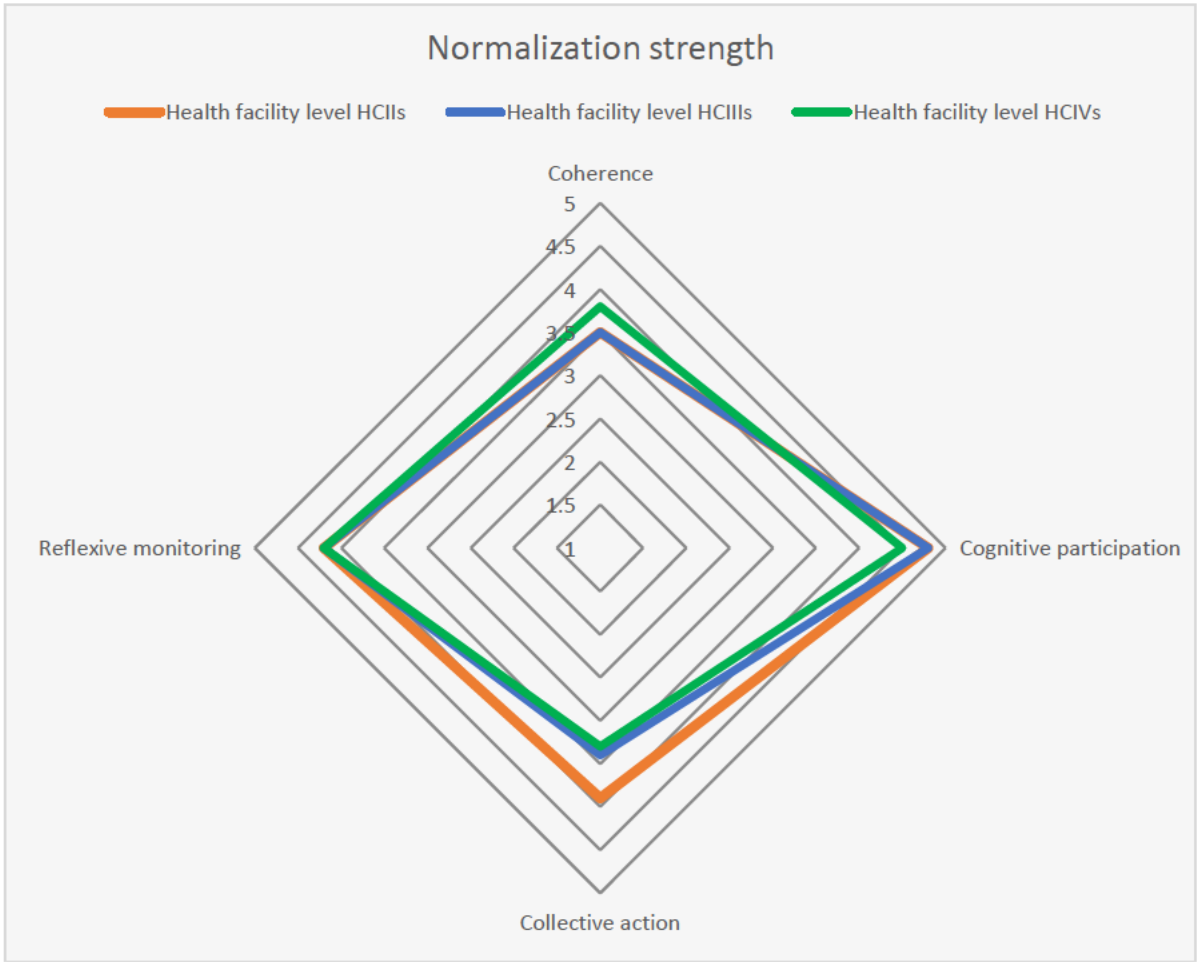

Figure 2 - Spider web chart of median scores for the 4 domains of normalization strength, based on responses from 91 respondents to the normalization tool

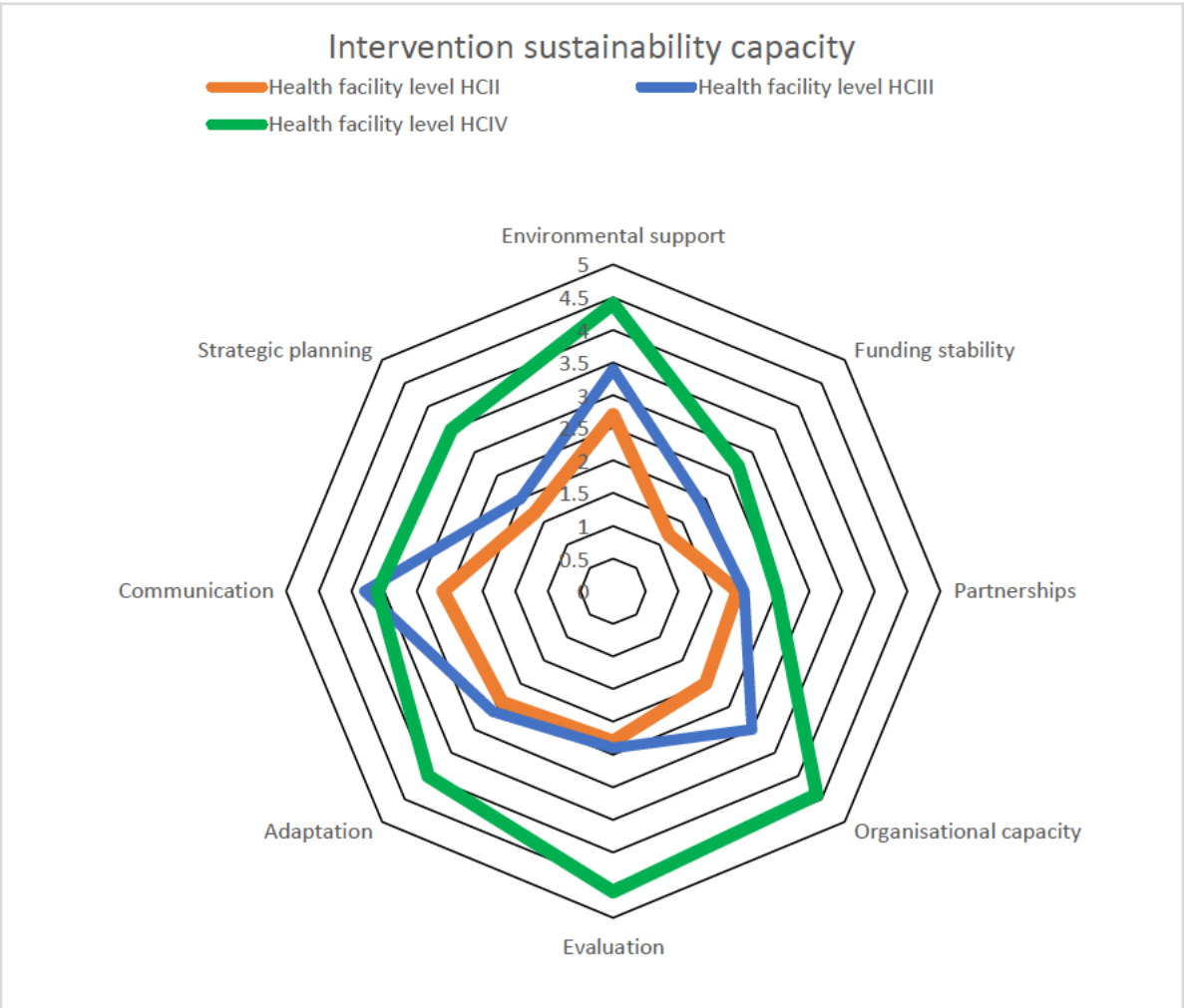

Figure 3 - Spider web chart showing median scores for the 8 domains of intervention sustainability capacity, based on responses from 110 respondents to the PSAT

Chapter 7: Additional work

Apart from the assessments described in chapters 5 and 6, the following chapter presents qualitative supplementary studies that I conducted to explore:

(i) The role of patient clubs in sustaining the HT and DM intervention

(ii) The views of key stakeholders about the intervention, its implementation, and its sustainability of the HT and DM intervention between 2016 and 2020

7.1. The role of patient clubs

7.1.1. Abstract

Towards the end of EACDRP trial and the last trial review meeting with HF heads and focal persons; an idea had been birthed following experience from the higher-level HFs in Uganda that had structured patient associations around their HT and DM clinics, to create similar "patient clubs" at lower-level units as well. Most of the HFs had agreed to create these patient clubs by trial's end. In the MeLoHanD study, we assessed club functionality as an aggregate score of the coded responses to 6 questions on patient club attributes in a tool which included: existence of a patient club, whether it had elected leadership, held regular meetings, whether members made contributions, whether any financial records were kept and whether they held any annual general meetings. Patient clubs were created in 19 out of the 22 MeLoHanD assessed facilities.

The effect of patient club functionality was strongest (p=0.05) in the model that adjusted for FPS scores in 2016 which indicates that the patient club functionality may still be a weak confounder of facility performance. Only high patient club functionality could be associated with a protective effect on facility performance. Patient club functionality does not seem to have the same effect on QoCE. Only low functionality seems to be negatively associated with QoCE in both the unadjusted model and the model adjusting for 2016 scores (p=0.05), but this effect is diminished in the final adjusted model (p=0.87)

Optimising the functionality of patient clubs seems to be crucial to the sustainability and durability of HT and DM services at primary care settings in the absence of programme or research support.

