

## **Appendix – 1: Published papers from this thesis**

## The Scope of Cell Phones in Diabetes Management in Developing Country Health Care Settings

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### Abstract

Diabetes has emerged as a major public health concern in developing nations. Health systems in most developing countries are yet to integrate effective prevention and control programs for diabetes into routine health care services. Given the inadequate human resources and underfunctioning health systems, we need novel and innovative approaches to combat diabetes in developing-country settings. In this regard, the tremendous advances in telecommunication technology, particularly cell phones, can be harnessed to improve diabetes care. Cell phones could serve as a tool for collecting information on surveillance, service delivery, evidence-based care, management, and supply systems pertaining to diabetes from primary care settings in addition to providing health messages as part of diabetes education. As a screening/diagnostic tool for diabetes, cell phones can aid the health workers in undertaking screening and diagnostic and follow-up care for diabetes in the community. Cell phones are also capable of acting as a vehicle for continuing medical education; a decision support system for evidence-based management; and a tool for patient education, self-management, and compliance. However, for widespread use, we need robust evaluations of cell phone applications in existing practices and appropriate interventions in diabetes.

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### Introduction

Diabetes is currently a major public health problem in developing nations. Of the 284.6 million people with diabetes globally, more than 70% live in low- and middle-income countries.<sup>1</sup> Large populous nations such as China and India are witnessing an increase in the burden of diabetes with rapid urbanization and aging of the population.<sup>1</sup> Countries in the African and Middle-Eastern nations also have a growing burden of diabetes. It is estimated that global expenditures on diabetes will be at least \$316 billion in 2010 and at least

\$490 billion in 2030.<sup>1</sup> The monetary value associated with disability and loss of life as a result of diabetes itself and its related complications account for the largest economic burden.<sup>1</sup>

Changing to a healthy diet and increasing physical activity has the potential to prevent more than 60% of new-onset diabetes.<sup>1</sup> Similarly, a healthy diet, maintaining a normal weight, regular physical activity, and not smoking are central to diabetes management to maintain optimal

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**Abbreviations:** (CME) continuing medical education, (EHR) electronic health records, (ID) international dollars, (IT) information technology, (SMS) short messaging service

**Keywords:** cell phones, decision support system, diabetes, mHealth, wireless

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blood glucose, lipid, and blood pressure levels in order to reduce the risk of future complications, particularly cardiovascular diseases.<sup>1</sup> Even in low-resource settings, there is much that can be done to detect undiagnosed cases from the community and provide care and support that will produce and sustain the desired improvements in the health of persons with diabetes. However, public health systems in most developing countries are yet to integrate effective prevention and control programs for diabetes into routine health care services. This brings into focus the tremendous advances in telecommunication technology, which can be harnessed to improve diabetes care. In order to combat the increasing burden of diabetes and its consequences, innovative approaches are needed. The scope of cell phones as a multipurpose portable device for use by both health care providers and patients for diabetes care is discussed in this article.

### Importance of Cell Phones in Health Care

The versatility and high levels of accessibility of mobile phone technologies provide enormous potential for novel uses to promote health globally (termed mHealth within the broader eHealth movement). The American Medical Informatics Association Global Partnership Program, the 2008 Rockefeller Foundation month-long conference on eHealth, and the creation of the mHealth Alliance by the United Nations all indicate the extent of importance of mHealth. Two-thirds of all mobile phone users live in low-income and low-middle-income nations,<sup>2</sup> and the user base is growing fast. This easy-to-use technology is widely accessed by the illiterate and poor.<sup>3</sup> Mobile phones and other mobile technologies require fewer infrastructures than other eHealth systems,<sup>4</sup> making them a promising investment for developing countries to strengthen and transform their weak health systems<sup>5</sup> and to overcome health care worker shortages.<sup>3</sup> Further, many features [e.g., short messaging service (SMS), digital camera, capability of running custom software applications] of cell phone technology can strengthen health services through removing physical barriers to care and service delivery and by improving choice, evidence-based care, management, supply systems, and communication. In addition, it is likely that high-end cell phone (smartphone) prices will continue to drop and capabilities continue to increase (e.g., more sophisticated 3G networks capable of fast Internet connectivity), making them highly cost-effective.

### Cell Phones in Diabetes Care

Similar to many other chronic diseases, diabetes requires multidisciplinary care, and patients require education

on self-care such as blood-sugar monitoring, adherence to recommendations on diet, exercise, and regular foot inspection. A growing body of evidence suggests that diabetes-management programs need an information technology (IT) backbone in order to be effective.<sup>6</sup> From a health system perspective, high-quality data on disease trends, cost, and quality of care are vital to developing, monitoring, and evaluating diabetes prevention and control programs. Increasing the computing power of high-end cell phones, i.e., smartphones, and the rollout of 3G and 4G networks have a positive impact on increasing the access to the Internet in developing countries, particularly in rural areas. This low-cost communication platform is capable of addressing the data requirements of the health system and continued care for people with diabetes as well. The benefits from the application of cell phones in diabetes care falls into three domains: benefits for the health system, benefits for physicians, and benefits for patients (Table 1). A description of each of these domains is discussed here.

#### Benefits to the Health System from the Application of Cell Phones in Health Care

##### Development of Diabetes Registries

There has been much interest in using information services to systematically collect and manage an individual's or population's health care records in electronic form, i.e., electronic health records (EHR) in order to reduce medical errors and improve quality of care and promote evidence-based medicine. These systems are resource intensive due to the huge investment required for procuring and maintaining computer hardware and networking. However, Internet-capable smartphones can host a limited, basic version of EHR in selected health facilities in

**Table 1.**  
**Application of Cell Phones in Diabetes Care**

Domains	Application of cell phones
Health system	<ul style="list-style-type: none"> <li>• Development of real-time diabetes registries</li> <li>• Screening (targeted) of undiagnosed diabetes at primary health care settings</li> <li>• Health promotion messages using SMS</li> <li>• Promoting evidence-based management through decision-support software applications</li> <li>• Integrating laboratory/diagnostic applications</li> <li>• Remote patient monitoring</li> </ul>
Physicians	<ul style="list-style-type: none"> <li>• Tool for CME</li> <li>• Medical reference</li> </ul>
Patients	<ul style="list-style-type: none"> <li>• Patient education</li> <li>• Tool for self-management and reminders for drug intake and follow-up visits</li> </ul>

developing countries at minimal cost. Such smartphone-based diabetes registries improve diabetes control programs in a number of ways. Data from these facilities will provide long-term tracking of patient data, trends in prescription/management and quality of care, and surveillance data. Unlike paper-based systems, a smartphone-based system can act as a real-time information system, providing high-quality data for planning and monitoring diabetes control programs. A schematic diagram on the architecture of a cellphone-based health information system for diabetes is shown in Figure 1.

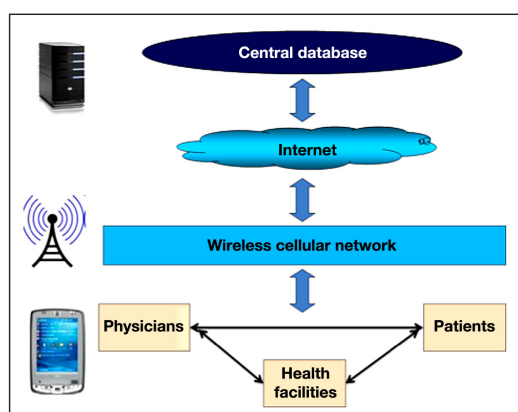


Figure 1. Schematic of the architecture of a cellphone-based health information system for diabetes.

#### Use of Cell Phones in Screening of Undiagnosed Diabetes

Undiagnosed diabetes accounted for 70–85% of those with diabetes in studies from Africa and 71% in India.<sup>7</sup> Early detection and treatment could help reduce the burden of complications due to diabetes.<sup>1</sup> There are several simple, noninvasive clinical risk score tools available for screening to identify people at high risk of diabetes in the Indian,<sup>8–10</sup> Chinese,<sup>11</sup> and Thai<sup>12</sup> populations. These clinical risk scores utilize noninvasive parameters for computing clinical risk. Custom-made software applications that run on mobile phones can help health workers to compute the risk scores to predict subjects with diabetes or those at high risk for developing diabetes. Mobile phones with integrated glucometers are available in the market.<sup>13,14</sup> Interpretation of these screening systems can facilitate a targeted screening approach, which can cut costs tremendously. For example, the health workers can initially screen individuals using the mobile phone, and those predicted to have diabetes

or at high risk for diabetes can undergo glucometer screening in the next step. In addition to screening individuals, integrating the screening information from the mobile phone by synchronizing it to the health management information system will help in patient tracking and generating diabetes incidence data in low- and middle-income countries. Such a stepwise approach could also help reduce costs of screening where large populations are involved.<sup>15</sup>

#### Cell Phones as a Medium for Information Dissemination

Traditional mass awareness programs rely on newspapers, television, or radio programs. Cell phones, being ubiquitous and portable, are an alternate medium for propagating simple messages on understanding of the signs and symptoms, risk factors, long-term complications, and ways to live with diabetes. Short messaging services can be used effectively for this purpose. Many telecommunication operators and handset manufacturers offer SMS in regional languages. For illiterate groups, voice and picture messaging are alternate options.

Another application of cell phones is in computing calorie consumption, which is often a difficult task. Several mobile phone applications are already on the market that help people with diabetes to make healthier meal choices with information on carbohydrates, portion size, and food labels.<sup>16</sup> The challenge will be in making this application affordable and accessible, particularly among those with a low level of education.

#### Use of Cell Phones in Supporting Evidence-Based Management

Management of diabetes revolves around maintaining optimal control of blood pressure, lipids, and glucose to defined targets. However, in most developing-country settings, a wide gap exists between practice recommendations and delivery of diabetes care. For example, several reports from India have highlighted the suboptimal use of various evidence-based drugs (angiotensin-converting enzyme inhibitors, statins, and hypoglycemic medications) at all levels of care.<sup>17–20</sup> Similarly, the Diabcare-China surveys that compared the differences in subject characteristics, glycemic control, diabetes complications, and treatment between 1998 and 2006 in persons with type 2 diabetes in China has highlighted the large gap between guidelines and their actual use.<sup>21</sup> These facts highlight the importance of decision support systems to facilitate evidence-based medicine and improve the quality of care. Quinn and colleagues<sup>22</sup> carried out a pilot trial to examine the health care provider's adherence to prescribing guidelines using a cell-phone-based

diabetes management tool. The results from this study were encouraging, as it facilitated treatment decisions, provided organized data, and reduced logbook review time for analyzing patient data trends. Evidence from effectiveness trials are required to assess the effect size on glycemic control of subjects with diabetes. Furthermore, if found successful, such cell-phone-based decision support systems could help nonphysician health workers in managing uncomplicated cases of diabetes in developing countries where severe shortages of trained physicians is a constraint.

#### Cell Phones and Laboratory/Diagnostic Applications

Historically, rural areas in developing countries have been deprived of laboratory facilities and expensive manpower such as physicians, thereby seriously affecting access to diabetes care. Bluetooth-enabled glucometers integrated into cell phones is a newer innovation. As discussed earlier, health workers in developing-country settings could use such novel diagnostic tools at the community level for screening and detecting people with undiagnosed diabetes. Because this method reduces the dependence on laboratory facilities for diagnosis, the outreach of diabetes care can be improved even through nonphysician health workers.

Another innovation is the application of cell phone cameras. Digital mobile eye fundus camera for screening of persons with type 2 diabetes mellitus was introduced in the Finnish county of South Ostrobothnia. This study showed feasibility of covering fundus examination in 87% of individuals with diabetes in their nearest health center in a short timeframe.<sup>23</sup> In developing-country settings, health workers could be trained to examine these pictures to identify changes due to diabetic retinopathy. Alternatively, picture messages can be sent to physicians for assessments and management.

#### Remote Monitoring

Remote monitoring is another application for cell phones in diabetes care.<sup>14,24</sup> Rami and associates<sup>24</sup> evaluated the feasibility of a telemedical support program and its effect on glycemic control in adolescents with type 1 diabetes mellitus. Patients sent their daily data (date, time, blood glucose, insulin dosage) via mobile phone to a central server, and diabetologists sent back their advice via SMS once a week. Glycemic control improved during the telemedical phase compared to the control phase in which the participants used a paper diary for daily monitoring.

Logan and coworkers,<sup>25</sup> in another similar study with a before-and-after design, assessed the effect of remote monitoring of uncontrolled ambulatory hypertension in 233 patients. The remote diabetes monitoring system comprised a Bluetooth-enabled home blood pressure monitor, a mobile phone to receive and transmit data, and a central server for data processing. In this pilot study, 24 h ambulatory blood pressure fell significantly. The participants also felt the system was acceptable and effective.

Cell phone applications can also help in remote monitoring of difficult carbohydrate counting. Diabetes Interactive Diary is a novel program designed to be used on a mobile phone.<sup>26</sup> This application facilitates the communication between a dietitian and diabetes subjects, particularly in type 1 diabetes, by using a SMS so that the dietitian can monitor glycemic control and suggest insulin doses that correspond directly with the amount of carbohydrate consumed.<sup>26</sup> Clinical trial data on effectiveness of this tool are yet to be published.

#### *Benefits to Physicians from the Application of Cell Phones in Health Care*

Clinical guidelines and advice and alerts for physicians can be easily delivered through cell phones to stay informed about recent developments.<sup>27</sup> This information could complement continuing medical education (CME). There are several cell phone applications currently available for CME: Skyscape CME STAT, MedPage Today, and QuantiaMD. For example, Skyscape, a medical information service provider, offers CME through its Web site Skyscape CME STAT. Registered account holders of CME STAT will receive CME activities on any platform mobile device, personal digital assistant, smartphone, or laptop. A CME article (e.g., articles by experts in the field, news briefs and published journal articles, and reports from conferences and medical meetings) on specialty subjects can be chosen, which is followed by a set of multiple-choice questions. Such services have the potential to provide convenient and widespread availability of CME programs.

Medical reference is another domain where cell phone application could provide solutions for information-intensive clinical practice. For example, Epocrates, an online medical reference company, provides drug reference for clinicians through a mobile platform that is reported to be reducing medical errors and saving time in pharmacy-related queries.<sup>27,28</sup>

### **Benefits to Patients from the Application of Cell Phones in Health Care**

Patient education and self-management are important components of good diabetes care. Simple-to-follow and always-with-you information will have the maximum influence on subjects with diabetes to make positive choices on diet, physical activity, and compliance to therapy. Cell phones can host software applications that are programmed to provide encouraging messages to remind them of adherence to medication, food intake, physical activity information, and more.

A systematic review that evaluated the evidence on the impact of cell phone interventions for persons with diabetes in improving health outcomes has found that cell phones were useful tools for not only providing general information on diabetes and weight reduction, but also for providing educational intervention and support tailored to an individual care plan.<sup>29</sup> The care plan includes monitoring and advice based on individual blood sugar measurements, medications, insulin dose information, diet, weight, and physical activities.<sup>29</sup> Most of these studies relied on SMS and voice calls as tools for providing these services. For example, one study compared two groups of individuals with diabetes in which one group was requested to input their blood glucose levels weekly for 3 months to a Web site using their cell phone.<sup>30</sup> This group received weekly optimal recommendations for 3 months using SMS while the other group received usual care. Participants in the intervention group had a significant mean change in the 2 h postmeal glucose level while those in the control group had no difference.<sup>30</sup>

### **Potential Opportunities of Business-Driven Sustainable Solution**

Advances in nanotechnology and biomedical engineering will transform cell phones into an integrated point-of-care solution. As cell phones morph into low-cost smartphones and software applications develop high capabilities that can incorporate advanced functionalities for handling complex disease diagnostic and management solutions at low cost, business opportunities will arise for telecom network providers. In a competitive market, the cost of mobile phone solutions for diabetes will come down, enabling the poor and rural populations to access such services. Government regulation to enforce compliance by the industry to various standards (e.g., context-specific practice guidelines and data standards for interoperability) are essential to avoid the chaotic nature of these IT solutions in future.

### **Drawbacks of Cell Phone Solutions**

The major obstacle in scaling up of mHealth infrastructure is the lack of clear evidence of its benefits. The reasons include lack of well-designed randomized control trials, small size of studies, the quasi-experimental and pre-post design, and inadequate power to evaluate effectiveness and cost-effectiveness.<sup>31-33</sup> The small size of the display screen and keypad are other impediments. But advances in technology to produce low-cost, large display screens with touchpad capabilities could improve these bottlenecks in future.