7.1.2. Introduction

At the end of original intervention trial in 2016 - following the last trial review meeting with HF heads and focal persons; the intervention team made a visit plan for the last round of support supervision and asked the NCD focal persons at each health facility to invite clinicians, all available HT and DM

patients and local leaders for a special meeting at their facility so that we could hand over the last buffer stock of essential HT and DM drugs and supplies and bid them farewell.

In that meeting we gave a brief description on how the study had performed and shared some of the immediate outcomes. We also informed patients that the study had ended and there would be no more supplies from the EACDRP trial team including drugs. We alerted them to the fact that the routine MoH drug supply may not be sufficient to meet their needs once the buffer drugs stock provided would run out.

We proposed an idea of a self-help initiative which could ensure continued availability of basic drugs and supplies for HT and DM patients at the intervention facilities.

It involved each patient contributing a small, uniform amount of money at every future clinic visit which they would pool together as a group to enable them to buy essential drugs and related supplies for their treatment at wholesale price. This could avoid stock-outs that would inevitably lead to poor adherence related HT and DM complications. We also advised them to contribute a uniform annual membership fee of a figure unanimously agreed upon by all members in a general meeting. A receipt was to be issued for every payment.

The funds collected on clinic days were strictly to be used to buy drugs in bulk while annual membership fees could be used to open a bank account, buy glucose test strips, or a cupboard for storing drugs or stationery e.g., receipt books, Additionally, it could also be used to replenish batteries, replace broken BP machines and glucometers and if any funds remained, to add to the purchase of essential medicines.

We advised patients who consented to forming a “patient club” to select a governing committee comprised of 4-5 members from among themselves. The committee’s main responsibility was to manage club finances, buy drugs and related supplies during stock outs. Patient club members were advised to elect the committee members for the following posts: chairperson, secretary, treasurer, mobiliser and 1 or 2 committee members. The committee was to give periodic reports to the health facility in-charge and or facility NCD focal person. Health workers were strongly advised to only offer patronage, and to avoid engaging in the day-to-day administration of the patients’ club and financial transactions.

Each club was advised to get a club name, write a club constitution, and get registered with the sub-county or division community-based organisation (CBO) Office. After registration, a club was required to open a bank account at the nearest bank.

The club committee was advised to hold regular monthly meetings until the club was stable and were also mandated to call an all-members’ general meeting at least twice a year.

The idea of forming clubs was embraced by most patients present at the meetings and at all facilities including those in the control arm that had participated in the trial. In the review meetings we held, the MoH NCD program officer encouraged and supported this patient club model, but no policy structure or guidelines were ever provided.

Development of patient clubs over the period from 2016 – 2020

1. By the close of the study, patients from all 46 trial HFs (in Wakiso and Mpigi districts) had agreed to form patient clubs; and in 2020 most of them were formed and were still active and registered. For example, of the 22 HFs selected for the MeLoHanD study only 3 (14%) had not formed patient clubs.
2. Many patients subscribed to the patient clubs continue to get adequate monthly treatment at their HFs at an affordable cost.
3. Health workers trained during the course of the EACDRP trial introduced HT and DM clinics and the "patients' club" model to non-trial health units where they got transferred.
4. HT and DM "patients' club" model has since been adopted by HFs even outside Wakiso and Mpigi districts
5. The consistent and regular availability of HT and DM drugs and supplies provided by patient clubs has boosted the morale of health workers in managing HT and DM patients
6. Some new HT and DM patients attended and sought treatment at public HFs because they receive it at low cost once they subscribed to the patients' clubs.

7.1.3. Methods

Definition and measurement of patient club functionality

In the MeLoHanD study, I defined club functionality as an aggregate score of the coded responses to 6 questions on patient club attributes in the routine supervision checklist tool (Appendix B) (**Table *13***).

(i) existence of a patient club (1-2 points)
(ii) whether it had an elected leadership (1-3 points)
(iii) held regular meetings (1-7 points)
(iv) whether members made contributions (1-5 points)
(v) whether any financial records were kept (1-5 points)
(vi) whether it held annual general meetings (1-3 points)

Table 13 - Measurement of club functionality[1]

Exploratory variables	Question or definition	Final measurement
Patient club functionality	Aggregated scores of functionality attributes e.g., +/- existence of a patient club, +/-elected club leadership, +/-regular meetings, +/- member contributions, +/-financial records, +/- annual general meetings	Highly functional or Moderately functional or Lowly or non-functional

Footnote

[1]this was extracted from the chapter on methods, (see chapter 4, and **Error! Reference source not found.**)

Each HF could score between a minimum score of 6 points (most highly functional) and a maximum of 25 points (least functional).

These coded attributes were summed up into an aggregate score of club functionality. The coded attributes were scored higher for low or no functionality and lower for high functionality, as shown in the example below. The aggregate score was split into three bands of equal 33rd centiles i.e., the lower band or lower 33rd centile = high functionality, middle band or middle 33rd centile = moderate functionality, and the upper band or upper 33rd centile = low to non-functionality.

An example of a coded attribute question on patient club functionality – if one entered "quarterly" the coded score for the question would be "4".

How frequently are patient club meetings held?

1 – Weekly
2 – Biweekly
3 – Monthly
4 – Quarterly
5 – Twice a year
6 – Infrequently
7 – N/A (or if no meetings are held)

7.1.4. Results

Patient clubs were created to varying degrees of functionality in 19 of the 22 HFs in this study. Of the 19 HFs, 6 (27%) were highly functional, 7 (32%) were moderately functional, and 9 (41%) were low or not functional in 2020. Three HFs (i.e., 1 HCIIIs and 2HCIIs) did not form any clubs during the period 2016-2020.

Assessing the effect of patient club attributes e.g., level of functionality of the club on facility performance.

Table 14 - Effect of patient club functionality on facility performance (FPS)[1]

Variable	Level	Model 1 Coefficient, (95% CI)	Model 2[2] Coefficient, (95%CI)	Model 3[3] Coefficient, (95%CI)
Mean FPS score in 2020		P<0.01 -0.45 (-0.77, 0.12)	P<0.01 -0.45 (-0.77, -0.12)	P<0.01 -0.55 (-0.89, -0.21)
Patient club functionality		P=0.26	P=0.05	P=0.09
	High	ref	ref	ref
	Moderate	-4.98 (-14.30, 4.34)	-5.62 (-13.25, 2.00)	-6.30 (-14.96, 2.35)
	Low or none	-5.11 (-13.94, 3.72)	-6.82 (-14.12, 0.47)	-4.96 (-12.97, 3.06)

Footnote

[1]the data for this sub-study were extracted from the data set collated for the study of service readiness and service quality, (see chapter 5)

[2]Adjusted for baseline FPS scores in 2016

[3]Adjusted for baseline FPS, patient club functionality, facility level, area, district and pairing at randomisation

In the crude analysis, patient club functionality seems to be associated with a decrease in mean FPS of 5-points for both moderate (95%CI=-14.30, 4.34) and low or no functionality (95%CI=-13.94, 3.72) relative to high functionality but did not show any evidence of an association with mean FPS in 2020 alone (p=0.26) (**Table *14*).**

Adjusting for FPS in 2016, patient club functionality was associated with a 5.6-point drop (95CI=-13.25, 2.00) in mean FPS in 2020 for the moderate group and a 6.8-point drop -6.82 (95%CI -14.12, 0.47) for the low or none group with borderline evidence of an association (p=0.05) with mean FPS in 2020.

In the final model that adjusted for the baseline FPS, patient club functionality, facility level, area, district and pairing at randomisation, the effect of patient club functionality was diminished (p=0.09) but the overall mean FPS in 2020 decreased further from a 0.45-point drop (95%CI=-0.77, -0.12) to a 0.55-point drop (95%CI=-0.89, -0.21) (**Table *14***).

The effect of patient club functionality was strongest (p=0.05) in the bivariate analysis that adjusted for FPS scores in 2016 which indicates that the patient club functionality may still be a weak confounder of facility performance whose effect is removed when all possible other confounders at p<0.2 are also controlled for. This effect seems to be largely similar for both moderate and low to non-functionality groups (**Table *14***).

Assessing the effect of patient club attributes e.g., level of functionality of the club on the QoCE.

Table 15 - Effect of patient club functionality quality of patient care and experience (QoCE)[1]

Variable	Model 1 Coefficient (95%CI)	Model 2[2] Coefficient (95%CI)	Model 3[3] Coefficient (95%CI)
Mean QoCE score in 2016	P=0.71 0.13 (-0.53, 0.78)	P=0.71 0.13 (-0.53, 0.78)	P=0.75 0.08 (-0.42, 0.58)
Patient club functionality	P=0.05	P=0.05	P=0.87
High	Ref	ref	Ref
Moderate	0.71 (-0.62, 2.04)	0.68 (-0.65, 2.02)	0.31 (-0.88, 1.51)
Low or none	-0.90 (-2.18, 0.37)	-0.92 (-2.19, 0.36)	0.09 (-1.26, 1.43)

Footnote

[1]the data for this sub-study were extracted from the data set collated for the study of service readiness and service quality, (see chapter 5)

[2]Adjusted for baseline FPS scores in 2016

[3]Adjusted for baseline FPS, patient club functionality, facility level, area, district and pairing at randomisation

In the QoCE assessment, patient club functionality seemed to be negatively associated with a decrease of 0.90-point (95%CI=-2.18, 0.37) in mean QoCE scores in 2020 for the low functionality group compared to the highly functional one and a 0.71-point increase (95%CI=-0.62, 2.04) in mean QoCE scores in 2020 for the moderately functional group both relative to the highly functional one and this effect showed weak evidence of association (p=0.05) (**Table *15***).