### **Conclusion**

Cell phones offer exciting possibilities to serve as a tool for diabetes prevention and management in developing countries. Given the positive results so far from feasibility trials and the increasing uptake of mobile technologies, cell phones may improve existing practices and interventions in diabetes. However, effectiveness trials as well as evaluation of cost-effectiveness of this technology need to be carried out for providing robust evidence to scale this technology in the prevention and management of diabetes in developing countries.

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gOPINION  
EDITORIAL VIEWPOINT

## Role of Mobile Phone Technology in Tobacco Cessation Interventions

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The health benefits of tobacco cessation are well established [1]. Cessation is a key element within the World Health Organization's (WHO) MPOWER strategies (*M*onitoring tobacco consumption and the effectiveness of preventive measures; *P*rotect people from tobacco smoke; *O*ffer help to quit tobacco use; *W*arn about the dangers of tobacco; *E*nforce bans on tobacco advertising, promotion, and sponsorship; and *R*aise taxes on tobacco) that are intended to assist in the country-level implementation of WHO's Framework Convention for Tobacco Control guidelines. The potential impact of cessation interventions in low- and middle-income countries is considerable given the large numbers of tobacco users and relatively low quit rates when compared with high-income countries [2].

Traditional tobacco cessation programs include both population-based and individual strategies. Research evidence supports the effectiveness of clinic-based tobacco cessation interventions such as physician-delivered tobacco cessation advice [3], group therapy [4], individual counseling [5], self-help materials [6], telephone counseling [7], and nicotine replacement therapy [8]. However, these strategies are found to be resource-intensive, requiring dedicated professional support and participant adherence. In addition, these methods cover only a small group of the smoking population. Systematic reviews have identified community-based interven-

tions and mass media campaigns as an effective way to disseminate antitobacco messages to wider population groups and to reduce tobacco use, but these interventions need to be sustained to be effective, which can be costly [9,10]. Given the growing burden of the tobacco epidemic in the low- and middle-income countries, there is an urgent need for a cost-effective innovative communication media to deliver tobacco prevention and cessation services at the population level. This review aims to summarize the evidence on the effectiveness of mobile phone technology in tobacco cessation, the theoretical basis of mobile-based interventions, and the scope of mobile technology as a tool for population-based tobacco cessation interventions.

### THE REACH AND SCOPE OF MOBILE TECHNOLOGY FOR HEALTH IMPROVEMENT

Mobile phones became an integral part of daily life even in low-income nations. According to the International Telecommunication Union, there are close to 5 billion mobile phone subscriptions worldwide with over 70% of users residing in low- and middle-income countries and over 85% of the world's population is now covered by a commercial wireless signal [11].

Mobile phones support a number of communication functions. Voice and short message services

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(SMS) enable 2-way communication in real time or near-real time. Most mobile phones now have a built-in camera. Pictures and short-duration videos captured using mobile phone cameras can be downloaded to one's computer or transmitted to others. With the advancement of technology, storage and processing capabilities of mobile phones also have increased. The data in a mobile phone can be transmitted in a variety of forms, including text, numerical, graphic, audio, and video files. The introduction of smart phones has extended the scope of mobile phone from a simple communication device to the level of personal computers. In contrast to digital divide, which arguably limited the reach of computer and Internet-based health behavior interventions to upper socioeconomic groups, mobile phone use has been widely adopted across socioeconomic and demographic groups and appears greater among those populations most in need of these interventions [12,13]. Technical capabilities of mobile phones combined with its personal nature can reduce the barriers of communication and increase acceptance of phone-based health interventions.

Mobile phones are currently used for public health interventions in both developing and developed countries. Mobile health interventions in developing countries are focused primarily on communicable disease control interventions (e.g., human immunodeficiency virus, malaria) and maternal and child health initiatives. SMS have been used to raise health awareness. In developed countries, mobile health interventions have been attempted in much broader areas such as smoking cessation [14,15], diabetes education [16,17], patient follow-up in a primary-care setting [18], and chronic disease management [19,20]. It is likely that the use of mobile phones in health interventions will continue to grow as they become even more ubiquitous and as technological advances increase the number of applications and functions available.

#### EFFECTIVENESS OF INTERVENTIONS USING MOBILE TECHNOLOGY ON TOBACCO CESSATION

A recent Cochrane review on mobile phone technology for smoking cessation concluded that trials involving text message programs showed a significant increase in short-term self-reported quitting. When the data from the text message programs and combined Internet-mobile phone programs were pooled, statistically significant increases in both short- and long-term self-reported quitting

was observed [21]. However, there is a paucity of research studies in low- and middle-income countries on the feasibility, acceptability, and effectiveness of mobile phone-based interventions for smoking cessation.

Most studies on mobile-based tobacco-control interventions for smoking cessation were carried out in New Zealand, Norway, the United Kingdom, and the United States, ranging from small pilot and quasi-experimental studies [22-24] to randomized controlled trials [14,15,22,25,26] (Table 1). These studies used multiple methods for broadcasting smoking cessation messages—for cessation advice and motivational messages—using standard SMS, voice messages, interactive voice response functions, and mobile- and Internet-based message delivery. Some studies, which entirely relied on mobile technology, used standard text messages as the medium for broadcasting smoking cessation messages [14,15]. Advanced mobile functionalities such as video messages [22] and interactive voice response [25] along with the standard SMS have also been attempted for smoking cessation. Another study combined Internet and mobile technology along with pharmacotherapy—a nicotine replacement therapy [26].

Most of the randomized controlled trials of mobile-based smoking cessation were small pilot studies with very short follow-up periods [22,25,26]. But 2 randomized controlled trials, carried out by Rodgers *et al.* [15] in New Zealand and Free *et al.* [14] in the United Kingdom were well conducted and had a considerably larger sample size. These 2 trials were similar in their content as well as method of delivery. In both studies, people wanting to quit who owned a mobile phone were randomized to intervention and control arms. Apart from the regular personalized quit advice or motivational SMSs, both programs offered an interactive platform to the participants through a number of polls and quizzes. The novel "Quit Buddy" concept (which encouraged participants to text other trial participants) used in both trials provided an opportunity for social support [14,15]. In addition, the participants could request additional text messages on demand to help beat cravings. The New Zealand trial demonstrated a significant quit rate at 6 weeks in the intervention arm compared with quit rates in the control group (28% vs. 13%). The Smoking Cessation Support Delivered via Mobile Phone Text Messaging Trial (txt2stop Trial) demonstrated a similar relative benefit at 6 months (10.7% txt2stop vs. 4.9% control group).

Author (Year); Location	Summary of intervention	Sample size	Summary of intervention results
Rodgers et al. (2005); New Zealand [15]	Intervention group received regular, personalized text messages providing smoking cessation advice, support, and distraction (eg, general interest, sports, fashion, trivia, travel). Control group participants only received 1 text message every 2 weeks, which were unrelated to smoking cessation.	Intervention group: 832 Control group: 653	Statistically significant high quit rate at 6 weeks in the intervention group versus the control group (28% vs. 13%).
Brendtzen et al. (2007); Norway [25]	The intervention group received internet- and cell phone-based intervention for 54 weeks, consisting more than 400 contacts by e-mail, Web pages, interactive voice response, and SMS. The control group received a self-help booklet. Additionally, both groups were offered free NRT.	Intervention group: 197 Control group: 199	Participants in the intervention group reported clinically and statistically significantly higher repeated point abstinence rates than control participants did (22% vs. 13.1%). Improved adherence to NRT and a higher level of post-cessation self-efficacy were observed in the intervention group compared with in the control group.
Brendtzen et al. (2008); Norway [26]	Same as Brendtzen et al. (2007), but NRT was not offered to both the groups.	Intervention group: 144 Control group: 146	Participants in the intervention group reported clinically and statistically significantly higher repeated point abstinence rates than control participants did (20% vs. 7%).
Riley et al. (2008); United States [31,32]	Observational study was conducted among daily smokers on a college campus.	N = 31	46% abstinence rate in 6 weeks on biochemical verification.
Whittaker et al. (2008); New Zealand [27]	It was a pilot study to test the content as well as the feasibility of a mobile phone-based smoking cessation intervention. Participants received video and text messages for smoking cessation, over a period of 6 months.	Pre-testing: 41 Pilot study: 15	Pre-testing confirmed the importance of selecting "real" and "crucial" role models with believable stories, and animations for smoking cessation. Thirteen of 15 participants were available for follow-up and 5 participants (68%) stopped smoking during the program.
Zbikowski et al. (2008); United States [34]	An evaluation study was conducted among the participants who enrolled in the Free and Clear Quit For Life Program (a commercially available, integrated phone/Web program across the United States) between May 2006 and October 2007.	N = 11,143	Phone services were used more than Web services were. Women were more adherent to the overall program. Older smokers (526 years) and moderate smokers (13 to 20 cigarettes/day) used the services more than the others did. Thirty-day quit rates at the 6-month follow-up were 4.7% using responder analysis and 21% using intent-to-treat analysis.
Haug et al. (2009); Germany [23]	Participants were randomly allocated to 1 of 3 study groups: 1) control; 2) intervention with 1 weekly SMS feedback; 3) intervention with 3 weekly SMS feedbacks. Individualized SMS feedbacks were based on data from the baseline assessment, and a weekly SMS assessment of the stages of change according to the transtheoretical model. The control group received no intervention.	1 SMS group: 50 3 SMS group: 60 Control group: 64	No significant differences between the 3 study groups were observed in terms of examined smoking variables such as, for example, number of cigarettes smoked per day, 24-h quit attempt during study period. The acceptance of the program did not differ between the intervention groups and support intensity did not affect the acceptance of the program.

(continued on next page)

Author (year); location	Summary of intervention	Sample size	Summary of intervention results
Whittaker et al. (2011); New Zealand [22]	The intervention group received an automated package of video and text messages over 6 months that was tailored to self-selected quit date, role model, and timing of messages. Extra messages were available on demand to beat cravings and address lapses. The control group also set a quit date and received a general health video message sent to their phone every 2 weeks.	Intervention group: 110 Control group: 116	This study was not able to demonstrate a statistically significant effect of the complex video messaging mobile phone intervention compared with simple general health video messages via mobile phone.
Free et al. (2011); United Kingdom [14]	Intervention group received motivational and behavioral change text messages, while the control group received messages unrelated to smoking cessation.	Intervention group: 2,915 Control group: 2,885	Biochemically verified continuous abstinence at 6 months was significantly increased in the intervention group (10.7% in intervention group vs. 4.9% in the control group), and the same results were obtained in the intention-to-treat analysis (9% vs. 4%).

NRT, nicotine replacement therapy; SMS, short message services.

The Happy Ending Trial [26] in Norway involved a single fully automated, intense 1-year smoking cessation program delivered via both the Internet and the mobile phone. The intervention arm included e-mail reminders, educational SMS, interactive voice response messages, and Web-based tobacco cessation support. Nicotine replacement therapy was offered to participants in both intervention and control arms. The trial reported clinically and statistically significantly higher repeated point abstinence rates (22.3% vs. 13.1%), improved adherence to nicotine replacement therapy, and a higher level of post-cessation self-efficacy in the intervention group at 1, 3, 6, and 12 months after cessation. A later trial by the same research group, which included similar intervention components but did not include the provision of nicotine replacement therapy, reported a similar improvement in the quit rate (20% vs. 7%) at 1, 3, 6, and 12 months after cessation [25]. The results from both studies suggest that psychological support for smoking cessation can be effectively mediated through mobile- and Internet-based interventions.

Complex and individually tailored mobile phone interventions were found to be less effective in promoting cessation than generic, simple phone interventions [22,27]. Whittaker et al. [22] designed a theory-based intervention comprising an automated package of video and text messages over 6 months, which was tailored to self-selected quit date, role model, and timing of messages. Extra messages were also available on demand to beat cravings and to address lapses. However, this trial was not able to demonstrate a statistically significant effect of the complex video messaging mobile phone intervention compared with simple general health video messages via mobile phone.

Mobile phones provide the opportunity for incorporating user input-based tailoring of smoking cessation interventions, which could improve the acceptance of the intervention particularly among youngsters. This was attempted in a pilot trial carried out at the University of Greifswald in Germany [28]. Although the results were not promising, this may be due to the small number of participants. Further evaluations of this approach are required to assess the utility of this method.

It is important to assess the impact of mobile phone interventions on known socioeconomic status disparities in tobacco use. However, only a small number of studies have examined this. Haug

et al. [28] examined the effectiveness of a SMS-based intervention delivered to 33 socially deprived young adults from an institution for occupational rehabilitation in Germany delivered over 12 weeks. Participants could request SMS support whenever they suffered from withdrawal symptoms or cravings. Although none of the participants reported abstinence after the intervention, before-and-after comparisons revealed a reduction in the number of cigarettes smoked per day and an increase in risk perception. A mobile phone-based counseling intervention delivered to 20 patients infected with the human immunodeficiency virus at a primary care clinic in Texas over a 2-week period reported 75% abstinence from smoking at 2-week end-of-treatment [29].

#### HEALTH SYSTEM APPLICATIONS

The versatility and high levels of accessibility of mobile phone technologies provide enormous potential for their use in primary healthcare settings. The health workers at the community level can screen individuals for tobacco and other risk factors using the mobile phone-based applications in order to develop local databases in primary care settings. Such information could be invaluable for planning tobacco-control programs at the state/provincial and national levels.

#### SCALABILITY OF INTERVENTION

As a mode of wider dissemination of public health messages, SMS could be a cost-effective way to address a large group of the population, regardless of locations and personal characteristics. The ability to tailor messages to the target audience, real-time delivery of messages, and the ability to link the user with others for social support makes mobile phones an ideal tool for tobacco cessation interventions.

Evaluation of a small number of scaled-up interventions suggests that these may have a beneficial impact on tobacco cessation. For example, the Free and Clear Quit for Life Program is a commercially available, integrated phone/Web program that is widely available through quit lines, health plans, and employers across the United States. This telephonic smoking cessation program includes proactive phone-based counseling, an interactive Website, and printed quit guides. Evaluation of experience of 11,143 enrollees of Free and Clear Quit for Life Program between May 2006 and

October 2007 showed that participants used the phone services more than the Web services. Thirty-day quit rates at the 6-month follow-up were 41% using responder analysis and 21% using intent-to-treat analysis. Women and older smokers were more adherent to phone-based interventions [30].

#### BEHAVIOR CHANGE MECHANISM

The basis for many of the behavior change interventions in public health have been health behavior theories and models such as the Health Belief Model, Relapse Prevention, Theory of Planned Behavior, Social Cognitive Theory, the Transtheoretical Model, and Self-Regulation and Self-Determination Theory [31] (Table 2). Most of the mobile-based tobacco cessation interventions mentioned in this review have a theoretical basis for their intervention design. The theory of the Self-Regulation and Social Cognitive Behavioral Model are the basis for most of the interventions [15,22,25,26,32]. The Transtheoretical Model was used in interventions designed by Obermayer et al. [24] and Riley et al. [32] to adapt the content of the text messages to the preparation, action, and maintenance stages of the quit process. Transtheoretical Model-based messages were tailored to adapt to the high-risk situation and the stage of change. Two large randomized controlled trials of mobile SMS for smoking cessation did not cite any of the conventional behavioral theories to support their interventions [14,15].

Behavioral change theories are predominately linear and static in nature, which limits their ability to guide interventions that are dynamic and adaptive [31]. For example, the content and timing of mobile phone-based behavioral change interventions are mostly driven by a range of varying factors: (1) frequency, duration, and intensity of the target behavior; (2) socioenvironmental and psycho-physiological states of the individual; and (3) the effect of prior interventions on target behavior. Therefore, health behavior theories and models having dynamic, regulatory system components must be used to develop and explain such adaptive interventions delivered through mobile phones [30].