In adjusting for QoCE mean scores in 2016, the effect of patient club functionality was similar for both groups relative to the highly function group and again with weak evidence of association (p=0.05).

In the final adjusted model that controlled for the QoCE scores in 2016, club functionality, external support, facility level, area, and district the effect of patient club functionality on mean QoCE scores in 2020, there was no evidence for a statistically significant association (p=0.87) (**Table *15***).

Whereas the effect of patient club functionality on QoCE was found to be very weak overall, it still seems to have a borderline effect in the models 1 and 2. However, overall mean QoCE scores only decreased slightly from 0.13 (p=0.71) to 0.08 (p=0.75) with no evidence of statistical difference after controlling for all the possible confounders at a p<0.2 level (**Table *15***).

7.1.5. Discussion

By deduction, only a high level of patient club functionality would therefore seem to be associated with a protective effect on facility performance. This is probably true because highly functional clubs

would mitigate the decline in FPS through maintaining a regular and consistent supply of essential drugs and supplies as well as providing an organisational structure to support NCD or HT and DM clinics at the facilities. However, this finding must be interpreted with caution as this study might not have been sufficiently powered to measure this effect or indeed the very weak association (p=0.09) is in fact a chance finding.

Patient club functionality does not appear to have a similar effect on QoCE as it has on FPS perhaps because again of inadequate study power. Only the lowly functionality group seems to be negatively associated with QoCE, but this is only marginal (p=0.05). Patient club functionality can affect provider-dependent service quality (QoCE) mainly through its effect in providing organisational support to non-clinical HT and DM services or activities during hectic or busy NCD clinics at the health facility and perhaps by freeing up health workers' time so that they are able to concentrate on the needs of the patients. Highly functional clubs could also ensure replenishment of patient monitoring equipment such as BP machines or glucometers, glucometer strips, batteries, or stationery.

Patient clubs are unique in the sense that they combine the attributes of both an activist group and an adherence club.

Adherence clubs have been well documented in improving the efficiency of HIV chronic care clinics in Africa (81). They also help chronic care clinics to become more efficient, accessible, convenient, patient-friendly, supportive, accommodating of the needs of working people, as well as decreasing the workload for the clinic (82). However, there are some challenges with adherence clubs, and these include issues to do with perceived stigma, perceived lack of support from club members or health facility staff, frustration, coercion, feeling of being punished, and laxity (85). Findings from exit interviews (in section 7.2) indicated that poor leadership and mishandling member's contributions may also be problematic. However, due to a lack of a clear policy from the Uganda MoH, there is no accountable structure within which they can thrive and be supported at both district and lower levels. Interestingly, even with this ad-hoc and semi-structured "patient club model", I have found that highly functional or even moderately functional patients clubs may improve both service readiness and service quality, but their effect is probably stronger on service readiness than on service quality in this setting.

7.1.6. Conclusion

Optimising the functionality of patient clubs seems to help in achieving sustainability and durability of HT and DM services at primary care setting in the absence of other programme or research support.

7.2. The views of key stakeholders about the intervention, its implementation, and its sustainability of the HT and DM intervention between 2016 and 2020

7.2.1. Abstract

As part of the MeLoHanD study, I thought it was important to capture some qualitative data on supervision and implementation of the HT and DM intervention between 2016 and 2020. Such data were to be collected through guided stakeholder study-exit meetings and key informant interviews with selected health facility (HF) leaders from different facility levels and districts or Uganda ministry of health (MoH) officials.

Data were collected by notetaking and/or voice recording. Data were transcribed and a simple thematic analysis was done to capture stakeholders' views on probed topics. No thematic analysis software was used. Responses to the probed topics were explored until saturation was achieved. All coded data was also reviewed by a senior social scientist for cross validation to assess bias of the coders.

These stakeholders reported that key achievements of the intervention included an increase in the number of HT and DM patients utilising the facilities particularly at lower-level units and improved skills among health workers (HWs). Active screening and creation of NCD clinics were also reported. The main challenges faced included inadequate supplies of essential drugs, poor storage capacity, political interference, misrepresentation of patient clubs and overwhelming patient numbers at NCD clinics at some units. Some HWs needed re-training and district-wide awareness on HT and DM was still low.

To achieve better sustainability at district level or lower unit level, stakeholders felt that there is a need for specialist mentorship or on-job training, more investment in creating public awareness on HT and DM through regular outreaches and improvement of unit staffing levels at lower units. At the national level, an increase in the NCD-related health budget, more consistent monitoring and support supervision, incentivising outreaches, sensitization of the community and stakeholders on the realities of HT and DM management and empowering lower units, for example HCIIs, to decongest higher units were suggested.

7.2.2. Introduction

As part of the work involved with this PhD project, some of the soft information about the intervention and the period after, as seen through the eyes of our key stakeholders intrigued me. I thought it was important to capture this qualitative data through guided stakeholder study-exit meetings and key informant interviews with selected health facility (HF) leaders by facility level as well as the district or

Uganda ministry of Health (MoH) officials. This was restricted to the post intervention period (2016-2020) and included four aspects: (i) support supervision for HT and DM management at the different levels, (ii) what had been achieved by the intervention, (iii) what had been the barriers (or challenges) that hampered intervention efforts, and (iv) what can be done to sustain or improve the intervention going forward.

7.2.3. Methodology

A group discussion (GD) based on a topic guide, was conducted with health workers from health centres II (HCIIs) and III (HCIIIs) within Mpigi and Wakiso districts. The GD explored the views surrounding policy and sustainability at the different implementation levels. Topics discussed included integrated district support supervision or any HT- or DM-specific supervision, challenges faced, and positive achievements during implementation and after, how best to improve district supervision, suggestions for improvement, and scale-up of the intervention at the district level and sustainability of the intervention.

A sample of 12 participants (4 HWs from each HF level; 6HWs per district) that had participated in the intervention were purposively selected to take part. The GD was conducted using a participatory method (i.e., facilitated by a former intervention officer using participatory learning and action techniques), took 120 min and was voice recorded with permission from the participants.

Individual key informant interviews were also held to further investigate the issues explored during the GD with 25 participants (3 officials from Mpigi district offices, 4 officials from Wakiso district offices, 2 officials from the MoH, 6 officials from HCIII, 5 officials from HCII and 5 former intervention officers) (**Table 16**). A semi-structured topic guide was used which contained open-ended and suggested probing questions. Interviews were held in private rooms and each interview lasted 45-60 min with the aim of capturing views around policy and sustainability at the different implementation levels. The interviews were also voice-recorded with permission from the participants.

Main topics of the discussion included:

- How the HT and DM management support supervision was carried out from 2016 - 2020 without research support and how this could be sustained or improved.
- Achievements and challenges (or barriers) of the HT and DM intervention by level e.g., lower facility level (HCIIs and HCIIIs), HCIV and district level as well as the MoH level.
- Suggestions on which improvements could be prioritised without additional funding.

- Suggestions on which improvements should be prioritised if additional funding were to become available.

Data collection and coding

Data were collected by notetaking and/or voice recording. Data were transcribed and a simple thematic analysis was done to capture stakeholders' views. No thematic analysis software was used. All interviewers were research-experienced and referred to the interview guides for direction. All data was transcribed and coded by the study QC field worker that had been trained and experienced in carrying out both FDGs and IDIs. Responses to the probed topics were explored until saturation was achieved. All coded data was also reviewed by a senior social scientist for cross validation to assess bias of the coders.

Table 16 - Roles of the key informant respondents interviewed

District or Ministry office /position	Respondent	Role(s) of respondent within health facility or district office or ministry
Mpigi DHO	Resp1	Plan and coordinate HT and DM activities in all district health facilities
	Resp2	Ensure availability of drugs, equipment, and focal persons.
	Resp3	Assess and ensure HT and DM patients are fully assessed. Also, to refer those who cannot be managed at that particular facility to higher facilities
Wakiso DHO	Resp1	Supervision of HT and DM activities, quantifying and supplying drugs and equipment.
	Resp2	Mentoring and supporting health workers
	Resp3	Quantification of supplies.
	Resp4	Participated in implementation of the study while still in charge at a HCIV and currently as the acting DHO involved in advocacy and continuity of intervention activities.
Ministry of Health	Resp1	Coordinate efforts towards the control of HT and DM. Formulating policy. Support supervision of HFs and general mobilization for HT and DM related activities Lobbying for resources for the prevention of HT and DM.
	Resp2	Patient group strengthening Institutional memory
HCIII	Resp1	Registering and reviewing patients
	Resp2	Counselling
	Resp3	Giving advice on lifestyle, nutrition, and screening, taking clinical measurements (e.g., Blood pressure, Height, Weight, Height) and recording in registers.
	Resp4	Carrying out HT and DM related outreaches.
	Resp5	Supervising other intervention facilities within the district to mentor and find better ways of implementing the intervention.
	Resp6	Doing monthly reports, following up on patients, supervising health workers and reminding them of their role in the intervention.
HCII	Resp1 & 4	Screening, prescribing, administering medicines and lifestyle advise to patients.
	Resp2, 3 & 5	Screening, prescribing, carrying out outreaches and referring those patients whose BPs are high and those with diabetes.
	Resp1	Establishment of intervention sites and mobilization for the intervention.