#### OPPORTUNITIES

Self-monitoring is an essential component of smoking cessation. It requires individuals to re-

<b>Table 2. Theories of behavioral change</b> <i>Health Belief Model (HBM)</i>	
<p>HBM is one of the first theories of health behavior developed in the 1950s. The model suggests that the likelihood of an individual taking action for a given health problem is based on the interaction among 4 key variables, they are:</p> <ol style="list-style-type: none"> <li>(1) Perceived threat, which consists of two components:           <ul style="list-style-type: none"> <li>• Perceived susceptibility: people believe they can get the ill effects of smoking</li> <li>• Perceived severity: people believe that the consequences of the ill effects are significant enough to try to avoid smoking</li> </ul> </li> <li>(2) Perceived benefits: people assess the positive consequences of adopting smoking cessation</li> <li>(3) Perceived barriers: people identify their personal barriers to tobacco cessation and explore ways to eliminate or reduce these barriers</li> <li>(4) Cue to action: events either bodily or environmental that motivate people to take action. For example, reminder cues for action in the form of incentives or reminder messages (SMS).</li> </ol>	<p><i>Social Cognitive Theory (SCT)</i></p> <p>This theory evolved from research on Social Learning Theory, which asserts that people learn not only from their own experiences, but also by observing the actions of others and the benefits of those actions. According to SCT, factors such as self-efficacy, individual goals, and outcome expectancies determine the behavior. SCT says each behavior witnessed (smoking behaviors or undesirable models) can change a person's way of thinking (Cognition). Similarly, the environment one is raised in may influence later behaviors (eg, ease of availability of tobacco products, absence of stringent antitobacco laws).</p> <p><i>Self-Determination Theory (SDT)</i></p> <p>According to this theory, maintenance of behaviors over time requires that people internalize values and skills for change, and that they experience self-determination. The theory further argues that by maximizing the regulator of health-related behaviors are more likely to be internalized, and behavior change will be better maintained.</p> <p><i>Self-Regulation Theory (SRT)</i></p> <p>According to this theory, a self-regulating person controls and manages his or her reactions and behavior to achieve goals despite changing conditions and priorities. Behavior and outcomes are aspects of self-regulation that we can observe, but there are always many implicit and unobservable influences such as the person's perceptions and emotional state.</p>
<p><i>Trans-theoretical Model (TTM)</i></p> <p>Also known "Stages of Change", the model was developed in the 1980s for smoking cessation. The model's fundamental premise is that behavior changes occur in 5 stages:</p> <ol style="list-style-type: none"> <li>(a) <i>Pre-contemplation</i>—not intending to quit smoking in a planned duration (say next 6 months)</li> <li>(b) <i>Contemplation</i>—intending to quit smoking in the next 6 months</li> <li>(c) <i>Preparation</i>—intending to quit; For smokers, this may involve a mental preparation for quitting. They may plan ahead by setting a quit date and marking it on the calendar. They may also tell others about their quit date so that they have some accountability from others.</li> <li>(d) <i>Action</i>—change in behavior. This is when the quit date arrives and the smoker stops smoking. If the action stage occurs and the behavior change is not maintained, then people fall back into a previous stage.</li> <li>(e) <i>Maintenance</i>—this is where one maintains the changed behavior (smoking cessation) and incorporates the new behavior as a way of life. <i>Theory of Planned Behavior (TPB)</i>: This theory explores the relationship among behavior and beliefs, attitudes, intentions, and perceived control. Behavioral intention is influenced by a person's attitude toward performing a behavior and by beliefs about whether individuals who are important to the person approve or disapprove of the behavior (subjective norm). The TPB includes "perceived behavioral control." For example, a smoker decides to quit smoking, but anticipates withdrawal symptoms. However, he or she is confident that by engaging in any other activities such as yoga or cycling will help in overcoming the withdrawal symptoms.</li> </ol>	<p><i>Social Cognitive Theory (SCT)</i></p> <p>This theory evolved from research on Social Learning Theory, which asserts that people learn not only from their own experiences, but also by observing the actions of others and the benefits of those actions. According to SCT, factors such as self-efficacy, individual goals, and outcome expectancies determine the behavior. SCT says each behavior witnessed (smoking behaviors or undesirable models) can change a person's way of thinking (Cognition). Similarly, the environment one is raised in may influence later behaviors (eg, ease of availability of tobacco products, absence of stringent antitobacco laws).</p> <p><i>Self-Determination Theory (SDT)</i></p> <p>According to this theory, maintenance of behaviors over time requires that people internalize values and skills for change, and that they experience self-determination. The theory further argues that by maximizing the regulator of health-related behaviors are more likely to be internalized, and behavior change will be better maintained.</p> <p><i>Self-Regulation Theory (SRT)</i></p> <p>According to this theory, a self-regulating person controls and manages his or her reactions and behavior to achieve goals despite changing conditions and priorities. Behavior and outcomes are aspects of self-regulation that we can observe, but there are always many implicit and unobservable influences such as the person's perceptions and emotional state.</p>

Adapted, with permission, from Davies M, Macdonald W. Health Promotion Theory. Maidenhead, United Kingdom: Open University Press; 2005.

cord their own smoking behavior patterns (e.g., number of cigarettes, frequency), time, place, activity, mood, and level of desire for smoking. Mobile phone applications for self-monitoring could be achieved by means of quickly self-documenting complex behaviors and using sensors to log real-time behaviors and physiological states influencing the smoking behavior of the individual. By integrating such real-time assessment and intervention, we may be able to deliver real-time tailoring of the intervention. For example, algorithms that make use of computing capabilities of mobile phones may be able to detect behavioral/biological patterns. For example, mobile phones with biosensors could identify one's smoking frequency, factors that warn of a smoking craving long before a person who is attempting to quit smoking has recognized it, and direct action to avoid or defuse the craving [33]. The technology for such developments has yet to evolve.

## CONCLUSIONS

Tobacco use is a major public health concern. Mobile phones appear to be a valuable tool for the delivery of smoking cessation interventions, even to historically hard-to-reach groups due to high penetration of mobile across all socioeconomic groups. Current evidence supports the short-term efficacy of mobile phone-based intervention in smoking cessation. More rigorous studies testing the long-term effects of mobile phone interventions are needed in both high- and low-income countries to establish their effectiveness. Further research is needed particularly in the developing world to assess both their cost and cost-effectiveness. It is important that future studies describe the likely mechanisms through which the mobile-based interventions work. In summary, the rapid advances in mobile technologies, continued growth in coverage of cellular networks could open up new opportunities for tobacco prevention and control.

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# Cardiovascular research in India: A perspective

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With cardiovascular disease (CVD) emerging as a major cause of mortality in India, clinical research in CVD is becoming increasingly important. There are several favorable factors that offer robust growth of clinical research infrastructure in India: well-established system of governance, a large investment in medical education infrastructure, growing interest in building capacity in clinical research, the presence of regulatory mechanisms governing clinical research, a large pharmaceutical industry, and a highly developed information technology and data processing infrastructure. However, the lack of trained research manpower, inadequate public spending on health, uneven distribution of health infrastructure, and the large prevalence of pretransitional diseases are major weakness in undertaking high-quality clinical research in CVD. Analysis of the contemporary scenario reveals that there are 3 important opportunities for clinical research in India: the need to identify low cost but cutting edge and context-specific interventions to address the health needs of India's large population, the potential for high-quality research, and the high degree of interest (domestically and internationally) in investing in clinical research education and infrastructure. (Am Heart J 2011;161:431-8.)

Clinical research is the cornerstone of efforts to develop and implement evidence-based policies that can improve the health of individuals and populations. With cardiovascular disease (CVD) emerging rapidly as a major cause of mortality in India, research to provide the base of evidence to combat this epidemic is urgently needed. However, CVD research output from India is miniscule when compared with that of Western nations with strong academic traditions and long-term economic stability. A systematic review of CVD research literature from 90 countries has shown that 82% of publications regarding CVD originate from countries in the upper economic tier, particularly North America and Europe.<sup>1</sup> Low- and middle-income countries such as India, on the other hand, contribute a small proportion (18%) of the world's CVD clinical research.<sup>1</sup> In addition, India's research output largely comprises small descriptive epidemiologic studies. Research related to health systems, health policies, and quality of care remains scanty.<sup>1</sup> Moreover, most of

the research output originates from a small number of large medical research institutions in India.<sup>2</sup>

Future projections regarding clinical research enterprise in India are highly optimistic. Indeed, in light of the country's large population and the burgeoning CVD epidemic, clinical research in India is likely to increase substantially. According to an estimate by McKinsey & Co, major global pharmaceutical companies alone will invest \$US1.5 billion in pharmaceutical-related research in India by 2010.<sup>3</sup> To understand current dynamics and what these projections portend for India, an in-depth review of unmet needs, disease burden, capacity (individual, institutional, and infrastructural), and the availability of funds to conduct research is needed. In this review, we discuss these issues, focusing on an evaluation of the strengths and weaknesses of the Indian clinical research enterprise and analyzing the needs and opportunities for conducting quality research capable of reducing the CVD burden in India.

## CVD in India: the scenario

Cardiovascular disease has reached epidemic proportions in India and is estimated to result in more than 3 million deaths each year.<sup>4-6</sup> Although CVD burden is high among Indian urban residents, in certain regions even in rural populations, CVD has emerged as the leading cause of death.<sup>7</sup> Estimates from the World Health Organization (WHO) show that by 2030, CVD will be the main cause of death throughout India as a whole, accounting for more than 35% of mortality cases. Compared with Western populations, CVD occurs at a relatively younger age in Indians with a higher rate of mortality.<sup>8,9</sup> These

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premature deaths due to heart disease, stroke, and diabetes are projected to increase cumulatively, and India's financial losses due to CVD are estimated at US \$237 billion for the period of 2005 to 2015.<sup>4</sup> Furthermore, because the majority of these deaths are premature, there is a substantial loss of lives during the peak productivity years as compared with other countries. The potentially productive years of life lost due to CVD among those aged 35 to 64 years was 9.2 million in 2000 and is expected to rise to 17.9 million by 2030—more than the losses predicted for China, Russia, the United States, Portugal, and South Africa combined (16.2 million).<sup>10</sup>

The prevalence of coronary heart disease has been reported to be between 6.5% and 13.2% in urban settings and between 1.6% and 7.4% in rural India.<sup>11</sup> Similarly, stroke prevalence is between 136 and 842/100,000 population in urban areas and between 143 and 165/100,000 population in rural areas.<sup>11</sup> Although self-reported surveys such as the National Family Health Survey-3 and World Health Survey suggest that wealthier persons have a higher prevalence of CVD risk factors such as diabetes<sup>12,13</sup> and obesity,<sup>12</sup> well-designed studies show that risk for myocardial infarction is higher by more than a factor of 2 among the uneducated, the undereducated, and the poor.<sup>8</sup> The differences observed between these national surveys and the regional surveys are largely due to low-risk factor awareness and control among the less educated and the poor. Individuals with low levels of education and low socioeconomic status and those from rural settings have a high prevalence of smoking. Furthermore, in certain settings such as worksites, a high prevalence of diabetes and hypertension has been observed among the less educated.<sup>14,15</sup>

In summary, CVD in the Indian population is characterized by 3 facets: (1) early occurrence (Indians acquire the disease at least 10 years earlier than their Western counterparts), (2) higher case fatality (a comparatively higher proportion die after acute coronary syndrome [ACS] as compared with Western populations), and (3) the occurrence of disease at lower-risk factor thresholds, particularly overweight and obesity.<sup>8,15</sup>

The profound social and economic transformations in the Indian population together with rapidly evolving demographic and epidemiologic transition have fueled the CVD epidemic in India. Since 1991, trade liberalization has increased access to and desirability of prepackaged and processed foods, and rising incomes have resulted in increased consumption of sugar, oil, milk, and animal products.<sup>16</sup> Similarly, urbanization and industrialization reduce the opportunities for physical activity. These changes have occurred in a relatively compressed time frame posing new challenges to the health system and requiring innovative solutions to reduce the CVD burden.

## What are the strengths and gaps of CVD research in India?

### Strengths

The potential strengths of clinical research in India include (1) a well-established system of governance, (2) a large investment in medical education infrastructure, (3) a growing interest for building capacity in clinical research, (4) the presence of regulatory mechanisms governing clinical research, (5) a large pharmaceutical industry, and (6) a highly developed information technology (IT) and data processing infrastructure.

**Governance.** India is the largest democracy in the world with a well-established judiciary. The Indian constitution affords citizens freedom of the press and freedom of speech and expression. Such democratic institutions have the potential to promote ethical conduct of clinical research, including protection of vulnerable populations such as children, women, and marginalized groups. The government has promoted health research through large funding bodies such as the Indian Council for Medical Research (ICMR), the Department of Science and Technology, and the Department of Biotechnology. These government bodies are actively involved in formulating, coordinating, and promoting biomedical research with the goal of reducing the total burden of disease and promoting the health and well-being of the population. Furthermore, chronic disease prevention is a high policy priority of the government, as evidenced by the recent launch of National Program for Prevention and Control of Diabetes Cardiovascular Diseases, Stroke and Cancer, which has dedicated funds for clinical research.

**Medical education.** India has a large medical education sector. Over the last 2 decades, the number of medical schools in India has increased rapidly; most of this growth has occurred in the private sector.<sup>17</sup> Currently, there are about 300 medical colleges that offer training at undergraduate and graduate levels in medical and paramedical curricula. Medical education is provided in English, thus enabling Indian health care professionals to align with international academia. A few of these academic institutions offer training programs in basic science research related to cardiovascular medicine, epidemiology, and clinical research.

There are also several other initiatives providing impetus for capacity development in clinical research in CVD. The Public Health Foundation of India, a public-private partnership, aims to establish 11 public health schools in India to ameliorate the country's limited institutional capacity for training, research, and policy development in the area of public health. Parallel to the medical colleges is the training of postgraduates through the national board of exams. Currently, India has more than 13,500 postgraduate seats across various medical disciplines which is set to increase to 23,500 seats by 2010 with US\$300 million funding from the central

government to the government medical schools.<sup>18</sup> Developing a network of medical schools that host multiple registries covering a range of disease conditions could serve as benchmark for assessing quality of care, augmenting medical training and monitoring efficient use of resources.

**Interest in clinical research.** In 2001, an assessment of global resources for health research noted that India is one of the very few developing nations that met the 1990 Commission on Health Research for Development's recommendation by spending notably closer to 2% of the national health budget on research.<sup>19</sup> Funding for health research in India has increased substantially over the past few years. For instance, the budget for the ICMR has more than tripled from 2001 to 2008.<sup>20</sup> In addition, collaborative funding efforts by Indian agencies such as the Department of Biotechnology and the UK-based Wellcome Trust for a Biomedical Research Career Program are attempting to improve public health research and capacity in India.<sup>20</sup>

These efforts have paralleled an increasing readiness on the part of international bodies (such as the US National Institutes of Health, the Medical Research Council [UK], and the Wellcome Trust of UK) to invest in cardiovascular research. For example, the Public Health Foundation of India has recently established a Center of Excellence in Cardio-metabolic Risk Reduction in South Asia and a South Asia Network for Chronic Diseases with the support of the National Institutes of Health and United Health, and the Wellcome Trust, respectively. The St John's Research Institute of Bangalore is hosting another Centre of Excellence in noncommunicable diseases (NCDs) that, along with the Center of Excellence in Cardio-metabolic Risk Reduction in South Asia, is part of the Global Health Initiative of the US National Heart, Lung and Blood Institute and United Health Group, launched in 2009.<sup>21</sup> These institutions are expected to lead clinical research training in CVD in India. Other initiatives include the recently funded interdisciplinary training program in NCDs in India by the Fogarty International Center. This program will focus on the epidemiology and prevention of NCD across the life course in cross-connecting subject areas (e.g., children's health, nutrition and lifestyle, environmental health, obesity and diabetes, stroke, and other vascular diseases) and population science disciplines (e.g., epidemiology and biostatistics, clinical trials, translational research, social sciences, and economics). The goal of this undertaking is to produce a critical mass of CVD researchers and incorporate them within integrated NCD research programs in India (N. Tandon, personal communication). Some of the government medical schools in India have made commendable contribution to CVD-related biomedical and public health research in India. For example, the Sree Chitra Tirunal Institute of Medical Sciences and Technology at

Trivandrum developed a range of medical devices, such as mechanical heart valve prosthesis, blood oxygenators, and disposable blood bag systems. In addition, the Public Health Wing Institute led the way of public health training in India by offering a masters in public health with a focus on clinical research. Reflecting the growth in clinical research, the training investment from the private sector catering to pharmaceutical research is another trend.