Former intervention officers	Resp2	Training health workers.
	Resp3	Visiting health units and supplying basic equipment and drugs.
	Resp4	Assist the formation of patient clubs in 2016 towards the end of the study to sustain treatment.
	Resp5	Advisory role.

7.2.4. Results

How HT and DM management support supervision was carried out over this period without research support and how can it be sustained or improved?

Integrated district supervision and HT and DM specific supervision.

Health workers reported that integrated supervision was done quarterly or occasionally by district staff. However, one respondent said,

"…Between 2016 and 2019, it was also occasionally done by a non-governmental organisation like Mildmay International…" (Resp1; HCIII, Wakiso)

On the other hand, HT and DM services supervision as part of the integrated supervision was also reported to have been done quarterly or occasionally over the same period. However, that same participant reported that

"...We have never received any support supervision after the end of the trial…" (Resp1; HCIII, Wakiso)

All respondents said that lower-level facilities never had HT and DM service specific supervision visits for DM and HT between 2016 and 2019. One said that they only receive this kind of supervision when there is a sponsor or research study related to HIV or NCDs. Another respondent said that they lack resources for specific HT and DM supervision and that they therefore incorporate this in an integrated supervision (i.e., integration of the supervision of several different service components at HFs e.g., routine general facility inspection with specific services such as mother and child (MCH) health services, HT and DM services and HIV care services etc..).

Benefits associated with the supervision system after 2016

Participants listed several benefits that supervision by district officials brought about: it helped them to understand what happened at the facility and this enabled them to make necessary improvements locally. Secondly, they gained additional knowledge about HT and DM case management and documentation. Thirdly, unlike before, they were able to use supervision reports and lobby the Uganda ministry of health (MoH) to increase the allocation of specific HT and DM drugs. The fourth benefit was that it was also a way of monitoring and supporting staff in different aspects of HT and DM care by the supervisors, which improved their relationship. The fifth benefit was that it improved stock management at lower-level facilities. In addition to that, lower-level facilities were able to treat HT and DM to an extent which was not the case before.

Challenges associated with the supervision system

The main challenges faced during the district supervision of HT and DM services was the lack of funds leading to lack of fuel and cars for transport. This had also led to difficulties in actively following up lost patients. Additionally, little time was allocated to health facilities during supervision visits and sometimes supervisors did not show up at all, it was also reported that supervisors did not visit as frequently as they were supposed to and that some supervisors went to the facilities as a formality and did not conduct a thorough supervision. Lack of implementation or follow through of what health facilities suggested to supervisors during support supervision was also mentioned as a challenge and consequently health workers had stopped airing out their problems during supervision since no effort was done to solve them. Another challenge reported was that the districts were large, and supervisors could not cover all the facilities in the allocated time, given the many activities to be done within a limited time. There was less time allocated for HT and DM supervision as one health worker from Mpigi summed it up,

> ***"When the supervisors come it's like they are just doing it just for formality. They never give us enough time. For example, they come for just a few minutes to do integrated supervision hence missing out on so many important aspects due to the limited time allocated. HFs have stopped airing out their problems during supervision since the very same supervisors keep coming back without making any effort to address the problems." (Resp4, Mpigi HCIV)***

The quantity and quality of the HT and DM supervision

To improve the quality and quantity of the district supervision of HT and DM services, participants mentioned the following strategies:

- Provision of adequate resources, for example, fuel and allowances
- Better planning, for example, route planning, using fewer cars more efficiently
- Provision or improvement of HT and DM supervision tools within the integrated support supervision

Suggestions for improving district supervision of HT and DM services, as proposed by stakeholders

- Increasing facilitation for supervisors to be able to reach facilities in remote areas e.g., by providing fuel or vehicles
- Providing guidelines for the lower-level supervisors and ensuring that they visit the facilities on specific clinic days
- Increasing the time allocated to supervising specific health facilities if necessary.
- Disintegrating the supervisions: there are a lot of things that cannot be fully covered using the integrated approach so there is need to have disease or programme specific or targeted supervisions looking at every aspect of a disease or programme separately in order to wholistically improve the execution
- Carrying out more frequent supervision visits to health facilities

Positive achievements of the intervention

The HT and DM intervention at primary care facilities was generally seen as a big relief to higher-level health units (i.e., hospitals and HCIVs) which were overwhelmed by uncomplicated cases. Some participants revealed that there is now better consideration of HT and DM drug orders by the MoH. Equipment such as weighing scales, blood pressure machines etc., which had been supplied prior to 2016 by the intervention had helped improve the screening and management of HT and DM. It was also mentioned that active screening is now being done and this has led to the early diagnosis of conditions which has improved people's wellbeing, hence an increased number of people presenting to the facilities for treatment.

Similarly, patients at lower-level health facilities were happy that HT and DM services have been extended to them and so they don’t have to move far to access services, and this has improved their livelihood and attitude towards the management of their conditions.

Creation of patient clubs or associations helped patients to contribute money to the buying of essential HT and DM drugs and some equipment. The patients have also gained the ability to do self-care through these clubs. Through capacity building or training, health workers at lower units had improved their knowledge and skills in the management of HT and DM. Health workers have started to include HT and DM related messages in the routine health education talks hence raising awareness

among the community. They had also improved their record keeping and documentation through use of the intervention-introduced NCD registers.
The village health teams (VHTs) were also sensitized. And lastly there was the establishment of a referral mechanism for HT and DM.

Challenges of the intervention at the district or ministry level

There was lack of proper storage capacity for essential drugs and supplies, and oftentimes drugs stocked out. It was reported that this mostly affected those patients who were not able to contribute to buying drugs through the patient club, leading them to, for example, experience uncontrolled BP levels.
There was also lack of adequate support and physical infrastructure to hold the NCD clinics at some health units and thus no continuity of the intervention. There were also stock outs of some essential HT and DM equipment like glucometers and the breakdown of existing ones without replacements, which affected screening efforts.
The lack of capacity building or training of some health workers in the management of HT and DM after 2016 was another challenge. Some of them said they developed a low morale due to fear of the new intervention while others expected incentives. There was also a limited number of available staff at some HFs and are often overwhelmed by the big numbers of patients that present on NCD clinic days. The quality of care given to the patients is sometimes affected by the absenteeism of some of the health workers on those NCD clinic days.
Some patient leaders and health workers seem to have viewed patient clubs as a money-making venture and had mismanaged the money contributed by the patients, while some local politicians discouraged patients from contributing money to the clubs because they were not knowledgeable about the intervention. There was still a lack of information on the intervention within the districts and HT and DM services were still not provided at some of the non-intervention units as these units did not implement the HT and DM intervention previously.
The pre-printed NCD patient registers got used up and were not replenished which disrupted record keeping. Also, some health workers had seen the extra documentation as additional work.
Absence of support supervision and oversight from the HCIV level made coordination of lower-level support supervision difficult and awareness of the intervention remained low in the community.

Suggestions for improvement and scale up of the intervention

At local level

The participants suggested the following activities to improve the situation: visits from specialists for mentorship and in-service training at lower level, having an adequate budget to invest in human resource, creation of awareness of HT and DM, improved supervision at the health units, improved drug supply especially first line drugs to all facilities and provision of additional equipment. All these were perceived as ways to implement the services better and to scale them up. Additionally, they mentioned setting up a district level association of the facility-based patient clubs, as well as clear governing policies and structure for the patient clubs at various levels. Identifying an active and interested district focal person who would do support supervision at the HFs was thought to be key. Training of health workers to manage HT and DM and enhancing infrastructure like tents to provide better space at HFs was recommended. Additionally, carrying out outreaches for HT and DM that would bring services nearer to the people. A cost effectiveness study to generate evidence that such an approach works as well as the consequent mobilisation of resources for scale up were also recommended. Lastly, participants suggested that stakeholders at all levels needed to be involved in the intervention and their terms of reference clearly laid out.

At national level

The participants mentioned the following as ways to improve the intervention better: logistical support to enhance supervision and monitoring, as well as lobbying for more resources through re-engaging with the MoH on the supply of more HT and DM drugs as well as physical and non-physical supervision of HT and DM activities. They also mentioned approval of national funding for the facilitation of outreaches by giving incentives, sensitization of communities and stakeholders, health education, development of IEC materials, standardizing refresher trainings, empowerment of patient groups by creating guidelines, empowerment of HCIIs to manage and maintain treatment for HT and DM and budgeting for lower HFs to decongest higher HFs. Furthermore, supply of basic HT and DM drugs and equipment, promotion of early diagnosis and emphasizing the need for referrals were also included.