**Regulatory mechanisms in clinical research.** In recent years, India has developed regulatory mechanisms to promote an environment conducive to ethical, high-quality clinical research, a commitment demonstrated by the ICMR's release of the *Ethical Guidelines for Biomedical Research on Human Subjects* in 2000.<sup>22</sup> Furthermore, there is an increasing emphasis on the adoption of Good Clinical Practice (GCP) guidelines in clinical research. Approval from an institutional review board is a mandatory requirement for conducting clinical research in India.

In addition, the ICMR has established the Clinical Trials Registry-India to encourage all clinical trials conducted in India to be prospectively registered before the enrollment of the first participant. As part of this process, investigators must disclose details of the 20 mandatory items of the WHO International Clinical Trials Registry Platform data set.<sup>23</sup> Trials registered with the Clinical Trials Registry-India will be monitored to ensure increasing voluntary disclosure, to improve transparency and accountability, and to conform to accepted ethical standards. Most recently in 2007, the government of India introduced a bill in Parliament to constitute a Central Drug Authority for enforcing comprehensive regulation of the pharmaceutical industry, drug development, and drug exports in the country. The Central Drug Authority is expected to follow a legal framework for taking appropriate action against those who violate standards and regulations governing the conduct of clinical trials in India.

**Pharmaceutical industry.** India has a large indigenous pharmaceutical industry that possesses substantial generic drug manufacturing facilities. The New Patents Act of 2005, implemented to conform to the requirements of the World Trade Organization's Trade-Related Aspects of Intellectual Property Agreement, was expected to provide an impetus to pharmaceutical innovation.<sup>24</sup> This strategy is evident from the increased spending on research and development in comparison with previous years by Indian pharmaceutical companies. Current research and development expenditures have reached approximately 10% of sales revenue in 2010, as compared with 2% a few years ago.<sup>24</sup> The research and development expenditure of contract research organizations and multinational companies is estimated to be US\$500 to US\$600 million in 2010.<sup>24</sup> Indian firms have also shown changes in terms of their investment in

research with a focus on basic science. Although not even a single firm engaged in drug discovery a decade ago, 40 molecules were developed by the Indian companies in 2006 to 2007.<sup>24</sup> These changes signify a strategic shift toward indigenous capacity building in research in India.

**IT and data processing infrastructure:** With rapid growth in its software and IT sectors, India has been expanding its national technological infrastructure, particularly in information management, and data processing. These capabilities have tremendous potential for life science research in general and for CVD research in particular. The large workforce in these areas is a core strength that would benefit fields such as bioinformatics, genetics, other “omics,” and biostatistics.

#### Gaps

**Gaps in surveillance and screening.** Surveillance and screening are central to disease prevention and control in public health. Currently, CVD surveillance is confined to monitoring of risk factors in selected states in India. There are several unmet gaps, especially in regard to information on disease incidence, mortality, complications, health care costs, and quality of care. In addition, there are no screening programs (either mass or targeted) for CVD risk factors. A few screening tools developed from simple, noninvasive measures are available, but these need to be formally evaluated.<sup>25</sup> Multiple agencies are engaged in collecting population level information, relevant to CVDs at the national level. Some of these include the National Family Health Surveys of the International Institute of Population Health, surveys of the National Sample Survey Organization, Health Information Systems of various National Health Programs, and the Integrated Disease Surveillance Project. However, innovative ways for linking these data sets at the national level to produce meaningful interpretations for CVD prevention and control planning are yet to be developed.

**Gaps in capacity.** Capacity for controlling CVD at various levels has not been assessed thoroughly in India. Such exercises are important for identifying weaknesses and establishing priorities for investing in health systems. Another area of concern is a current lack of evidence-based policies. For example, with the exception of tobacco control laws, policies specific to CVD prevention and control are nonexistent in India.<sup>26</sup> Considering the complex nature of CVD epidemiology, prevention and control policies must span multiple sectors of health care and research. Robust evidence from clinical research is fundamental to formulating policies capable of cushioning the deleterious impact of disease on economic development and on populations. Finally, monitoring and evaluation research is needed to manage and assess the efficiency and effectiveness of investments in CVD control policies and programs. Current monitoring and evaluation of disease control programs is largely related to financial audits.

**Gaps in clinical care and the need for quality assurance.** One of the most striking features of the clinical management of CVD patients in India is its heterogeneity. Although patients treated at tertiary care and teaching hospitals receive relatively better evidence-based care, the poor and the rural populace are poorly treated.<sup>27</sup> The WHO PREMISE study has documented that close to half of ACS patients and stroke patients in India do not receive evidence-based medicine.<sup>28</sup> Similarly, the “Treatment and outcomes of acute coronary syndromes in India” (CREATE) Registry highlighted the fact that the poor are less likely to get evidence-based prescriptions after ACS due to the high cost of the drugs and coronary interventions.<sup>8</sup> When compared with wealthier patients, smaller proportions of poor patients received key treatments such as thrombolytics (52.3% vs 60.6%), lipid-lowering drugs (36.0% vs 61.2%), angiotensin-converting enzyme inhibitors or angiotensin receptor blockers (54.1% vs 63.2%), percutaneous coronary intervention (2.0 vs 15.3%), or coronary artery bypass graft surgery (0.7% vs 7.5%). Poor patients also had greater 30-day mortality (8.2% vs 5.5%).<sup>8</sup> These differences disappeared after statistical adjustment for in-hospital treatment, suggesting that provision of evidence-based secondary prevention may play a large role in improving survival among ACS patients.

Furthermore, a recent study from Rajasthan, a large northern Indian state, has documented suboptimal prescription of evidence-based medication for coronary heart disease (i.e., prescription of the 4-drug combination of aspirin,  $\beta$ -blockers, angiotensin-converting enzyme inhibitors, and statins) by physicians at all 3 levels of health care: tertiary (43%), secondary (28%), and primary (7%).<sup>29</sup> Relatively small-scale initiatives such as standard admission orders and patient-directed discharge instructions have demonstrated improvement in management of ACS patients in terms of significantly reducing the time to thrombolysis and adherence to evidence-sensitive guidelines for incorporating evidence-based, cost-effective treatments for both primary and secondary preventions that are appropriate to various levels of care and quality improvement programs.<sup>30</sup> Widespread use of these strategies throughout India could improve overall CVD outcomes by reducing the variation and disparities in care, but requires coordination by the cardiology community as a whole to adopt and implement these systems and processes.

**Distortion in health care delivery.** The provision of health care by the public sector is a responsibility shared by central (federal) and state (provincial) governments, as well as by local administrative bodies such as the municipal corporations of towns and cities. However, under the Indian constitution, health care is a “state subject,” and state governments are responsible for health service delivery. This delineation leads to heterogeneity and distortions in the public health system, because financial allocation to health care by states is highly

variable. Also, even when the central government plans a program and provide funds, the states are responsible for its implementation.

Health service delivery at the primary health care level in India is centered on the 13 national health programs, with emphasis on communicable diseases and maternal and child health. The National Program for Prevention and Control of Diabetes Cardiovascular Diseases, Stroke and Cancer, launched in 2008 as a pilot program focusing on preventive and promotive care, is being integrated with cancer and is being expanded to 100 districts of India. A large proportion of health care is provided by the private sector due to inadequate hospital beds and an insufficient workforce in the public sector. Furthermore, most high-technology diagnostics and health care professionals are concentrated in urban areas; consequently, large segments of the rural population are at a disadvantage in terms of accessing CVD-related health care.<sup>31,32</sup> These facts highlight the need for health system research to improve the quality, accessibility, and reach of affordable CVD services for rural Indians.

#### Infrastructural weaknesses in undertaking CVD research

**Lack of training.** Given the population size, the number of universities in India, currently, are few and inadequate to fulfill India's increasing need for higher education. Moreover, current medical curricula and teaching methods do not adequately emphasize the development of research aptitude among undergraduate and graduate trainees in their formative years. Because the educational focus is largely on clinical services, there is shortage of role models and mentors in academic research—a major weakness when attempting to build capacity in clinical research. The rigid academic regulations prevailing in the country seldom offer any incentive for the academic faculty at medical schools in undertaking clinical research. Clinical research excellence as a metric is largely ignored in determining career paths, promotions, and perks. Acute shortage of teaching faculty at medical schools put too much of strain on existing faculty to spare time for research from teaching.

These factors cumulatively result in a severe shortage of trained investigators capable of undertaking high-quality clinical research in CVD. A corresponding shortage of trained biostatisticians and data managers who are an essential part of the multidisciplinary team is another shortcoming. The emphasis on International Conference on Harmonization technical requirements regarding registration of pharmaceuticals for human use and lack GCP training is only a recent trend. Finally, the lack of a clinical research career track for clinicians and teachers in the academic environment deters young talent from pursuing a career in research. The recent advent of degree/diploma programs in clinical research will, it is hoped, address some of these issues.

**Financing and expenditure.** According to WHO statistical information for 2006, India spent 4.9% of its gross domestic product (GDP) on health care.<sup>5</sup> This spending comes largely as out-of-pocket expenditure, which accounts for 80.4% of total health expenditure, whereas the government and other sources, such as insurance, contribute the remaining 19.6%.<sup>5</sup> These statistics, which reflect inadequate public spending on health in India, are of special relevance for CVD, where the high cost of medication coupled with the longer duration of treatment constitute a disproportionate financial burden for low-income groups. Studies carried out in urban and rural regions of 7 states in India have shown that the cost of treating diseases such as diabetes has doubled from 1998 to 2005, particularly among urban households.<sup>33</sup> The lower-income groups are reported to spend a higher proportion of their income on diabetes care, and the highest increase in percentage of household income devoted to diabetes care was seen in the lowest income group (34% of income in 1998 vs 24.5% in 2005).<sup>33</sup>

Acute CVD is associated with major health expenses owing to high costs of drugs, therapeutic procedures, other hospital expenses, and loss of wages. A study carried out in southern India among patients with ACS or stroke showed that catastrophic health spending as a result of treating an acute event of CVD was experienced by about three fourths of households, particularly among those in the lowest socioeconomic group, whereas distress financing was lower among the richest (36%) as compared with the poorest (51%) (S. Harikrishnan, personal communication). Income loss was also highest among poor households. Impoverishment due to CVD care has not been estimated. These data reflect the high individual and family burden caused by CVD and highlight the need for health economics and health financing research that can develop alternative financing models that protect citizens from the catastrophic financial impact of CVD.

**Uneven distribution of health infrastructure.** Almost three quarters of the Indian population lives in predominantly rural areas, whereas health care, teaching, and research infrastructure are concentrated in urban locations. Uneven distribution of such institutions hinders health care delivery, training of the health care workforce, and the conduct of context-specific clinical research. In addition, these distortions sometimes mean that the most pressing health issues are ignored and/or excessively costly solutions are offered.

**Unfinished agenda of pretransitional diseases.** The burden of pretransitional diseases such as infectious, nutritional, and maternal and child health diseases still continues to exceed that of chronic diseases and remains the major priority of health systems and research funding bodies. Therefore, priorities in research funding are skewed toward this group of diseases, and radical

changes are needed to reorient the health system to the looming threat of chronic disease and to advancing the CVD research agenda.

### Opportunities and threats to clinical research in CVDs

The 3 most important opportunities for clinical research in India are (1) the country's large population and its health needs, (2) the potential for high-quality research, and (3) the high degree of interest (both domestic and international) in investing in research.

With an estimated 1.123 billion citizens as of 2007, India is the second most populous country in the world, accounting for one sixth of the global population and growing at a rate of 1.4% annually.<sup>34</sup> Despite enormous achievements by India's health system in controlling communicable disease, CVD control services remain largely inadequate. To achieve affordable, equitable, and evidence-based CVD care, clinical research must be reoriented to address the range of topics listed in Figure 1.

The Disease Control Priorities Project report suggests that policy changes and provision of evidence-based CVD care have the potential to create large savings for national income.<sup>35</sup> The WHO has estimated that a 2% annual reduction in national-level chronic disease death rates in India would result in an economic gain of US 15 billion for the country over the next 10 years.<sup>4</sup> Modeling studies have shown that the per capita real GDP in India would grow by an additional 87% of the year 2000 per capita GDP if the annual CVD mortality declines by 1%, whereas a 3% annual decline in CVD mortality would increase per capita income by 218% by the year 2030 (M. Suhrcke, personal communication).

The cost of health research in general and clinical trials in particular is perceived to be lower in India relative to

wealthier nations.<sup>3</sup> In addition, the larger pools of potential research subjects, human resources, and technical skills, as well as the presence of a legal framework and regulatory authority conducive to high-quality research, have made India the preferred destination for outsourcing for drug development and global studies of new drugs.<sup>3</sup>

In addition, the new patent regime aims to boost innovations (measured in patent filings), especially in the pharmaceutical, chemical, and biotechnology sectors,<sup>24</sup> and the new Trade Related Aspects of Intellectual Property Rights regime provides opportunities for developing newer drugs. However, it is worth noting that many patent filings have been contributed by Indian entities rather than foreign firms.<sup>24</sup> Also, Indian institutions, notably the Council of Scientific and Industrial Research (CSIR), are responsible for most of the increase in patent filings in the United States as well as in India in the key sectors mentioned.

The growing interest and investment in "omics" approaches in clinical and technology programs both in India and globally also show promise. The Institute of Genomics and Integrative Biology in New Delhi and the Centre for Cellular and Molecular Biology in Hyderabad are among the leading institutions in India in this new research arena. Other new developments in the field include the establishment of large biorepositories for storing samples and the creation of collaborative approaches to research that include the pooling of resources, samples, and expertise for -omics analysis.

### Threats

The several threats to the emerging clinical research enterprise in India are largely related to issues of governance and the balance of commercial interests of commercial research organizations (CRO) and the need

Figure 1

1. Incidence and mortality of CVD and diabetes in multiple population groups
2. Exploring temporal and spatial trends in CVD/risk factors
3. Relationships among social factors including nutrition and health throughout the life course
4. Relationships between environmental factors and cardiovascular health
5. Utilization and costs of CVD care services at different levels and settings
6. Strategies to improve quality of CVD care at different settings
7. Financing for CVD care services
8. Outcomes of specific clinical and therapeutic interventions
9. Long-term follow-up of outcomes and complications among persons with CVDs and impact of interventions
10. Studying the complex interaction among biological factors, social factors and health outcomes in Indians

Suggested areas of research to reduce CVD burden in India.

for an independent voice of practitioners and academics representing the public health and the well-being of individual research participants. Chief among these concerns is the relatively low level of education among many Indian patients, which threatens to compromise the informed consent process and constitutes a serious threat to ethical conduct of clinical research in India. Given the tremendous financial pressure on the pharmaceutical and device industries, the CRO industry attempting to provide responsive timelines could potentially result in nonadherence to GCP guidelines. Thus, there is a greater need for close monitoring of clinical trials. Also, concerns have been expressed about the relevance of trials to the research participants and their understanding of the research process. A strong infrastructure of practitioners and academic investigators should provide a balancing force to this financial pressure.

However, the current trend is that CROs have gradually assumed much of academia's traditional role in clinical research, particularly in drug development, over the past decade by offering greater speed and efficiency in conducting studies.<sup>36</sup> Dependence of academic institutions on pharmaceutical/international funding agencies for financial support has often led to mismatches in national priorities in clinical research. Furthermore, there are numerous examples of clinical trials conducted in India that have focused on serving the lucrative markets of developed nations rather than the markets of developing countries.<sup>24</sup> Thus, some of the drugs tested in clinical trials in India may not be available to most consumers in India and to the poor in particular, due to their substantial costs, further restricting access to affordable medicines.

Entrenched government bureaucracy and resistance to change are a significant barrier to the development and growth of research capacity in India. Lack of interdisciplinary and transdisciplinary research are another concern. Current attempts to expand the tax base by bringing clinical research in India within the ambit of services that have tax implications may increase the cost of research and development and thus impede the ability to do conduct research relevant to public health.

### What is the future?

Clinical research in cardiovascular health is critical to addressing the complex array of social, financial, behavioral, and organizational barriers to high-quality CVD care that the population of India currently faces. Thus, there is a clear need to design and conduct research studies that are context-specific and socially relevant. We have argued earlier that through careful planning and shared partnership among sponsors, host-country research practitioners, government agencies, and the community, many of the challenges in the conduct of clinical research can be overcome in the medium to long term.<sup>37</sup>

Key research areas that need immediate attention include: the effects and costs of innovative methods for reducing CVD risk through health policy changes, methods for ensuring integration of chronic disease services in the health system, innovative financing strategies, and best methods of applying existing knowledge for development, implementation, and evaluation of CVD programs. Translational research, both T1 (from the laboratory to studies in humans) and T2 (from clinical research to clinical practice and beyond) is needed to develop multipronged approaches that address the patient, provider, health care system, public health, and public policy. Local research and publications are most likely to change clinical practice, and the best way of applying research findings to practice in India is by conducting high-quality translational and operational research in local settings.

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## **Appendix – 2: Health Facility Assessment Tool**



**Development of a Smartphone enabled hypertension and diabetes management package to facilitate evidence-based care delivery at primary health care facilities in India: A formative research to inform intervention design**

**Health Facility Assessment Tool**

Name of the Team Members:

No	Assessment Questions	Observations	Comments
1	Period of visit		
2	Name of Health Facility Visited		
<b>Services Offered</b>			
3	Treatment and referral of complicated cases of hypertension (Outpatient care)		
4	Treatment and referral of complicated cases of diabetes (Outpatient care)		
5	Health promotion activities pertaining to prevention and control of hypertension and diabetes		

No	Assessment Questions	Observations	Comments
6	Screening and diagnosis of Hypertension and diabetes		
7	Screening and diagnosis of other cardiovascular conditions		
8	In-patient care for acute/ emergency of hypertension and diabetes		
<b>Drugs available</b>			
9	Tab Atenolol		
10	Tab Metoprolol		
11	Tab Amlodipine		
12	Tab Captopril		
13	Tab Enalapril		
14	Tab Hydrochlorothiazide		
15	Tab Metformin		
16	Tab Glipizide		
17	Tab Glibenclamide		
18	Inj insulin		
19	Tab Atrovastatin		
20	Tab Aspirin		
21	Inj Streptokinase		

No	Assessment Questions	Observations	Comments
<b>Equipment available</b>			
22	ECG Machine		
23	BP Apparatus		
24	Stethoscope		
25	Ophthalmoscope		
<b>Laboratory investigations/ diagnostics available</b>			
26	Blood Sugar		
27	Blood Cholesterol		
28	Lipid Profile		
29	Kidney Function Test (Blood Urea/creatinine)		
30	Liver Function Test		
31	EKG		
32	Urine Albumin		
33	Urine Sugar		
<b>Manpower available</b>			
34	Block Medical Officer		
35	Specialist physician in General Medicine		
36	General duty medical officers (MBBS)		
37	Lab-Technician		
38	ECG technician		
39	Nurse		

No	Assessment Questions	Observations	Comments
<b>Other parameters</b>			
40	Timing of OPDs		
41	Average OPD strength		
42	Average number of hypertension patients attended per day at OPD		
43	Average number of diabetes patients attended per day at OPD		
44	Presence of specialist clinics		
45	Method of record keeping at OPDs		
46	Presence of staffing from NRHM		
47	Mode of monthly reporting of hypertension cases		
48	Mode of monthly reporting of diabetes cases		
49	Use of NPCDCS guidelines at the health facility		
50	Provision of mobilephones to healthcare team		
51	Other Observations		

**Development of a Smartphone enabled hypertension and diabetes management package to facilitate evidence-based care delivery at primary health care facilities in India: A formative research to inform intervention design**

**Health Facility Assessment Tool for Sub-Centres**

Name of the Team Members:

No	Assessment Questions	Observations	Comments
1	Period of visit		
2	Name of the Sub-centre visited		
<b><i>Services Offered</i></b>			
3	Health promotion activities pertaining to prevention and control of hypertension and diabetes		
4	Screening and diagnosis of Hypertension and diabetes		
<b><i>Equipment available</i></b>			
5	BP Apparatus		
6	Stethoscope		
7	Weighing scale		

No	Assessment Questions	Observations	Comments
8	Stadiometer		
9	Measuring tape		
<b>Diagnosics available</b>			
10	Uristix (for Urine Protein)		
11	Urine Sugar		
<b>Manpower available</b>			
12	Female Health Worker		
13	Male Health Worker		
<b>Other parameters</b>			
14	Population covered		
15	Timing & monthly schedule of filed visits		
16	Mode of monthly reporting of hypertension/diabetes care, if any		
17	Electricity connection		
18	Mobilephone coverage		
19	Provision of mobilephones to health workers		
20	Other Observations		



### **Appendix – 3: Interview Guides used during the design phase of the intervention**





**DIRECTIONS:** The qualitative interview begins with open ended questions that point to starting a dialogue. The interviewer should encourage the study participant to do most of the talking, but should use the questions listed here as a guide. After you ask each question, wait for the study participant to respond and go on to the next question when you are satisfied with the answer. If it seems as though the study participant did not understand a question, then repeat it or ask it in another way. If the study participant goes on talking without much prompting, then let them guide the conversation. Bold indicates major questions and probes are in parentheses. Mentally check off these questions as they are asked so you do not repeat a question if it has been discussed previously.

Remember to audio record each interview. Use a back-up recorder to prevent technological problems.

**Thank you for participating in this interview. This interview will be different than others that you might have participated in. I will ask you questions and ask you to talk freely about your experiences. Please ask me at anytime if you do not understand a question, need more clarification, or would prefer to not answer a question. We ask that you provide honest answers that will provide us the best information possible to understand your personal experiences and opinions about hypertension and diabetes care and new technologies for health care.**

**Q1: I would like to begin with a few questions about your background. Can you tell me about where you are from, and how long you have lived in Solan?**

(Where were you born? Where are your parents from? Where did you receive your medical training? For how long have you been to administrative cadre? Have you only worked in Solan district, or have you worked elsewhere, as well? If you have worked elsewhere, can you please describe that experience and position?)

**Q2: Can you tell me about your daily routine working as a District Health Officer in Solan?**

(When do you begin your day? Can you walk me through a typical day? [What do you do in the morning vs afternoon/etc] Is every day very similar or do you find variation between days, weeks or months?). What are your responsibilities as DHO?

**Q3: I am interested in how health care delivery is organized for hypertension and diabetes at the level of sub-centers, CHCs and District hospital in Solan. Since you are the expert and so knowledgeable about the health system in Solan, would you explain the multiple levels of health care delivery for us?**

(Where do people with hypertension/diabetes approach for care – CHC, District hospital or any others? What do you perceive to be the main role of the medical officers in CHCs in

diabetes/ hypertension management? What do you perceive to be the main role of the Health Workers in diabetes/hypertension management? How do physicians at CHCs ensure follow-up care of patients?

Do Health Workers carry out screening of hypertension or diabetes at sub-centre level? Do they provide health education – tobacco, salt, fat/oil intake, fruits and vegetable, exercise- at the community level or patients? Do they provide any treatments including supplying drugs to patients at community level?)

**Q4: Could you provide us with an example of the functioning of the CHCs? Do you think that they are well-resourced, meaning: do they have sufficient number of health workers and support staff, drug supplies, and lab support for patients with diabetes and/or hypertension?**

(What are the options available for the medical officers at CHC, district hospitals and the health worker at sub-centres to rectify these deficiencies at their facilities [ e.g. untied funds for purchasing drugs, appointing adhoc staff etc])

**Q5: What is your opinion on setting up of NCD clinics at CHCs envisaged in the National Program on Prevention and Control of Cancer, Diabetes, Cardiovascular diseases and stroke?**

[The National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular disease and Stroke (NPCDCS) envisages a nurse/Health Worker opportunistically screen people above the age of 30 years at the OPD for diabetes and hypertension and send them to physician for management] Do you have any suggestion on how to set up these clinics at CHC more efficiently to deliver hypertension/ diabetes care?

**Q6: Do you believe that the CHCS are equipped to ensure high quality of care for people with diabetes and/or hypertension? Can you describe for me the standard protocol that health workers follow to carry out standard care for diabetes and/or hypertension? Are there any guidelines or manuals prepared by the health department or central government for the physicians and health workers for managing these conditions?**

(How the health department ensure that physicians adhere to guideline based practice? What additional training would be required for Physician to efficiently deliver diabetes/ hypertension care at CHC? Has the health department issued any printed management guidelines to physicians for the use at OPDs? If not, what is your suggestion to improve the quality of care for hypertension/diabetes at these facilities?)

**Q7: What is your perspective on introducing a smartphone version of guidelines/ clinical protocols for physicians at the NCD clinic in an attempt to promote guidelines and optimize the care? [Show the Probe]**

(Do you think using such a tool would improve the care delivery? What might be some positive outcomes of such a tool? What might be some challenges that you could see arising from using this software? What would be the ideal work flow at the CHCs to incorporate such a system to improve quality of care?)

**Q8: The Government of India plans for nurses and/or health workers to take over opportunistic screening of all people 30 years of age and older attending the OUT PATIENT DEPARTMENTS (OPDs) of the CHCs. They will do screening, history taking, glucometer based diabetes screening, and blood pressure measurements of eligible patients while they wait for their turn at the out patients departments. Then, the patients are sent to the medical officers for management. Do you think that with this technology, could nurses/health workers compute the management plan thereby ease the workload for the medical officers? Do you think this will be a good opportunity for task-shifting? Or do you think that the nurses and health workers will be overburdened?**

(What do you think is the best way of positioning screening activities at the OPD? Do you think that screening management activities can be routinely done on all the OPD days? If you think, a nurse/health worker can compute the management plan, what additional skills/training would these staff require carrying out these activities? Do you think that medical officers would trust the results that nurse/health worker sending in)

**Q9: What challenges might we face in implementing this method at CHCs?**

(Do you think people would use the technology? Why or why not? What do you think the benefits of this technology might be for the health system, including the health information system? What additional training would the staff require to overcome these challenges?)

**Q10: How do you perceive this new technology affecting the workload at CHC in delivering routine care for people with hypertension and/or diabetes?**

(If you were to implement the smartphone tool into a NCD clinic, how would you plan to train the staff to utilize the tool and incorporate the new “task” into their current disease management routine?)

**Q11: As you know, regular and prolonged follow-up and repeated messages for compliance to drug therapy are required for hypertension and diabetes patients. Do you think that using automated SMS reminders for diabetes self-care, such as medicine adherence, would improve health outcomes? Could you explain whether such a follow-up plan might benefit the people with diabetes/hypertension? What language would be the best for people who utilize this technology?**

**Q12: How much do you think using this technology would cost the district? Would the health department be willing to cover a fixed cost of monthly rental for SMS and phone calls? Can you tell me why/or why not the district would invest in this new technology?**

**Q13: Do you believe that the district hospital at Solan would be able to provide care for all the complicated cases of diabetes and hypertension cases from CHCs and vice versa?**

(Does the Solan District Hospital have enough facilities and staff to provide care for diabetes and hypertension complication cases? Which is the preferred hospital for most patients to treat complications? If it is not District hospital, why is it so? Is it possible to address those deficiencies?)

**Thank you very much for taking the time to speak with me. Is there anything else you would like to share with me about your work as a medical officer in Solan? Is there anything else you would like to share with me regarding your views on new technologies for chronic disease care?**



**Qualitative Interview Guide  
Primary Care Physicians**

**m-POWER Heart Study**

**DIRECTIONS:** The qualitative interview begins with open ended questions that point to starting a dialogue. The interviewer should encourage the study participant to do most of the talking, but should use the questions listed here as a guide. After you ask each question, wait for the study participant to respond and go on to the next question when you are satisfied with the answer. If it seems as though the study participant did not understand a question, then repeat it or ask it in another way. If the study participant goes on talking without much prompting, then let them guide the conversation. Bold indicates major questions and probes are in parentheses. Mentally check off these questions as they are asked so you do not repeat a question if it has been discussed previously.

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**Thank you for participating in this interview. This interview will be different than others that you might have participated in. I will ask you questions and ask you to talk freely about your experiences. Please ask me at anytime if you do not understand a question, need more clarification, or would prefer to not answer a question. We ask that you provide honest answers that will provide us the best information possible to understand your personal experiences and opinions about hypertension and diabetes care and new technologies for health care.**

**Q1: I would like to begin with a few questions about your background. Can you tell me about where you are from, and how long you have lived in Solan?**

(Where were you born? Where are your parents from? Where did you receive your medical training? For how long have you been a primary care provider? What other training have you received? Have you only worked in Solan district, or have you worked elsewhere, as well? If you have worked elsewhere, can you please describe that experience and position?)

**Q2: Can you tell me about your daily routine working as a medical officer in Solan?**

(When do you begin your day? Can you walk me through a typical day? [What do you do in the morning vs afternoon/etc] Is every day very similar or do you find variation between days, weeks or months? Can you describe what is the most common way you spend your morning? Can you describe what is the most common way you spend your afternoon?)

**Q3: I am interested in how much time you spend providing care for people with either diabetes or hypertension. Can you describe what those tasks are and how they differ from other tasks that you conduct caring for people without these conditions? If you don't treat hypertension or diabetes at CHC, could you please elaborate the reasons/challenges that prevent you from doing so? If you don't provide any care or education to patients at CHC, could you please elaborate the reasons/challenges that prevent you from doing so?)**

(What types of tasks are you expected to conduct on a daily basis? What percentage of patients you see at your OPD has diabetes or hypertension? How much of your day do you

**Qualitative Interview Guide**  
**Primary Care Physicians**

**m-POWER Heart Study**

spend caring for people with diabetes and hypertension? What percentage of those tasks includes diabetes/hypertension education and/or support for people managing these conditions? Does your work on diabetes/hypertension overlap with education or care for other diseases/problems?

**Q4: When people are treated for diabetes, it's equally important to treat their hypertension, and vice-versa. Do you address other co-morbidities in your primary care? If you do not treat any co-morbidity, could you please elaborate the reasons/challenges that prevent you from doing so?)**

(Can you provide an example where you might be caring for someone with diabetes/hypertension and address other problems that the patient might face (e.g., obesity, depression, and so on)? How would you address a co-morbid problem? Do your patients with diabetes and/or hypertension ever present with symptoms of depression or anxiety? How do you address these co-morbidities in your treatment regimens?

**Q5: I am interested in what types of things you do for disease care and management and education for people with diabetes and/or hypertension.**

(Do you focus on physical aspects of the disease, such as managing diet, physical activity, and medicine adherence? Are there social aspects of diabetes care that you address, such problems related to family, friends, or one's environment? Are there emotional problems that people face when they have diabetes and/or hypertension? Do you take care of these emotional problems? What portion of the time you provide for diabetes and/or hypertension care addresses the physical part of diabetes and/or hypertension? What portion of the time that you provide for diabetes and/or hypertension care addresses the social or emotional part of having the disease? Can you provide with me an example of when you had to care for the emotional state of someone with diabetes and/or hypertension? Do you think this is common in your practice? Why or why not?)

**Q6: How do you define the term "diabetes management"? What is the main role of the medical officer in diabetes management? What is the role of the Health Workers in diabetes management?**

(What are the main tasks that you do when you help people manage their diabetes? What do you perceive to be the main role of the medical officer in diabetes management?

Do you think that diabetes care tasks should be divided between medical officers and Health Workers? Why or why not? What jobs do you think is NOT the role of the medical officer,



**Qualitative Interview Guide  
Primary Care Physicians**

**m-POWER Heart Study**

and should be the role of the health worker? How these tasks can be divided in a way that benefits a patient's diabetes care? Can you provide me an example of what you mean?)

**Q7: What is your perspective on the extent of use of standard guidelines by physicians at the CHC for the management of chronic diseases like diabetes and hypertension? Have you ever used tools such a printed copy of a standard clinical management guideline at the OPD for managing hypertension or diabetes? [See the Probe]**

(Do you think using standard guidelines at all the CHCs for managing hypertension and diabetes patients would improve the quality of care? If you don't use guidelines, could you please elaborate the reasons/challenges that prevent you from doing so?) )

**Q8: What is your perspective on using your own mobile phone as a tool for guideline based management of diabetes and hypertension at the OPD?**

(*Show the PROBE and explain the advantages of smartphone version of the guideline. Would this new technology improve the care that you provide or make it more difficult to provide care for people with diabetes or hypertension at the OPD? What might be some positive outcomes of such a tool? What might be some challenges that you could see arising from using this software?*)

**Q9: Do you think it would be easy to learn how to use Smartphone Decision Software? Do you have experience using this type of software? How might using this software improve your ability to provide diabetes and/or hypertension care in Solan? Can you provide me with some challenges that you might face in implementing this software in your diabetes practice in Solan?**

**Q10: If this decision support tool was implemented into diabetes and/or hypertension care in Solan, what would you recommend to people implementing this software?**

(What would be some important things that people would need to consider when teaching people how to use the technology? Are there any existing tools that might assist in the use of this new technology? Do you think people would use the technology? Why or why not? What do you think the benefits of this technology might be for your work at a medical officer? What might be the challenges to your work as a medical officer with this new technology? What additional training would you require to overcome these challenges?)