Suggestions on which improvements should be prioritised without need for additional funding

They emphasized that they would encourage documentation at health units to improve the supply of drugs through national medical supplies stores (NMS) and strengthening of leadership at the MoH, district and at HF level. They also mentioned health promotion, continuation of patient clubs for patient empowerment and increasing community awareness through prioritizing HT and DM in mass communication and IEC messages. They further stated that more health workers should be trained on

job since some get transferred. They added that improving efficiency within the facility by ensuring that the required equipment works as well as doing screening at all entry points of the health unit to boost the number of patients attending the NCD clinic. This could have the added benefit of making an individual's patient club contributions much less. In addition to that they would encourage consultations within the facility, for example, between staff from maternity, HIV and HT and DM services as well as strengthen the integration of services at the health facility level. The participants also mentioned continuing to actively lobby among philanthropists or well-wishers, MoH and donor funders as one of the ways to sustain the intervention with little or no external funds.

Suggestions on which improvements should be prioritised if additional funding were to become available.

At local level

Firstly, participating stakeholders recommended the creation of awareness and health promotion through health education and use of VHTs in the community and at health facilities. Secondly, they suggested intensifying screening, early diagnosis, and management of HT and DM and conducting HT and DM outreaches. Additionally, purchasing additional essential equipment and drugs, and procurement of basic commodities or supplies e.g., batteries that the MoH through the national medical stores (NMS) cannot supply. Thirdly, they recommended further capacity building at health centres including training of the health workers and also orientation of the VHTs on the signs and symptoms of HT and DM to enhance early detection of these diseases within the community. Lastly, putting up an adequate physical infrastructure for NCD or HT and DM clinics.

At the national level:

Stakeholders within the MoH suggested an increase in the national and MoH budgets for the HT and DM components and equipment like medicines and laboratory supplies, training health workers and their trainers, improved staffing, community sensitization through use of IEC materials, radio, and TV advertisements plus revision of HT and DM management guidelines to include management at HCII level to screen, diagnose, treat, and refer. Furthermore, improving HF infrastructure, improving the regular supply of basic drugs and equipment, and enabling HCIIs get HT and DM first line drugs.

Additional comments

Respondents reported that patient clubs sometimes experienced internal conflicts related to the money they had pooled together so there is need to have a clear guideline and a national policy for

patient clubs going forward. The respondents also stated that the MoH provide simple treatment protocols to follow so that HT and DM can be managed at HCIIs or even at community level. They further said that nursing assistants particularly at lower-level units should be phased out more gradually and not abruptly. And lastly, it was reported that many of the HWs that had earlier on viewed the intervention as additional work came to appreciate it later.

7.2.5. Conclusion

In conclusion, stakeholders suggested that in order to improve the quantity and quality of HT and DM services supervision there is need to: i) provide adequate resources, for example, fuel and allowances; ii) better planning, for example, route planning, using fewer cars more efficiently and, iii) to provide improved HT and DM supervision tools within the integrated support supervision. Stakeholders also reported that the main achievements included a general increase in the number of HT and DM patients seen and utilization of HT and DM services at most health facilities, better skills and increased turn up of patients at the lower units which had served only a few HT and DM patients in the past. Active screening and creation of NCD clinics was also reported. The main challenges faced included inadequate essential drug supplies, poor storage capacity, political interference and misrepresentation of patient clubs and the overwhelming number of HT and DM patients on clinic days at some units. Some health workers needed re-training, and district-wide public awareness of HT and DM was still low.

For better sustainability at district level or lower unit level, there is need for specialist mentorship or on-job training, more investment in creating awareness on HT and DM through regular outreaches and improvement of unit staffing levels at lower units. At the national level, an increase in the HT and DM-related health budget was suggested, as well as more consistent monitoring and support supervision, incentivising outreaches, sensitization of the community and stakeholders on the realities of HT and DM management, formulation of clear guidelines and a national policy for patient clubs and empowering lower units such as HCIIs to treat uncomplicated HT and DM so that higher level facilities could be decongested.

Chapter 8: General Discussion

8.1. Work that led to this PhD research

In 2013, as part of the EACDRP we conducted a cross-sectional survey in a stratified random sample of 28 urban and rural Ugandan HFs to document the burden of selected chronic diseases by analysing service statistics, service availability and service readiness using a modified WHO SARA questionnaire as well as a clinical knowledge test in health workers (this was the same test that was also used in the trial and now in this PhD research). We found that among adult outpatient visits at hospitals, 33% were for chronic diseases including HIV infection and NCDs versus 14% and 4% at medium-sized and small health centres respectively. Many HFs lacked guidelines, diagnostic equipment, and essential medicines for primary management of chronic diseases; training and reporting systems were weak. Lower-level facilities routinely referred patients with uncomplicated hypertension and diabetes. HIV services accounted for most chronic disease visits and their quality was stronger than for NCD services. Systems were weaker in lower-level HFs while non-doctor clinicians and nurses lacked knowledge of and experience in NCD care (4). Similar findings were also reported from Tanzania (21).

Between 2014 and 2016, the EACDRP cluster randomised trial and later its evaluation was conducted in Uganda and Tanzania. In Uganda, it involved the stepped-wedge delivery of a comprehensive intervention package initially to 19 of 38 lower-level intervention facilities and 6 higher level referral facilities that received the package regardless. That package included 10 major elements that broadly included: training of health workers on management of HT and DM, supply of basic essential equipment, supply of essential drugs for HT and DM, support for active screening for HT and DM, improving documentation e.g., through NCD registers, patient cards, and regular support supervision. Findings from this intervention showed that at intervention health facilities the mean performance score on service availability and readiness (a combination of the facility inspection score and HW knowledge on HT and DM) doubled that at control facilities (81 vs 40. P<0.001). With regards to service quality, 95% of the intervention facilities were scored as having adequately good quality of care or better compared to only 8% of the controls (p<0.001) (1).

8.2. Findings from Chapter 5

In this study, I explored the post-trial sustainability of the highly effective HT and DM intervention described above, that had been introduced during the EACDRP cluster randomised trial. In my study, conducted in 2020 I focussed on the 19 primary care facilities that comprised the original intervention

arm and on 3 of the 6 referral facilities that had also received the intervention during the trial. I compared i) their performance in terms of health worker knowledge, service availability and readiness (SAR), and ii) the patient quality-of-care and experience (QoCE) with the levels seen in 2016.
I found that the mean aggregate facility performance (FPS) in 2020 was lower than in 2016: 70.2 (95%CI= 66.0-74.5) vs. 74.8 (95%CI=71.3-78.3), respectively with no evidence of a significant difference (p=0.18). There was a decline in mean scores of 4 of SAR elements: *the availability of essential equipment, availability of essential drugs, and utilisation of HT and DM treatment services and preventive services*. Only the *quality of records* remained high and even improved slightly (p=0.001).

Overall, health worker knowledge was well preserved, and knowledge scores were similar across all facility levels whether by subject matter or the 3 disease case scenario questions. This indicates that over the post-trial period of 4 years, despite any decay or shortcomings in support supervision or motivation or even underutilisation of the facility; the HT and DM case management competence of HWs were largely sustained. Only 66% of HWs interviewed in 2020 took part in the assessment in 2016 which suggests that HT and DM related knowledge among new staff members was also adequate. This finding was also reinforced by a similar finding on adequate quality of care and experience which remained unchanged over this same period.
Despite the decline in most of the elements of service availability and readiness over the period 2016-2020, there was no evidence of difference in overall facility performance owing to the strong performance of HWs on the clinical knowledge test. Of the five constituent elements of SAR only the quality of records was preserved while the utilisation of HT and DM services and evidence of preventive activities declined most strongly. The availability of essential drugs and to a lesser extent the availability of essential equipment and consumables also declined, but less steeply. This suggests that the support obtained from functional patient clubs may have alleviated the performance decline to some extent, through the replenishment of consumables, repair or replacement of simple equipment and the direct purchase of essential medicines. However, with regards to the availability of essential medicines, the worst performing HFs scored <2 points out of possible 10 in 2020, indicating that some HFs were more severely impacted by inconsistent drug supplies than others, and also had little to no patient club support.
The utilisation of primary care services at public facilities usually reflects the availability of essential medicines and other consumables (59-61), and therefore the observed decline in utilisation was expected. This decline is most likely also a result of a reduction in screening efforts, consistent with my finding that preventive activities in 2020 occurred much less frequently than in 2016. This in turn implies that only a few new HT and DM cases were actively detected and put into HT and DM care.

Overall facility performance was negatively affected by rural or urban HF location relative to a peri-urban one (p<0.01). The association with patient club functionality (p=0.05) and facility level (p=0.08) was borderline. None of them affected facility performance independently despite a weak association with patient club functionality (0.09). My findings are reminiscent of a recent study from southern Nigeria which found that service readiness increased with the presence of some power sources (electricity, generators, batteries and solar), but was lower among lower-level units that did not have this support. Travel time to headquarters and rural facilities significantly also reduced indices of equipment availability ($p < 0.05$) (62). My findings differ from these with regards to the urban health facility location, which in Uganda I speculate may be due to an intervening local administrative level at the municipality or local town council that usually distorts the district office's direct influence. A district health officer or their team may not exercise the same direct supervisory oversight and authority over those units within a semi-autonomous local municipality as those outside because these usually report to the local municipality health officer instead. This gap often leads to poor district support in terms of consistent supervisory oversight and timely medical supplies or replenishments especially where the municipality or local authority administration is weak. Public health facilities in urban areas are often poorly utilised as urban-dwelling patients have more health care options such as services from commercial drug shops and private clinics (64). Public HFs in Uganda are also generally shunned because of inconsistent drug supplies, health worker absenteeism and poor overall supervision (65). However, these findings on the rural/urban negative association should be interpreted with caution as this association did not hold in univariate (p=0.10) and final adjusted models (p=0.23).