**Q11: The Government of India plans for nurses and/or health workers to take over opportunistic screening of all people 30 years of age and older attending the OPDs of the CHCs. What is your perspective on a nurse or health worker doing screening, history taking, and blood pressure measurement of the eligible patients while they wait for their turn at the OPD and send them to you for management along with the computed management plan using the smartphone software?**

(What would be your thoughts on the best way of positioning screening activities at the OPD? Do you think that screening management activities can be routinely done on all the OPD days? If you think, a nurse/health worker can compute the management plan, what additional skills/training would these staff require to carry out these activities?)

**Q12: How do you perceive this new technology affecting your workload? How might a new technology for providing care for diabetes or hypertension improve your working conditions? How might this new technology complicate your current work?**

(Have you had the opportunity to pilot or implement a new technology for another type of care? What benefits did you find from the implementation of this new technology? What challenges did you face as a result of this new technology?)

**Q13: Since regular and prolonged follow-up, and repeated messages for compliance to drug therapy are required for hypertension and diabetes patients, what is your perspective on using automated SMS to patients for health messages and reminders for drug intake and follow-up visits? Could you explain whether such a follow-up plan might benefit the people with diabetes who you provide care for? What language would be the best for people who utilize this technology?**

**Thank you very much for taking the time to speak with me. Is there anything else you would like to share with me about your work as a medical officer in Solan? Is there anything else you would like to share with me regarding your views on new technologies for chronic disease care?**



**DIRECTIONS:** The qualitative interview begins with open ended questions that point to starting a dialogue. The interviewer should encourage the study participant to do most of the talking, but should use the questions listed here as a guide. After you ask each question, wait for the study participant to respond and go on to the next question when you are satisfied with the answer. If it seems as though the study participant did not understand a question, then repeat it or ask it in another way. If the study participant goes on talking without much prompting, then let them guide the conversation. Bold indicates major questions and probes are in parentheses. Mentally check off these questions as they are asked so you do not repeat a question if it has been discussed previously.

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**Thank you for participating in this interview. This interview will be different than others that you might have participated in with previous visits. I will ask you questions and ask you to talk freely about your experiences. Please ask me at anytime if you do not understand a question, need more clarification, or would prefer to not answer a question. We ask that you provide honest answers that will provide us the best information possible to understand your personal experiences and opinions about diabetes care and new technologies for health care.**

**Q1: I would like to begin with a few questions about your background. Can you tell me about where you are from, and how long you have lived in Solan?**

(Where were you born? Where did you receive your Nurse training? For how long have you been serving as a Nurse? What other training have you received?)

**Q2: Can you tell me about your daily routine working as a Nurse?**

(When do you begin your day? Can you walk me through a typical day? [What do you do in the morning vs. afternoon/etc] Is every day very similar or do you find variation between days, weeks or months?)

**How many doctors work at your hospital? (MBBS & MDs)? How many staff works at the OPD? Do you have a lab technician?**

**Q3: Do you work at the Outpatient clinic? If so, what is the workflow that you experience at the Outpatient clinic and where is your position in the workflow? If not, can you explain on your indoor duties?**

**Q4: Do you spend time caring for people with hypertension or diabetes at OPD/Indoor duty? If not, why? If yes, I am interested in how much time you spend providing care for people with diabetes and/or hypertension. How much of your day do you spend caring for or educating**

people with diabetes and/or hypertension? How many hypertension patients and how many diabetes patients do you come across a day?

**Q5: What types of tasks are you expected to conduct on a daily basis? What percentage of those tasks includes hypertension education and/or support for people managing their hypertension? Similarly what proportion of those tasks includes diabetes education and/or support for people managing their diabetes?**

*[examples of diabetes/hypertension care that a Nurse can undertake: measuring blood pressure, providing health education to reduce salt intake, quit tobacco, reduce the use of sugary, oily foods, promote the vegetables and fruits consumption]*

**Q6: Do you think that you require any additional training or skills to provide the care for hypertension/diabetes patients in a much better way?**

**Q7: What are the common concerns that you encounter from people with hypertension? How do you manage treatment for people with hypertension?**

**Q8: What are the common concerns that you encounter from people with diabetes? How is this similar or different to hypertension? How do you manage treatment for people with diabetes?**

**Q9: Do you have enough supply of medicines at hospital for these two diseases? Do you have enough laboratory support for these diseases? If no, how these are managed currently?**

**Q10: Does other staff at the hospital influence your current duties and responsibilities in the project? If so, can you explain?**

**Q11: Do you face any other difficulties in performing your duties as Nurse? Can you elaborate on that?**

**Q12: Is there a guideline that is followed for the management of diabetes and hypertension patients by the doctor? If so can you explain that?**

**Q13: Do you think that a mobile phone software is of any help to your duties? (Use probe) If so, can you narrate on that?**

**Q14: Do you do lifestyle counselling and advise them on drug intake and compliance? If so what are the difficulties you face in educating and motivating the patients?**

**Q15: Suppose you are posted at the OPD, how many patients, you think you can comfortably manage in a day?**

**Q16: What additional level of linking with the system would make the care better for the patients and also for the routine followed in the hospital?**

**Thank you very much for taking the time to speak with me. Is there anything else you would like to share with me about your work as a Nurse? Is there anything else you would like to share with me regarding your views on new technologies for hypertension or diabetes?**



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**Q1: I would like to begin with a few questions about your background. Can you tell me about where you are from, and how long you have lived in Solan?**

(Where were you born? Where are your parents from? Where did you receive your Health Worker training? For how long have you been a Health worker? What other training have you received? Have you only worked in Solan district, or have you worked elsewhere, as well? If you have worked elsewhere, can you please describe that experience and position?)

**Q2: Can you tell me about your daily routine working as a health worker?**

(When do you begin your day? Can you walk me through a typical day? [What do you do in the morning vs. afternoon/etc] Is every day very similar or do you find variation between days, weeks or months? Can you describe what is the most common way you spend your morning? Can you describe what is the most common way you spend your afternoon?)

**Q3: Do you spend time educating and caring for people with hypertension or diabetes during your field visits as well as at sub-centre? If not, why? If yes, I am interested in how much time you spend providing care for people with diabetes and/or hypertension. How much of your day do you spend caring for or educating people with diabetes and/or hypertension? Can you describe what those tasks are and how they differ from other tasks that you conduct as a health worker?**



(What types of tasks are you expected to conduct on a daily basis? What percentage of those tasks includes hypertension education and/or support for people managing their hypertension? Similarly what proportion of those tasks includes diabetes education and/or support for people managing their diabetes? Does your work on hypertension/diabetes overlap with education or care for other diseases or health problems? Can you provide an example where you might be caring for someone with diabetes or hypertension [*examples of diabetes/hypertension care that a health worker can undertake: measuring blood pressure, providing health education to reduce salt intake, quit tobacco, reduce the use of sugary, oily foods, promote the vegetables and fruits consumption*])

**Q4: Do you see any role for the health worker in caring for hypertension and diabetes patients?**

During your field visits, do you get demands from people to measure their blood pressure or blood sugar and its treatment? What are the common concerns that you encounter from people with diabetes? How is this similar or different to hypertension? How do you manage treatment for people with hypertension? What are the most common concerns that you encounter from people with hypertension? What additional skills or training would you require to help these patients at the community level?

**Q5: Do you address other problems that the diabetes patient might face? How would you address this problem?**

(Are there social aspects of diabetes care that you address, such problems related to family, friends, or one's environment? Are there emotional problems that people face when they have diabetes? Do you take care of these emotional problems? What portion of the time you provide for diabetes care addresses the social or emotional part of diabetes? Can you provide me an example of when you had to care for the emotional state of someone with diabetes? Do you think this is common in your work as a Health Worker? Why or why not?)

**Q6: The new National Program on Prevention and Control of Cancer, Diabetes, Cardiovascular diseases and Stroke is intended for providing care for people with hypertension or diabetes. The Health Workers are supposed to diagnose people with hypertension or diabetes from the community and send them to CHC for care. In addition, Health Workers are supposed to provide health education to the villagers on how to prevent and control these conditions. In this context,**

**what additional training and support would you require from the health department to carry out these responsibilities?**

(Have you heard of NPCDCS? Do you require training on how to measure blood pressure; Do you require training on how to do finger prick and glucometer based measurement of blood glucose? Do you require training on providing health education to patients on managing diet, physical activity, and medicine adherence? Do you think that when you provide care for diabetes/hypertension patients at the community, that adds to your reputation?)

**Q7: How best a Health Worker can arrange care from a doctor for people whom they identify as suffering from either hypertension or diabetes during their field visit?**

(How closely would you work with the Community Health Center (CHC) for referring these patients to there? How many times a week are you at the CHC? Do you think people will go to CHCs when you refer hypertension/diabetes patients to CHCs? How best will you manage to get care for patients whom you refer to CHC? Do you have some alternate suggestions to arrange doctor's consultation without sending them to CHC?)

**Q8: Do you think that identifying diabetes or hypertension patients from the community and arranging their care from CHC overburdens your work?**

**Q9: As I said previously, when the National Program – NPCDCS- gets implemented in Solan, there will be an NCD clinic start functioning in all the CHCs. A Health Worker will be identifying people suffering from Hypertension or diabetes from patients coming to the Out-Patient Department (OPD). These patients are to be managed as per clinical guidelines [Let me describe what the standard guidelines or clinical protocols would involve -Show Probe - Picture].**

(Can you see yourself identifying people suffering from Hypertension or diabetes from patients coming to the OPD? Have you ever heard of using guidelines? What is your perspective on using guidelines or clinical protocols for treating diabetes and hypertension?)

**Q10: Since most Health Workers carry a mobile phone, what is your perspective on Health Workers collecting all the required information from the patient using their mobile phone to help the doctor in using the guidelines? [Show Probe - Picture]**

(Can you see yourself using this mobile phone software tool to collect patient data at the OPD to help the doctor in treating hypertension or diabetes patients? Do you think this would be a helpful tool for you to use in your work at the CHC? Would this new technology improve the care that you provide? Or would the new technology make it more difficult to provide care for people with diabetes at the CHC? What might be some positive outcomes of such a tool? What might be some challenges that you could see arising from using this software?)

**Q11: Do you have any suggestions about the best way to implement this technology in Solan?**

(What would be some important things that people would need to consider when teaching Health Workers how to use the technology? Do you think Health Workers would use the technology? Why or why not? What language would be the best for Health Workers who utilize this technology?)

**Q12: How do you perceive this new technology affecting your workload? How might a new technology for providing care for diabetes or hypertension improve your working conditions? How might this new technology complicate your current work?**

**Thank you very much for taking the time to speak with me. Is there anything else you would like to share with me about your work as a Health Worker? Is there anything else you would like to share with me regarding your views on new technologies for hypertension or diabetes?**



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**Thank you for participating in this interview. This interview will be different than others that you might have participated in with previous visits. I will ask you questions and ask you to talk freely about your experiences. Please ask me at anytime if you do not understand a question, need more clarification, or would prefer to not answer a question. We ask that you provide honest answers that will provide us the best information possible to understand your personal experiences and opinions about hypertension and diabetes care and new technologies for health care.**

**Q1: I would like to begin with a few questions about your background. Can you tell me about where you are from, and how long you have lived in Solan?**

(Where were you born? Where are your parents from? What is your occupation? Who are your family members?)

**Q2: First, I am interested in your health generally. Can you tell me about your health?**

(What is your illness? When were you diagnosed with hypertension or diabetes and how? Whom did you first approach for advice and care after the diagnosis?)

**Q3: How do you manage your health? Do you manage diabetes and/or hypertension by yourself or does someone help you?**

(Are you taking any medication? Are you able to take the medications regularly? Did you make any changes in life style –diet, smoking, exercise- to maintain health? Do stress and emotions affect your health? What do you do to manage stress in your life? Do you think that hypertension/diabetes is sufficiently under control?)

**Q4: In your experience what sort of care you get from the Health worker at the nearest sub-centre? Can you tell me about your last visit? Describe what your visit was like, (e.g., did you travel far? Do you wait long to see the health worker? Did you feel like the health worker listened to you? Did you feel like you received sufficient care after you left the sub-center?)**

(More probes: Do you get your blood pressure/ blood sugar checked from the Health Worker? Do you get any lifestyle advices from the health worker? Do they provide any medicine and follow you for regular medicine intake and check-ups from the government doctor? What sort of care the Health Worker give to diabetes or hypertension patients during their field visit? Have you ever got any care or advice from the Health Worker for your illness- diabetes/hypertension?)

**Q5: What are your expectations from a Health Worker that would help you in controlling hypertension/diabetes in a better way?**

(Do you think that Sub-centre or the Health Worker has medicines for treating diabetes/hypertension? Do you think that the Health Worker can check your blood pressure? Do you think that the Health Worker can test your blood for diabetes? Do you think the Health Worker could prescribe you medicines for hypertension and diabetes? Would you prefer additional consultation from a doctor before having these medicines? Would you prefer the Health Worker giving you medicines after testing your blood than consulting a doctor? Would you prefer a doctor over health worker for health advices for controlling diabetes/hypertension)

**Q6: What are your expectations from a government hospital that would help you in treating your illness- hypertension/diabetes-in a better way?**

(Do you think that you will be able to get free medicines (*including insulin injection*) for treating your blood pressure/diabetes from the government hospital? If not, why? Do you think that your blood tests for diabetes and hypertension can be done at the government hospitals? What additional care you would demand from the government hospitals for treating hypertension and diabetes)

**Q7: Do you have a cell phone? (If not, do any of your family members have that?) Do you get SMS and read it? Would you like it if the hospital sent you a SMS every day to remind you take medicines, exercise regularly, quit tobacco use, in order to help control your diabetes/hypertension? Can you describe why it would or would not be useful?**

(How regularly are you able to take medicines, and exercise? Is there anybody in your family who helps you reminding your daily medicines, follow-up consultations with the Health Worker, Doctor? Do you or your family have a cell phone? How good it would if you get reminders through SMS to your mobile phone? What would be your preferred language to receive these message and time? Would you prefer pictures in SMS as opposed to text? Would you recommend your spouse/children receiving these messages to help you more compliant to these advises? How often you change your mobile phone number? Are you willing to share your mobile number to a Health Worker to activate such a reminder?)

**Q8: Would you be receptive to a Health Worker regularly visiting your home to check your blood pressure and making changes to medication compared to you visiting a doctor at the government hospital for the check-ups? Do you think this would improve your health, and your ability to care for your diabetes and/or hypertension? Please explain why or why not.**

(Would you prefer a health worker who comes to your home to help you care for your health, or do you prefer seeking care at the hospital where you can meet the doctor?)

**Thank you very much for taking the time to speak with me. Is there anything else you would like to share with me?**

## **Appendix – 4: Clinical Management Guidelines used in the intervention**



**Clinical Management Guideline for hypertension**

<b>Clinical parameters</b>	<b>If Age&lt;55</b>	<b>If Age≥55</b>	<b>Messages</b>
if (SBP≥140<160) OR (DBP≥90<100)	Life Style Advices, If on medication, continue	Life Style Advices, If on medication, continue	
if ((SBP≥160) OR (DBP≥100)) AND (NO co-morbidities- COPD/ASTHMA, MYOCARDIAL INFARCTION, RENAL/LIVER FAILURE, PVD, HEART BLOCK, DIABETES)	1st: ACEi/ARB or CCB 2nd: ACEi/ARB + CCB or ACEi/ARB+Diuretic 3rd: ACEi/ARB + CCB + Diuretic	1st: CCB or Diuretics 2nd: ACEi/ARB + CCB or CCB + Diuretic 3rd: ACEi/ARB + CCB + Diuretic	If on medication, consider increasing the dose up or adding 2nd/3rd line drug.
if ((SBP≥160) OR (DBP ≥100)) AND (COPD/ASTHMA)	1st: CCB 2nd: CCB + ACEi/ARB or CCB + Diuretic 3rd: ACEi/ARB + CCB + Diuretic	1st: CCB 2nd: CCB + ACEi/ARB or CCB + Diuretic 3rd: ACEi/ARB + CCB + Diuretic	Avoid BB. If on medication, consider increasing the dose up or adding 2nd/3rd line drug.
if ((SBP≥140) OR (DBP ≥90)) AND (DIABETES)	1st: ACEi/ARB + ASA 2nd: ACEi/ARB + CCB or ACEi/ARB + Diuretic along with ASA 3rd: ACEi/ARB + CCB + Diuretic along with ASA 4th: Add Alpha Blocker or BB along with ASA	1st: CCB (PREFERRED) or ASA OR ACEi/ARB along with ASA 2nd: ACEi/ARB + CCB or ACEi/ARB + Diuretic along with ASA 3rd: ACEi/ARB + CCB + Diuretic along with ASA 4th: Add Alpha Blocker or BB along with ASA	If on medication, consider titrating the dose up or adding 2nd/3rd line drug. ASA Contraindicated if SBP>160 or DBP>100 or having gastritis or Aspirin Allergy
if ((SBP≥140) OR (DBP ≥90)) AND (MYOCARDIAL INFRACTION)	1st: BB + ASA 2nd: BB + CCB or BB + ACEi/ARB along with ASA 3rd: BB + ACEi/ARB + CCB/Diuretics along with ASA	1st: BB + ASA 2nd: BB + CCB or BB + ACEi/ARB along with ASA 3rd: BB + ACEi/ARB + CCB/Diuretics along with ASA	If on medication, consider titrating the dose up or adding 2nd/3rd line drug. ASA Contraindicated if SBP>160 or DBP>100 or having gastritis or Aspirin Allergy
if ((SBP≥140) OR (DBP	1st: CCB	1st: CCB	Avoid ACEi/ARB. If on medication,

<b>Clinical Management Guideline for hypertension</b>			
<b>Clinical parameters</b>	<b>If Age&lt;55</b>	<b>If Age≥55</b>	<b>Messages</b>
≥90)) AND (RENAL/LIVER FAILURE {CREATININE> 3mg})	2nd: CCB + Diuretic 3rd: ADD Alpha Blocker or BB or Other Diuretic	2nd: CCB + Diuretic 3rd: ADD Alpha Blocker or BB or Other Diuretic	consider titrating the dose up or adding 2nd/3rd line drug.
if ((SBP≥140) OR (DBP ≥90)) AND ((PVD))	1st: CCB + ASA 2nd: CCB + ACEi/ARB or CCB + Diuretic along with ASA 3rd: CCB + ACEi/ARB + Diuretic along with ASA 4th: Add Alpha Blocker or Other Diuretic along with ASA	1st: CCB + ASA 2nd: CCB + ACEi/ARB or CCB + Diuretic along with ASA 3rd: CCB + ACEi/ARB + Diuretic along with ASA 4th: Add Alpha Blocker or Other Diuretic along with ASA	Avoid BB. If on medication, consider titrating the dose up or adding 2nd/3rd line drug. ASA Contraindicated if SBP>160 or DBP>100 or having gastritis or Aspirin Allergy
if ((SBP≥140) OR (DBP ≥90)) AND ((HEART BLOCK))	1st: ACEi/ARB 2nd: ACEi/ARB + CCB or ACEi/ARB + Diuretic 3rd: ACEi/ARB + CCB + Diuretic 4th: Add Alpha Blocker or Other Diuretic	1st: CCB (PREFERRED) OR ACEi/ARB 2nd: CCB + ACEi/ARB or CCB + Diuretic 3rd: CCB + ACEi/ARB + Diuretic 4th: Add Alpha Blocker or Other Diuretic	Verify Again. DILTIAZEM & VERAPAMIL & BB Contraindicared. If on medication, consider titrating the dose up or adding 2nd/3rd line drug.
if DBP≥130	Hypertensive emergency. Refer the patient immediately	Hypertensive emergency. Refer the patient immediately	

<b>Clinical Management Guideline for Diabetes Mellitus</b>	
<b>FAIR CONTROL, INSUFFICIENT CONTROL=</b>	<b>((FBS&lt;110) AND (PP=200-300)) OR ((FBS =110 - 130) AND (PP=140-300)) OR (((FBS&gt;130) AND (PP&lt;=200))</b>
If (No OHA USE) AND (No INSULIN USE) AND BMI <= 23	1 Unit SU (5mg Glibenclamide OR 80mg Gliclazide)
If (No OHA USE) AND (No INSULIN USE) AND BMI > 23	500mg Metformin
If (1 or 2 OHA, NOT AT MAXIMUM DOSE is in USE) AND (NO INSULIN USE)	Consider 1 UNIT increment ( SU { 5mg Glibenclamide, OR 80mg Gliclazide}, OR 500mg Metformin, OR 15mg Pioglitzone)
If (2 OHA AT MAXIMUM DOSE IS IN USE) AND (NO INSULIN USE)	ADD 3rd OHA (500mg Metformin OR SU{ 5mg Glibenclamide, OR 80mg Gliclazide} OR 15mg Pioglitazone)
If (3 OHA AT MAXIMUM DOSE IS IN USE) AND (NO INSULIN USE)	Start Insulin-Bedtime NPH Dose (10 units or 0.2U/kg/day). MESSAGE*
<b>POOR CONTROL, VERY POOR CONTROL=</b>	<b>((FBS&gt;130) AND (PP=201-300)) OR ((FBS&lt;110) AND (PP≥301)) OR ((FBS=110-130) AND (P≥301)) OR ((FBS&gt;130) AND (PP≥301))</b>
If (No OHA USE) AND (No INSULIN USE) AND BMI <= 23	2 Unit SU (10mg Glibenclamide OR 160mg Gliclazide)
If (No OHA USE) AND (No INSULIN USE) AND BMI > 23	1000mg Metformin
If (1 or 2 OHA, NOT AT MAXIMUM DOSE is in USE) AND (NO INSULIN USE)	Consider 2 Unit increment (2 of the same or 2 different) ( SU { 10mg Glibenclamide OR 160mg Gliclazide} OR 1000mg Metformin OR 30mg Pioglitzone)
If (2 OHA AT MAXIMUM DOSE IS IN USE) AND (NO INSULIN USE)	ADD 1 Unit addition of 3rd OHA (500mg Metformin OR SU { 5mg Glibenclamide OR 80mg Gliclazide} OR 15mg Pioglitazone)
If (3 OHA AT MAXIMUM DOSE IS IN USE) AND (NO INSULIN USE)	Insulin-Bedtime NPH Dose (10 units or 0.2U/kg/day). MESSAGE*
IF (INSULIN IN USE) AND (FBS<=70)	Reduce NPH dose. MESSAGE*
IF (INSULIN IN USE) AND (FBS>120)	Increase NPH dose up to .5U/kg/day. MESSAGE*

*\*MESSAGE: Review FBS after 1 week (Target FBS: 80-110). If current insulin dose is @ .5U/kg, add AM NPH (10 units or 0.2U/kg/day), Maximum NPH upto 20 Units only. If target not achieved, shift to PM Insulin two times daily*

**Appendix – 5: List of data elements in the Smartphone-based clinical decision-support tool**

<b>List of Data Elements in the Smartphone-based clinical decision-support tool</b>			
<b>No</b>	<b>Original List of data elements</b>	<b>No</b>	<b>Data elements after iterations</b>
1	Male/Female	1	Male/Female
2	Age	2	Age
3	Tobacco use (Y/N)	3	Tobacco Use (Y/N)
4	History of diabetes (Y/N)	4	Alcohol Use (Y/N)
5	Post-menopausal Women(Y/N)	5	Regularly exercising
6	Family history of premature Coronary Artery Disease (males <55 years, female >65 years) (Y/N)	6	Peripheral vascular disease (Y/N)
7	History of heart disease (any history of heart attack, angina, heart failure, any surgical procedure on coronary vessels) (Y/N)	7	Myocardial Infarction (Y/N)
8	History of stroke or Transient Ischemic attack (Y/N)	8	Chronic Obstructive Pulmonary Disease /Asthma (Y/N)
9	History of Renal disease (renal failure - S. creatinine>2 mg/dl; or diabetic nephropathy) (Y/N)	9	Renal/Liver Failure (Creatinine>3mg) (Y/N)
10	History of vascular disease (peripheral arterial disease, eg, claudication; or aortic dissection) (Y/N)	10	Heart Block (Y/N)
11	History of hypertensive retinopathy (e.g. haemorrhages or exudates OR papilledema) (Y/N)	11	Diabetes (Y/N)
12	Any evidence of LVH (on an ECG) (Y/N)	12	Family History of Diabetes (Y/N)
13	Any evidence of microalbuminuria / proteinuria and or high serum creatinine (1.2-2.0mg/dl) (Y/N)	13	Waist Circumference (cm)
14	Any evidence of atherosclerotic plaques in the carotids (ultrasound or radiological) (Y/N)	14	Systolic Blood Pressure 1
15	Any evidence of hypertensive retinopathy (Y/N)	15	Systolic Blood Pressure 2
16	Diagnosed case of hypertension (Y/N)	16	Diastolic Blood Pressure 1
17	If yes, is the BP under control	17	Diastolic Blood Pressure 2
18	Systolic Blood Pressure 1	18	Height (cm)
19	Systolic Blood Pressure 2	19	Weight (Kg)
20	Diastolic Blood Pressure 1	20	Fasting Blood Sugar level
21	Diastolic Blood Pressure 2	21	Post-prandial blood sugar level
22	Height (Mtr)	22	Oral hypoglycaemic agent use
23	Weight (Kg)	23	Insulin Use
24	Waist circumference (cm)		
25	Hip circumference (cm)		
26	Total Cholesterol level		
27	LDL –Cholesterol level		
28	Triglyceride level		
29	HDL-Cholesterol level		
30	Serum Creatinine level		
31	Urinary albumin (Y/N)		
32	Fasting Blood Glucose level		
33	Uric Acid (Y/N)		

<b>List of Data Elements in the Smartphone-based clinical decision-support tool</b>			
<b>No</b>	<b>Original List of data elements</b>	<b>No</b>	<b>Data elements after iterations</b>
34	Haemoglobin level		
35	Serum Potassium level		
36	Urine Routine & Microscopic results		

**Appendix – 6: Interview-guides used for evaluation of the implementation of the intervention**





**DIRECTIONS:** The qualitative interview begins with open ended questions that point to starting a dialogue. The interviewer should encourage the study participant to do most of the talking, but should use the questions listed here as a guide. After you ask each question, wait for the study participant to respond and go on to the next question when you are satisfied with the answer. If it seems as though the study participant did not understand a question, then repeat it or ask it in another way. If the study participant goes on talking without much prompting, then let them guide the conversation. Bold indicates major questions and probes are in parentheses. Mentally check off these questions as they are asked so you do not repeat a question if it has been discussed previously.

Remember to audio record each interview. Use a back-up recorder to prevent technological problems. Please note down **AGE and GENDER**

**Thank you for participating in this interview. This interview will be different than others that you might have participated in. I will ask you questions and ask you to talk freely about your experiences. Please ask me at anytime if you do not understand a question, need more clarification, or would prefer to not answer a question. We ask that you provide honest answers that will provide us the best information possible to understand your personal experiences and opinions about hypertension and diabetes care and new technologies for health care.**

**Q1:I would like to begin with a few questions about your background. Can you tell me about where you are from, and how long you have lived in Solan?**

(Where were you born? Where are your parents from? Where did you receive your medical training? What other training have you received? When did you join government service? Have you only worked in Solan district, or have you worked elsewhere, as well? If you have worked elsewhere, can you please describe that experience and position?)

**Q2:Can you tell me about your daily routine working as a medical officer in Solan?**

(When do you begin your day? Can you walk me through a typical day? [What do you do in the morning vs afternoon/etc])

**Q3:In your opinion what are the inadequacies at this hospital that you feel as impediments in treating hypertension/diabetes patients? Are these generic issues?**

(In your opinion the manpower, drug supply, laboratory facilities, training and supervision of staff is adequate for treating hypertension/diabetes patients? Is it a generic/systemic issue?)

**Q4: In your opinion what could be potential solution for these barriers?**

(How to solve the inadequacies for each of these components: - explore for manpower, drug supply, laboratory facilities, training and supervision. Similarly how these systemic/generic issues can be solved)

**Q5: In your opinion what are the major challenge in achieving BP/sugar control from the perspective of a doctor? What are the patient motivation tactics used by you? What are the drugs with highest compliance observed?**

**Q6: What is your opinion about the mPower Heart Project that is being implemented in this hospital?**

In your opinion what impact does it have on hypertension/diabetes care at this hospital? explore about patient screening, patient evaluation, patient management

**Q7: How do you view the role of the new NCC in caring HTN/DM patients? What impact they had on caring HTN/DM patients (patient screening, evaluation, follow-up care)? What are your thoughts on patient experience with the care-coordinators?**

**Q8: What are your thoughts on the new counselling services by the NCC for hypertension/diabetes patients?**

Do you think that counselling services are effective? Do you find the any improvement in patient compliance? What are your suggestions to improve this service?

**Q9: In your opinion, what additional things can be done to improve the service of NCCs (training, critical skills, work flow)**

**Q10: What is your opinion regarding the new clinical management guideline that is being implemented at this hospital? Is there any difficulty you face in following the guideline? What are your suggestions to modify the clinical management guidelines used in this software more relevant to improve the care?**

**Q11: In your opinion, what are the difficulties that you face in following the clinical management plan suggested by the smartphone software?**

**Q12: How do the new smartphone software suggestions affect your practice? Is it easy to follow in your clinical practice? What impact it had on:**  
starting OHA /BP therapy  
SBP/FBS level the doctor reevaluates therapy  
BP/sugar monitoring frequency advice given to patients on diet/exercise  
BP monitoring frequency advice given to patients on drugs

**Q13: Will you recommend this software for other CHCs in this state? If no, Why? Do you have any suggestions to modify this software?**

**Q14: What is your opinion on the patient card and do you think that the new card help improving your practice?**

**Q15: What are the complexities that you feel about this project? What additional training/ knowledge are needed for various staff to address these complexities?**

**Q16: If you were to plan this new project implementation in this hospital, what additional changes you would bring in?**

In your opinion, what additional things are to be done to improve the implementation of this project? For example involvement of other health care staff, changing the timing of clinic, supplies, nature and relationship/collaboration between departments

**Thank you very much for taking the time to speak with me. Is there anything else you would like to share with me about your work as a medical officer in Solan? Is there anything else you would like to share with me regarding your views on new technologies for chronic disease care?**



**DIRECTIONS:** The qualitative interview begins with open ended questions that point to starting a dialogue. The interviewer should encourage the study participant to do most of the talking, but should use the questions listed here as a guide. After you ask each question, wait for the study participant to respond and go on to the next question when you are satisfied with the answer. If it seems as though the study participant did not understand a question, then repeat it or ask it in another way. If the study participant goes on talking without much prompting, then let them guide the conversation. Bold indicates major questions and probes are in parentheses. Mentally check off these questions as they are asked so you do not repeat a question if it has been discussed previously.

Remember to audio record each interview. Use a back-up recorder to prevent technological problems.

**Thank you for participating in this interview. This interview will be different than others that you might have participated in with previous visits. I will ask you questions and ask you to talk freely about your experiences. Please ask me at anytime if you do not understand a question, need more clarification, or would prefer to not answer a question. We ask that you provide honest answers that will provide us the best information possible to understand your personal experiences and opinions about diabetes care and new technologies for health care.**

**Q1: I would like to begin with a few questions about your background. Can you tell me about where you are from, and how long you have lived in Solan?**

(Where were you born? Where did you receive your Nurse training? For how long have you been to the NCD care coordinator position? What other training have you received?)

**Q2: Can you tell me about your daily routine working as a NCD Care coordinator?**

(When do you begin your day? Can you walk me through a typical day? [What do you do in the morning vs. afternoon/etc] Is every day very similar or do you find variation between days, weeks or months?)