I did not assess the effect of electricity or power sources on facility performance in this study which could have been interesting. However, lower-level facilities in Uganda have at least one power source from either solar panels or public electricity (63). The availability and functionality of the solar equipment or electricity system lies in the docket of the parent district; however, district location was not found to affect facility performance but was found to be an independent predictor of service quality instead.

Quality-of-care and experience declined slightly to 8.7 (95%CI=8.4-9.1) in 2020 vs 9.5 (95%CI=9.1-9.9) in 2016 (p=0.02) while the proportion of *adequate* quality care also declined slightly to 88.2% from 98.5% respectively, but with no evidence of significance (p=0.20). External support (p=0.02) patient club functionality (p=0.05) and the HF's parent district (p=0.08) showed strong to borderline associations with this decline but only parent district affected it independently (p=0.02). The influence

of district support for provider-dependent quality of care and service readiness has been well documented above. Factors that influence the provider- or health system-dependent service quality actually received by patients can be broadly classified as either provider-related or environment-related (86). I mainly looked at the environment-related factors because provider-related elements such as health worker knowledge or competence were a measure of service readiness.

A U-shaped relationship between service quality and patient volume has been previously described in a service quality assessment study from Ethiopia which indicated that service quality increases until a peak patient volume of 90 patients per day and then decreases (66). Whereas I did not measure patient volume directly as related to service quality, nonetheless I did measure service utilisation under facility performance which had dropped in 2020 to less than half of that observed in 2016 (8 vs 3-points; p>0.001). It can be argued that service utilisation in 2020 was only about half of that seen when the intervention had its peak optimisation in 2016. This might explain my mixed findings that while the proportion of health facilities with adequate quality of care did not seem to decline (p=0.20), there was strong evidence that the overall mean quality of care reduced by 1.8-points (p=0.02). I would speculate that indeed some HFs had in fact optimised and also reached their peak patient volume thresholds with a subsequent dip in service quality thereafter. While other HFs might still be optimising or re-optimising service quality below their patient volume thresholds currently.
Regarding sustainability of an intervention, external support from organisations such as NGOs or CBOs that may support parallel health services like HIV services, and patient club support is what comes closest to providing some form of funding stability. This may be obtained directly through provision of essential medical supplies or just a knock-on effect from support to a parallel service. For example, a support organisation that provides health worker incentives such as additional allowances or offers to cover the cost of locum health workers to facilitate the parallel service it supports, directly reduces the overall workload freeing up some of the health workers so that they can cover other services. This also boosts overall facility staff morale and enthusiasm. It may also de-incentivise absenteeism or weekly duty rotations in the longer run. Furthermore, the effect of a parent district on service quality cannot be understated as it persisted even after controlling for all other factors. Wakiso district was found to have 1.2-point higher increase in mean QoCE than Mpigi (p=0.02), this association appeared to be stronger after controlling for all other factors. Wakiso district geographically encircles the capital city of Uganda, Kampala, and as such benefits from the better road network that radiates from the capital city in a variety of directions. This has the double effect of ensuring quicker and more regular replenishment of essential medical supplies to most of Wakiso district as well as more regular support

supervision due to easier access to remote district HFs. However, this could also be a chance finding as logistical support to HT AND DM services did not seem to differ that much between the two districts.

While there was strong evidence for a decline from 2016 to 2020 in the availability of functional essential equipment (with scores reducing from 7.6 to 4.6; p<0.001) and essential medicines (8.3 to 3.7; p<0.001) service quality seemed to hold, indicating that it was probably more dependent on non-logistical elements like clinical competence or service supervision. Again, here health worker knowledge was preserved so clinical competence does not seem to be the main factor for a decline in service quality. Service support through district-led support supervision was probably more critical to this. From the study-exit meetings described in chapter 7, health workers at all HF levels indicated that there was a noticeable decline in both the quantity and quality of support supervision particularly for HT and DM services since the end of the intervention trial. Among the issues they suggested were transport difficulties, lack of incentives or timely allowances, and poor feedback. They also felt that supervisory teams did not give the process enough time and due to the integrated nature of the supervision some services like maternal and child health or HIV services were prioritised over others including the HT and DM services. They also reported little-to-no district-led HT and DM specific supervision to have been performed between 2016 and 2020.

8.3. Findings from chapter 6

Findings from this chapter involved new concepts in healthcare evaluation and sustainability assessment, but even though there are few studies with related findings from sub-Saharan Africa, I am nonetheless very happy to have contributed to this body of work in some small way.
Interventions on non-communicable diseases (NCDs) are increasingly implemented and evaluated in sub-Saharan Africa, but little is known about their medium to long term sustainability beyond the end of the research funding. Following the highly effective EACDRP trial that concluded in 2016, this study aimed to assess the sustainability of the post-trial effects of the original intervention in Uganda 4 years later.
My study aimed to assess their current capacity and practice (post-trial) to sustain ongoing intervention activities for HT and DM care in 2020. Through a cross sectional survey, health worker (HW) normalization within 4 pre-defined domains *(i.e., cognitive participation, coherence collective action and reflexive monitoring or adaptation*) was documented as well as 8 pre-defined domains for intervention sustainability *(i.e., organisational capacity, local environment, funding stability, partnerships, communication, evaluation, adaptation, and strategic planning)*, using standard tools.

Overall normalization strength was adequate at 4 (IQR: 3.8, 4.2) of a possible 5 with no evidence of association with HF level (p=0.40); *cognitive participation* and *reflexive monitoring* were strongest at >4 across all HF levels. All HF levels were also weak (<4) on *collective action* and *coherence*; with HCIIs faring strongest on *collective action* at 3.9 (IQR: 3.6, 4.0) while HCIVs were strongest on *coherence* at 3.8 (IQR: 3.5, 4.0). Only *collective action* was substantially stronger at HCIIs than at HCIIIs and HCIVs (p=0.002), although still only 44% of HCIIs achieved adequate strength (≥4) (87).

Regarding the sub-optimal domains, lower-level primary care units had gaps in HW knowledge (coherence) while higher-level units showed gaps in teamwork (collective action). These findings correlate quite well with findings from chapter 5 as relates to the HW clinical knowledge scores. Higher level units are probably more exposed to HT and DM patients than lower-level units and additionally the Uganda public health delivery structure is such that the level of in-service support and mentorship is better at higher levels as more competent, or specialist staff can be found there (**Table *1***). However, the sub-optimal findings indicate that that support was perhaps not quite adequate. This also ties in quite well with what was reported in the study-exit interviews in chapter 7. Of the 4 normalization domains, only collective action differed across health facility level (p<0.01) with lower-level units showing greater strength. The reasons for this are less clear but the observation may reflect that the necessity to act in a united fashion is particularly strong for small teams. Also having weekly shifts for a small team of 1 or 2 staff is less tenable at lower units with more services and higher patient volumes. Higher level units usually have more staff per service but that does not necessarily guarantee teamwork as some staff use this opportunity to absent themselves periodically, knowing that there will always be someone else to cover them.

All facility levels showed good strength with regards to cognitive participation which indicates that HWs internalised the intervention aims and processes, and to reflexive monitoring indicating an ability to adapt their work to the dwindling financial support after the end of the funding received during the trial. Furthermore, normalisation may occur during the course of an intervention project with regards to some but not all newly introduced activities and procedures (16). A South African study that examined implementation factors around provider-initiated HIV testing and counselling (PITC) after 2 years of embedding using the normalisation process model found that normalization was promoted by strong senior leadership, implementation support, appropriate accountability mechanisms, an intervention design that adapted to needs and practices, positive staff and patient perceptions, and a responsive organisational context (42). However, challenges were found in operational weaknesses, patient communication gaps and inadequate training (42). This is not very different from my findings which showed that HW coherence (sense-making) and collective action (teamwork) as the main

weakness at all levels while reflexive monitoring (or intervention appraisal) and cognitive participation (HW buy-in) were the strengths. Similarly, another recent South African study on PITC implementation found that the main facilitator was the participation of all healthcare workers although they also faced barriers such as a lack of workspace and under-appreciation (75). Another study that explored how solar electrification to off-grid rural primary health care facilities in Ghana and Uganda could improve the availability of maternal and child health services using normalization process theory constructs found that implementation with improved outcomes was associated with stakeholder engagement activities to promote internalization (or sense-making), provision of materials and information to encourage participation, and establishment of relationships to support integration (or teamwork). Barriers to achieving outcomes were also largely operational such as drug stockouts, lack of transportation and poor amenities as I have also found out in chapter 7.