**How many doctors work at your hospital? (MBBS & MDs)? How many staff works at the OPD? Do you have a lab technician?**

**Q3: What is the workflow that you experience at the Outpatient clinic and where is your position in the workflow?**

**Q4: Do you spend time caring for people with hypertension or diabetes at OPD? If not, why? If yes, I am interested in how much time you spend providing care for people with diabetes and/or hypertension. How much of your day do you spend caring for or educating people with diabetes and/or hypertension? How many hypertension patients and how many diabetes patients do you come across a day?**

**Q5** What types of tasks are you expected to conduct on a daily basis? What percentage of those tasks includes hypertension education and/or support for people managing their hypertension? Similarly what proportion of those tasks includes diabetes education and/or support for people managing their diabetes?

*[examples of diabetes/hypertension care that a NDC care coordinator can undertake: measuring blood pressure, providing health education to reduce salt intake, quit tobacco, reduce the use of sugary, oily foods, promote the vegetables and fruits consumption]*

**Q6:** Do you think that you require any additional training or skills to provide the care for hypertension/diabetes patients in a much better way?

**Q7:** What are the common concerns that you encounter from people with hypertension? How do you manage treatment for people with hypertension?

**Q8:** What are the common concerns that you encounter from people with diabetes? How is this similar or different to hypertension? How do you manage treatment for people with diabetes?

**Q9:** Do you have enough supply of medicines at hospital for these two diseases? Do you have enough laboratory support for these diseases? If no, how these are managed currently?

**Q10:** Does other staff at the hospital influence your current duties and responsibilities in the project? IF so, can you explain?

**Q11:** Do you face any other difficulties in performing your duties as NCD coordinators? Can you elaborate on that?

**Q12:** Is there a guideline that is followed for the management of diabetes and hypertension patients by the doctor? If so can you explain that?

**Q13:** Do you think that the mobile phone software is of any help to your duties? If so, can you narrate on that?

**Q14:** What are the difficulties that you face in using the mobile phone software? Can you narrate on that? Do you have any suggestion to rectify it?

Explore on ease, time spend, effect on work flow, quality, boredom, difficulty in reading and interpreting the prompts, difficult to implement suggestions

**Q15: Do you think the doctors are cooperating in the use of this software? Do they accept the software prompts on drugs?**

**Q16: What skills you have learned while working in this project? For example, taking medical history, lifestyle advises.**

**Q17: How patients respond you when you start asking them questions about diabetes/hypertension and take other clinical measurements?**

**Q18: Do you do lifestyle counselling and advise them on drug intake and compliance? If so what are the difficulties you face in educating and motivating the patients?**

**Q19: Do you find all the patients are getting follow-up care? How do you identify the follow-up patients? What are the difficulties you face in the identifying the follow-up patients?**

Do you think Mobile numbers are of any use?

**Q20: How does the patient referral care happening? Where are the patients referred? Do you get to see them back?**

**Q21: How much patients you think that you can comfortably manage in an OPD?**

**Q22: What additional level of linking with the system would make the care better for the patients and also for the routine followed in the hospital?**

**Thank you very much for taking the time to speak with me. Is there anything else you would like to share with me about your work as a NCD care coordinator? Is there anything else you would like to share with me regarding your views on new technologies for hypertension or diabetes?**





**DIRECTIONS:** The qualitative interview begins with open ended questions that point to starting a dialogue. The interviewer should encourage the study participant to do most of the talking, but should use the questions listed here as a guide. After you ask each question, wait for the study participant to respond and go on to the next question when you are satisfied with the answer. If it seems as though the study participant did not understand a question, then repeat it or ask it in another way. If the study participant goes on talking without much prompting, then let them guide the conversation. Bold indicates major questions and probes are in parentheses. Mentally check off these questions as they are asked so you do not repeat a question if it has been discussed previously.

Remember to audio record each interview. Use a back-up recorder to prevent technological problems. **Please also note age and gender of the participant.**

**Thank you for participating in this interview. I will ask you questions and ask you to talk freely about your experiences. Please ask me at any time if you do not understand a question, need more clarification, or would prefer to not answer a question. We ask that you provide honest answers that will provide us the best information possible to understand your personal experiences and opinions about hypertension and diabetes care and new technologies for health care.**

**Q1: I would like to begin with a few questions about your background. Can you tell me about where you are from, and how long you have lived in Solan?**

(Where were you born? Where are your parents from? What is your occupation? Who are your family members?)

**Q2: First, I am interested in your health generally. Can you tell me about your health?**

(What is your illness? When were you diagnosed with hypertension or diabetes and how was it diagnosed? Whom did you first approach for advice and care after the diagnosis?)

**Q3: How do you manage your health?**

(What are the medicines that you take for hypertension/diabetes? Is there anybody in your family who helps you reminding your daily medicines, follow-up visits? How frequently you do the follow-up visits?)

**Q4: Do you think that hypertension/diabetes is sufficiently under control? Can you explain us what difficulties you face to manage blood pressure/blood glucose under control)**

(What are the difficulties you face in changing life style - specifically for tobacco use, diet and physical activity? What are the difficulties you face in adhering to regular intake of medicines? How do you make sure that you take your daily medication and follow-up visit to the hospital?)

**Q5: When you visit CHC what sort of care you get from the CHC? Can you tell me about your last visit?**

**Do you find any difference in the care given from this hospital to you, and if so, can you explain us?**

(Describe what your visit was like, (e.g., did you wait long to see the NCC/Doctor? Did you feel like the NCC/Doctor listened to you? Do you get your blood pressure/ *blood sugar* checked from the NCC?)

**Q6: What advice you received from the NCC for your illness- diabetes/hypertension? Do you think this would improve your health, and your ability to care for your diabetes and/or hypertension?**

**Please explain why or WHY NOT?**

(Can you explain us about any changes, you made, in your life style –diet, smoking, exercise- to maintain health as per NCC's advice? Do you think that regularly consuming drug harms your health?)

**Q7: Can you explain us what are the difficulties you face because of the additional questions and examinations by the NCC?**

(Probe on additional wait time, commuting between NCC and Doctor, lab investigations etc.)

**Q8: Can you tell us your opinion on the NCC recording your health parameters in the 'Smartphone' during your hospital visit?**

(Do you think that such recording would improve the care given to you? Please explain why or WHY NOT?)

**Q9: What are the difficulties faced by you in following the advices suggested by the doctor and NCC?**

(Do you get medicines from this hospital till your next follow-up visit? Do you buy medicines from private chemist store? How expensive are these medications for you for consuming them regularly? How regularly are you able to take medicines, and exercise as advised by the NCC?)

**Q10: What difficulties you face in regularly coming to the hospital for follow-up visits?**

(Do you bring your OPD card during follow-up visit?)

*Use the Probe* – In your opinion is there any benefits in bringing this card back during your follow-up visit?)

**Thank you very much for taking the time to speak with me. Is there anything else you would like to share with me?**

**Appendix – 7: Ethics approvals from the London School of Hygiene & Tropical  
Medicine, Public Health Foundation of India and Centre for Chronic Disease Control,  
New Delhi**

**LONDON SCHOOL OF HYGIENE  
& TROPICAL MEDICINE**

**ETHICS COMMITTEE**



**APPROVAL FORM**

**Application number: 5833**

Name of Principal Investigator **Ajay Vamadevan Sarala**

Faculty **Epidemiology and Population Health**

Head of Faculty **Professor Laura Rodrigues**

**Title: A smart-phone enabled diagnosis and management services for hypertension and diabetes at primary health settings in Kerala, India**

This application is approved by the Committee.

**Chair of the Ethics Committee**



**Date** .....16 November 2010 .....

**Approval is dependent on local ethical approval having been received.**

**Any subsequent changes to the application must be submitted to the Committee via an E2 amendment form.**

London School of Hygiene & Tropical Medicine  
Keppel Street, London WC1E 7HT  
United Kingdom  
Switchboard: +44 (0)20 7636 8636  
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**Observational / Interventions Research Ethics Committee**

Ajay Vamadevan Sarala  
Research Degree Student  
NCDE/EPH  
LSHTM

26 July 2012

Dear Dr Sarala,

**Study Title:** Development of a Smartphone enabled hypertension and diabetes management package to facilitate evidence-based care delivery at primary health care facilities in India: A formative research to inform intervention design  
Previous title: A smart-phone enabled diagnosis and management services for hypertension and diabetes at primary health settings in Kerala, India

**LSHTM ethics ref:** 5833  
**LSHTM amend no:** A344

Thank you for your application of 28 June 2012 for the amendment above to the existing ethically approved study and submitting revised documentation. The amendment application has been considered by the Interventions Committee.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above amendment to research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

**Conditions of the favourable opinion**

Approval is dependent on local ethical approval for the amendment having been received, where relevant.

**Approved documents**

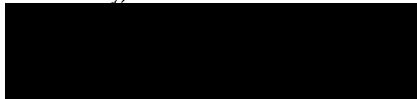
The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
LSHTM amendment application	n/a	28/06/2012
Protocol	V3	01/03/2012

**After ethical review**

Any further changes to the application must be submitted to the Committee via an E2 amendment form. The Principal Investigator is reminded that all studies are also required to notify the ethics committee of any serious adverse events which occur during the project via form E4. An annual report form (form E3) is required on the anniversary of the approval of the study and should be submitted during the lifetime of the study. At the end of the study, please notify the committee via form E5.

Yours sincerely,



Professor Andrew J Hall  
Chair

[ethics@lshtm.ac.uk](mailto:ethics@lshtm.ac.uk) <http://intra.lshtm.ac.uk/management/committees/ethics/>



TRC-IEC No:	TRC-IEC 82/11	Date:	15/4/11
Project Title:	A smart-phone enabled diagnosis and management services for hypertension and diabetes at primary health settings in Kerala, India.		
Principal Investigator:	Mr. V. S. Ajay		
Review	Full Review <input type="checkbox"/>	Expedited Review	<input checked="" type="checkbox"/>
Date of review:	NA		
Date of previous review:	NA (in case of re-submitted applications)		
Decision of the IEC:	Approval <input checked="" type="checkbox"/>	Resubmission	<input type="checkbox"/>
	Conditional Approval <input type="checkbox"/>	Study can begin <input type="checkbox"/>	Study cannot begin <input type="checkbox"/>
Requirements to be fulfilled in case of conditional approval:	NA		
Suggested alterations in case of resubmission:	NA		
In case of approval, recommended for a period of:	Duration of the project		
Comments:			

**Please note: Beginning of the research based on this approval implies acceptance of the following conditions:**

1. PI will inform the Secretariat of the start date of the study.
2. The PI will inform the IEC in case of any adverse events.
3. The PI will inform the TRC (Technical Review Committee) and IEC in case of any change of study procedure (including- changes in the informed consent form, recruitment procedure, potential research participant information), site and investigator.
4. The PI will inform the TRC - IEC Secretariat on termination of the study and submit a final report within 3 months of completion of the study.
5. Members of the IEC have the right to monitor the study with prior intimation.
6. Progress report to be submitted to the TRC-IEC Secretariat every 6 months from the date of start of study.
7. This permission is only for the period mentioned above.

  
**Dr. Beena Varghese**  
**Name and signature of Member Secretary**  
CHAIRMAN / MEMBER SECRETARY  
 PUBLIC HEALTH FOUNDATION OF INDIA

<sup>1</sup> Adapted from the ICMR form: available at <http://www.icmr.nic.in/bioethics/Communication%20of%20Decision%20of%20the%20IEC.doc>

# Institutional Ethics Committee

Public Health Foundation of India

Public Health Foundation of India (PHFI) | 4, Institutional Area | Vasant Kunj | New Delhi - 110 070 | INDIA

## Communication of Decision of the IEC<sup>1</sup>

Form II

TRC-IEC No:	TRC-IEC-82.1/11- Amendment	Date:	16/4/2012		
Project Title:	Development of a Smartphone enabled hypertension and diabetes management package to facilitate evidence-based care delivery at primary health care facilities in India: A formative research to inform intervention design				
Principal Investigator:	VS Ajay				
Review	Full review	<input checked="" type="checkbox"/>	Expedited review	<input type="checkbox"/>	
Date of review:	28/03/2012	(DD/MM/YYYY)			
Date of previous review:	(in case of re-submitted applications) (DD/MM/YYYY)				
Decision of the IEC:	Approval	<input checked="" type="checkbox"/>	Study can begin	Resubmission	<input type="checkbox"/>
	Conditional Approval	<input type="checkbox"/>		Study cannot begin	<input type="checkbox"/>
Requirements to be fulfilled in case of conditional approval:	Not applicable				
Suggested alterations in case of resubmission:	Not applicable				
In case of approval, recommended for a period of :	Duration of study				
Comments:	The following amendments were approved: Location: Changing the location from Kerala to Himachal Pradesh Setting: Changing the setting from Primary Health Centre to Community Health Centre				

**Please note: Beginning of the research based on this approval implies acceptance of the following conditions:**

1. PI will inform the Secretariat of the start date of the study.
2. The PI will inform the IEC in case of any adverse events.
3. The PI will inform the TRC (Technical Review Committee) and IEC in case of any change of study procedure (including- changes in the informed consent form, recruitment procedure, potential research participant information), site and investigator.
4. The PI will inform the TRC - IEC Secretariat on termination of the study and submit a final report within 3 months of completion of the study.
5. Members of the IEC have the right to monitor the study with prior intimation.
6. Progress report to be submitted to the TRC-IEC Secretariat every 6 months from the date of start of study.
7. This permission is only for the period mentioned above.

  
 Prof. Ramanuj Laxminarayan  
 Name and signature of Member Secretary  
 CHAIRMAN / MEMBER SECRETARY  
 INSTITUTIONAL ETHICS COMMITTEE  
 PUBLIC HEALTH FOUNDATION OF INDIA

<sup>1</sup> Adapted from the ICMR form: available at <http://www.icmr.nic.in/bioethics/Communication%20of%20Decision%20of%20the%20IEC.doc>



# CENTRE FOR CHRONIC DISEASE CONTROL

Dr. R. Tandon  
President

Dr. K. Srinath Reddy  
Secretary

Ms. Monika Arora  
Treasurer

## Institutional Ethics Committee (IEC)

IRB00006330 Expires on: JAN/03/2014

Organization No: IORG0005264  
Expires on : JAN/03/2014

OHRP Assurance No : FWA00012746  
Expires on : JAN/31/2014


### Protection of Human Subjects IEC Certification/Declaration of Exemption

1. Request Type <input checked="" type="checkbox"/> ORIGINAL <input type="checkbox"/> CONTINUATION <input type="checkbox"/> EXEMPTION	2. Type of Mechanism <input checked="" type="checkbox"/> GRANT <input type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> OTHER: _____	3. Name of Funding Agency and, if known, Application or Proposal Identification No.  <b>Medtronic Foundation</b>
4. Title of Application or Activity <b>m-Power Heart Project. Project Code: CCDC-IEC_08_2012</b>		5. Principal Investigator: <b>Dr. Dorairaj Prabhakaran</b> 6. Key Personnel at CCDC & Role : <b>Dr. Dorairaj Prabhakaran (PI)</b>

#### 7. Certification of IRB Review

- This activity has been reviewed and approved by the IEC in accordance with the Indian Council for Medical Research (ICMR) Guidelines and other GCP recommendations.  
by:  Full IRB Review on [25/JULY/2012]. or  Expedited Review on [DD/MONTH/YYYY]
- This activity contains multiple projects, some of which have not been reviewed. The IEC has granted approval on condition that all projects covered by the Indian Council for Medical Research Guidelines will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

#### 8. Comments: Approved

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution <b>CENTRE FOR CHRONIC DISEASE CONTROL PAWA's PRESIDENTIAL BUSINESS PARK, Tower No. 4 &amp; 5, C-9, Commercial Complex, Vasant Kunj New Delhi-110070</b>
11. Phone No. : +91- 11- 460-460-00 12. Fax No. : +91- 11- 416-485-13 13. Email : <a href="mailto:shifalika.goenka@ccdcindia.org">shifalika.goenka@ccdcindia.org</a>	
14. Name of Official: <b>Dr. Shifalika Goenka, MBBS, PhD.</b>	15. Title: <b>Member Secretary, CCDC Ethics Committee AND Associate Professor, Public Health Foundation of India</b>
16. Signature 	17. Date: <b>26 NOVEMBER, 2012</b>

Tower No. 4, C-9 Commercial Complex, Vasant Kunj, New Delhi-110070, India  
Tel: + 91-11-43421900 Fax: +91-11-43421975 E-mail: [ccdc@ccdcindia.org](mailto:ccdc@ccdcindia.org)