Regarding intervention sustainability, this was suboptimal overall at 3.1 [IQR 1.9,4.1]) of a possible 7 with weak scores on *funding stability* (2.0), supportive *partnerships* (2.2), and *strategic planning* (2.6). Domain differences by facility level were significant for *environmental support* (p=0.02) and *capacity in organisation* (p=0.01). Adequate strength at a mean cut-off of ≥5 did not differ by facility level for any domain. These findings also tie in well with findings from chapters 5 and 7 regarding the need for external support and perhaps the role played by patient club functionality in forestalling some of the decline in service readiness and service quality respectively. Organisation of patients into an active and functional club directly improves funding stability as buffer drugs or other critical supplies are made available. Additionally, organisation of clinics and patient management at the health facility can be assisted by patient leaders or peer supporters. Overall, strategic planning was generally low and weakly differed by HF level (p=0.08). It was lower for HCIIs and HCIVs (i.e., with less than 30% having adequate strength compared to 44% for HCIIIs). This finding is surprising as one would expect better strategic planning at HCIVs where more health services are offered. I would speculate that perhaps the rigorous way maternal and child services, and HIV chronic care services at HCIIIs are managed or prioritised by the district (or even the MoH) might be playing a part in the way long term planning for other services like HT and DM services is also perceived.
Also, lower-level primary care units and HCIIs in particular were weak in organisational capacity, evaluation capacity and long-term strategic planning. This again might point to the few staff at this level being overwhelmed or an organisational culture that does not see staff at this level as handling high burden or high value services such as maternity services. Thus, the need for service evaluation or

even long-term planning is not really felt at HCIIs, and perhaps supervisory feedback from the HCIV health sub-district or district authorities is also insufficiently given.

There is a paucity of PSAT findings within the sub-Saharan African context. However, one study from Malaysia used the PSAT to evaluate HT and DM sustainability within the context of disease programmes. This study found that whereas other domains were optimal with mean scores ≥4 only funding stability had a low mean score of 3.8 (79). Whereas that study was set within specific HT and DM disease programmes in a middle-income setting; it still demonstrates that the domain scores, I observed were not peculiar. It is also important to note that as one US study found; participants' reported PSAT scores about perceived sustainability capacity did not directly align with previously reported perceptions about PSAT domain importance or modifiability and so it might be important to identify potential barriers and enablers influencing program (or intervention) sustainability during the planning phase of an intervention (80). A Spanish study (88) that implemented a school-based, peer-led, social-marketing intervention that encouraged healthy diet and physical activity, in low socioeconomic adolescents and examined change in PSAT over time at two periods during intervention implementation: end of the first year and end of the second year found that strategic planning (4.43 +/- 1.98) and funding stability (4.38 +/- 1) were considered deficient domains, and at the end of the second year, these domains had improved by 1.67 points (p =0.043) and 0.59 points (p = 0.159), respectively. The funding stability increase was not significant, and the sustainability capacity final score was 5.93 +/- 1.13 (88). The sustainability capacity assessment earlier on in the intervention had allowed its improvement and perhaps even in the long term. It is unclear whether the modest sustainability capacity (3.1 [IQR 1.9,4.1]) that I found will continue to be maintained in the long term. It will be important to identify ways in which the HFs can maintain or establish new partnerships. Developing solutions to the lack of funding support will also be essential. The creation of patient clubs might be one option. The organisation of patients into an active and functional club directly impacts funding stability because drugs or other critical supplies would become available. Additionally, the organisational structure of clinics and the patient management at HFs can benefit from patient leaders or peer supporters.

Lastly, regarding overall sustainability capacity, these components are not linear or independent but have dynamic relationships with each other and other domains within the sustainability framework of an intervention or even my postulated conceptual framework (Figure 5), such as the organisational context, or local context or social norms (34). Also, It is not always necessary to maintain all original intervention activities for sustainability of the intervention to occur (16). Similarly, normalization is not

irreversible, and practices can be de-normalised over time as well (34). Also, both standard tools used in this assessment performed well in this setting. Validation in qualitative study methods is a measure of how reliable the tool used is in eliciting a true response in any given population. The normalization tool used was of fair reliability (Cronbach's α=0.6) while the sustainability assessment tool (PSAT) was of good-to-excellent reliability (Cronbach's α=0.9).

8.4. Findings from chapter 7

The effect of patient club functionality was strongest (p=0.05) when adjusted for mean FPS scores in 2016 but this association was diluted in the final model (p=0.09) which indicates that the patient club functionality may still be a weak confounder of facility performance. Only high patient club functionality could be associated with a protective effect on facility performance. Patient club functionality does not seem to have the same effect on QoCE. Only low functionality seems to be negatively associated with QoCE, but this is only marginal (p=0.05) in the initial models and negated in the final adjusted model (p=0.87). As hinted to in section 8.4, patient clubs have a direct influence on logistical aspects such as the availability of essential drugs and basic equipment or consumables which would directly affect facility performance or service readiness. The association with service quality is less obvious. However, both the better consistency in essential supplies and the better clinic organisational context that a patient club brings to work within a health facility, through its patient peer support and patient leadership, are believed to be at play. Patient clubs are also unique in the sense that they combine the attributes of both an activist group with those of an adherence club. Adherence clubs have been well documented in improving the efficiency of HIV chronic care clinics in Africa (81). Such as providing a more efficient, accessible, convenient, patient-friendly, supportive, accommodative space for the needs of working people, and decreasing the workload for the clinic (82). However, there are some challenges with adherence clubs, and these include issues to do with perceived stigma, perceived lack of support from club members or health facility staff, frustration, coercion, feeling of being punished, and laxity (85). Findings from study-exit interviews (in section 7.2) indicated that poor leadership and mishandling member's contributions may also be problematic. The lack of a clear guiding policy from the Uganda MoH means that there is no accountable structure within which they can thrive and be supported at both district and lower levels. However, even with this ad-hoc and semi-structured or pragmatic "patient club model", I have found that highly functional or even moderately functional patients clubs may improve service readiness and perhaps to a lesser extent service quality in this setting.

Regarding the study-exit and key informant interviews, stakeholders suggested that in order to improve the quantity and quality of HT and DM services supervision there is need to: i) provide adequate resources, for example, fuel and allowances; ii) better planning, for example, route planning, using fewer cars more efficiently and, iii) to provide improved HT and DM supervision tools within the integrated support supervision. They also felt that district management teams need to i) increase facilitation for supervisors to be able to reach facilities in remote areas e.g., by providing fuel or vehicles; ii) provide supervisory guidelines to lower-level supervisors; iii) increase the supervision time allocated to specific health facilities should the need arise and, iv) perhaps to dis-integrate the supervisions to allow more frequent and direct supervision of services that cannot be fully covered using the integrated model.

Stakeholders also reported that the main achievements of the intervention in the post-trial period 2016-2020, included a general increase in the number of HT and DM patients seen and utilization of HT and DM services at most health facilities, better skills and increased turn up of patients at the lower units which had served only a few HT and DM patients in the past. Active screening and creation of NCD clinics was also reported. The main challenges faced included inadequate essential drug supplies, poor storage capacity, political interference and misrepresentation of patient clubs, and an overwhelming number of HT and DM patients on clinic days at some units. Some health workers needed re-training and district-wide public awareness of HT and DM was still low.
For better sustainability at district level or lower unit level, there is need for specialist mentorship or on-job training, more investment in creating awareness on HT and DM through regular outreaches and improvement of unit staffing levels at lower units. At the national level, an increase in the NCD-related health budget was suggested, as well as more consistent monitoring and support supervision, incentivising outreaches, sensitization of the community and stakeholders on the realities of HT and DM management, formulation of clear guidelines and a national policy for patient clubs and empowering lower units such as HCIIs to treat uncomplicated HT and DM so that higher level facilities could be decongested.

8.5. Methodological strengths and challenges

Study design

This study was unique in the sense that it used two cross sectional surveys at different time points within the same health facilities and health worker and patient populations. This design holds some assumptions: that the average distribution of possibly confounding HW or patient characteristics was

constant or unchanging over this time-period. Four years were not long enough a time to lead to radical changes in the distribution of the variables that I assessed such as age, gender, HF level, functionality of the patient clubs, whether they received some external support, HF location (area), parent district or how HFs were randomised initially. Secondly, I was not able to collect data on service readiness and quality of care at additional time points between 2016 and 2020. I could therefore not assess whether the observed declines had occurred early on or later, and whether the decline followed a linear pattern or occurred at certain points in time. However, since there were no major changes in policy, infrastructure, or human resource or staff attrition in the assessed intervention facilities over this period; I can assume the deterioration occurred slowly.

Sampling and sample sizes

I achieved the necessary sample sizes to have adequate study power for all selected population samples and even where I did not achieve the required number e.g., for HWs for the clinical knowledge test due to covid-19 restrictions and related absenteeism in 2020, I still attained 91 (70%) out of the expected number of 131 HWs seen in 2016. The sample size of both health workers and patients in 2016 was fixed; therefore, my ability to increase the power of the study was limited. However, I sampled more patients in the 2020 survey so that I had reasonable power (>80%) to detect important changes in service readiness or quality of care.

Exposure measurement

Age and gender ratio did not particularly differ between the study populations for both HWs, and patients and the proportions observed were similar to what is expected in similar chronic care clinics. There was a difference in the proportions of HWs by facility level (p=0.001) mainly due to fewer HWs at HCIIs in 2016 (18% vs 28%) and yet more at HCIIIs (60% vs 47%) which could mean that HCIIs were over-represented or HCIIIs were under-represented in the 2020 HWs sample. However, since almost equal numbers at each facility level were selected in 2020; this disparity might be explained by the fewer number of health workers that were available for the survey in 2020 due to covid-19 restrictions or absenteeism.

HF level did not change much between 2016 and 2020; there were a few facilities that were upgraded towards the end of 2019, such as Mpigi HCIV which was elevated to a district hospital, but the upgrades were mostly in name only and the budgetary or resource allocation had not kicked in by the time our surveys were done. Patient club functionality was assessed as 3-levels of functionality (i.e., high, moderate, and low or none) over this period by the presence or absence of certain club activity

functions or attributes in 2020. External support was assessed by using a proxy question whether or not the HF received essential drugs or other medical supplies from a source outside the three established sources of the national medical stores (NMS) or district (MoH) or the patient club. Area, district and pairing at randomisation were physical or geographical attributes and therefore remained unchanged over this period.

Outcome measurements

I used summary measures such as mean, medians or proportions to illustrate any differences between the time points. Considerations were made for both within cluster and between cluster effects at analysis. For example, I used methods similar to those used in assessing cluster matched pairs in cluster randomised trials with each HF in 2020 being treated as paired with its observation in 2016 for the clinical knowledge test, and the service quality (QoCE) assessment. This allowed me to account for clustering when assessing potential confounding subsequently.

A random effects Tobit model was used for the QoCE analysis owing to the top-level ceiling of a maximum QoCE score of 10. Using ordinary linear regression would have led to a biased estimate of standard errors.

Overall, interpretation of results should be made with caution as effect for this study design does not indicate causality but rather an association with the outcome.

Strengths

The EACDRP intervention trial had provided a strong and effective HT and DM service intervention with fully optimised elements against which it was easy to study a potential decline or changes in service readiness or service quality.

Also, because record keeping had been optimised in the intervention HFs of the original trial, data quality was high both in 2016 and 2020. Routine data collection tools and records e.g., patient registers that were developed and validated previously; provided valuable and straightforward source documents to compare similar attributes of the intervention at the two evaluation points.

Identical and standardised study tools were used at both time points. Care was taken to ensure that study teams recruited were different from the original intervention team to avoid potential bias. Also, I recruited staff from the original evaluation team, and this helped to ensure comparability of the data sets generated at the two time points.

The 2020 survey was conducted 4 years after the end of the intervention trial. This interval was sufficiently long to study any possible decline in service readiness and service quality that may have occurred due to the discontinuation of research funding.

This MeLoHanD project is one of very few studies examining factors associated with health worker normalization and intervention sustainability among health facilities in SSA. I attempted to use a quantitative approach to answer a qualitative question on sustainability from the perceptions of primary stakeholders or those involved in ensuring the fidelity of this intervention. This approach helped me quantify the various contributory domains as well as easily identify areas of strength or weakness.

My study used standardised and previously validated tools to explore aspects of normalization and intervention sustainability. Overall, these tools showed fair-to-excellent reliability. This means that we can have confidence in the findings as a true reflection of this study population.

Limitations

I cannot ascertain whether any residual effect of the intervention was in fact optimised after 2016, and whether any positive post-intervention effects could be attributed to that residual optimisation rather than the intervention durability. However, the 4-year gap between assessments is likely to be long enough to provide an adequate wash-out period for any post-trial residual effects.

Both health workers and patients who participated in the MeLoHanD study represent clusters of participants: it can be assumed that individuals from the same HF were likely to be more similar with regards to the variables that we determined in this study than they were compared to their counterparts from other HFs. In the analysis, we accounted for this by using methods used for cluster matched pairs in cluster randomised trials for each HF with design-appropriate survey cross tabulation and regression models.

The sustainability capacity assessment was a one-time point cross sectional assessment as a similar assessment was not done at the end of the trial in 2016. Due to lack of this temporal comparison, there is reason to wonder about reverse causality – does current sustainability capacity say more about future capacity (post-intervention) or the previous intervention's residual capacity? However, the post-intervention period was about 4 years which should provide adequate time for washout of any temporary benefits attributable to the previous intervention. Any benefits still present are probably genuinely institutionalised and should continue to do so well into the future.

Response to scalar score-based questions is usually subjective and prone to respondents choosing the middle ground or null (i.e., between the extreme scores) or a regression to the mean. Additionally,

respondents may choose what is perceived as socially desirable or acceptable to them. These were both minimised by allowing for a lack of responses (e.g., if participants responded that a question was 'not applicable' or that they did not know the answer). Also, most respondents whether HWs or patients had interacted with the intervention for long which minimised the chance of difference between what they observed and what really prevails (83) (84). There was also a reasonable degree of heterogeneity in the way different types of respondents were selected, when possible, e.g., for the PSAT - patient leaders, HWs and district health office or MoH administrators were interviewed. Lastly, whereas there was no direct reliability assessment of data collectors or checking consistency of coded responses, the study did have a dedicated field worker to review filled paper questionnaires while in the field before data entry. Additionally, the electronic tablets used had some in-built consistency and validation checks that were tested and refined during the pilot study and just after.

8.6. Generalisability

These findings are generalisable to intervention or trial planning within primary care setting in LMICs like Uganda (89). Management for DM and HT in particular at lower levels of care such as at HCIIIs and HCIIs has only recently been started and the overall structure is still just forming. This situation prevails across most of the rest of sub-Saharan Africa (16) and service readiness for HT and DM services is still not adequate or just growing (21, 90).

8.7. On-going work and future research

I am aware of one recently concluded study in Malaysia that used the PSAT to evaluate HT and DM sustainability within the context of disease programmes (79). This study applied the mixed-method approach using the PSAT to assess the eight domains for program sustainability combined with 5 open-ended questions. The survey was administered to key leaders from the district health offices in Malaysia. Descriptive statistics and thematic analysis were conducted and a total of 80 key leaders responded to the survey. Overall, seven domains scored an average of ≥ 4 with the highest domain mean scores for 4.5 (communications) and 4.4 (organizational capacity). The lowest mean score domain was 3.8 (funding stability). The overall mean sustainability score was 4.2. The open-ended responses revealed challenges faced by department heads, including implementation difficulties, factors impeding the planning of the HT and DM program for sustainability, lack of financial resources, lack of human resources, and support for staff training which are largely consistent with the scores of each domain.

I am not aware of any study that has used the normalization tool within the NCD or health system context in Africa. It would be interesting perhaps if both tools are used elsewhere in similar settings to those that prevail in a LMIC or sub-Saharan Africa. Triangulation with the more mundane quantitative methods has helped provide me with a more complete picture to the durability or sustainability of an HT and DM intervention. Using this approach and reproducing similar findings in a similar setting would add validity to this mixed methods approach.

Another interesting finding of this MeLoHanD study is the background effect of patient clubs within the NCD or chronic care context. A randomised trial within these same facilities or similar districts in Uganda or other similar primary care setting to test the effect of optimising patient clubs would also be of research interest to me.

Additional research in a prospective cohort setting studying how these elements of service readiness and service quality and domains of normalization or programme sustainability change in real time over the medium to long term may help answer questions about exact optimisation of the components of an HT and DM intervention trial or programme both within the trial or programme setting and post-hoc.

8.8. Conclusion

From the facility performance assessment, logistical challenges in drug supplies and replenishment of basic HT and DM monitoring equipment have re-surfaced over time, however despite these, training inputs i.e., health worker knowledge and the availability of guidelines and quality of records were preserved over a 3–4-year period, perhaps indicating no real need for frequent refresher training if resources are few or unavailable. I would recommend continued refresher training every 2-3 years nonetheless, perhaps only longer at 3–4-year intervals if funds are not easily available until most of the other elements of service readiness are re-optimised.

The quality of patient care has reduced slightly but also appeared preserved across all primary care levels despite the logistical challenges. This could be a consequence of the preserved health worker knowledge and continued observance of clinical guidelines. However, despite this, service utilisation at lower-level units was still adversely affected, which probably is an indication that the logistical challenges e.g., inconsistent essential HT and DM drug supplies were far-reaching.

Reviewing the sustainability and normalization frameworks, strengths for sustainability capacity lies in adaptation, local environmental (or within facility) support and strong communication linkages while the weaknesses are in funding stability, fostering partnerships, strategic (long term) planning and organisational capacity particularly in the areas of implementor coherence and collective action. This

suggests that routinised in-service training with dedicated support supervision rather than more frequent refresher training on HT and DM management could be more effective at strengthening both organisational and normalization strength.

Overall, sustainability or durability of an HT and DM intervention in similar primary care settings may remain feasible despite glaring deficiencies in funding stability or logistical support that are usually provided for within a research-driven setting. However, this can only be possible if the post-intervention planning incorporates a strong investment in instilling a clear sense of implementor roles and the need for good collective action in strengthening organisational (or within facility) capacity. All in tandem with emphasizing the importance of building partnerships at the local community level or higher and nested within a clear medium to long term strategic plan.

Chapter 9: References

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