

A PROGRAM AND EVALUATION PLAN  
FOR ADVANCING MEDICATION EDUCATION  
AND ADHERENCE FOR DIABETES AND HYPERTENSION  
IN UMLAZI TOWNSHIP, KWAZULU-NATAL  
REPUBLIC OF SOUTH AFRICA

By

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A Master's Paper submitted to the Faculty of  
the University of North Carolina at Chapel Hill  
in partial fulfillment of the requirements for  
the degree of Master of Public Health in  
the Public Health Leadership Program

Chapel Hill

2019

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## ABSTRACT

Miranda Law: A Program and Evaluation Plan for Advancing Medication Education and Adherence for Diabetes and Hypertension in Umlazi Township, KwaZulu-Natal, Republic of South Africa  
(Under the direction of Lori Carter-Edwards)

Medication adherence plays a major role in the control and management of chronic disease states such as diabetes and hypertension. Methods to improve medication adherence through medication education or increasing social support alone have not always shown to improve adherence rates, but have found to be contributing factors.<sup>1-3</sup> As technology advances, mHealth has been increasingly explored as an avenue to combine efforts in communication, education, and support to patients to improve medication adherence and disease state control. This paper will begin with a review of the literature on mHealth programs targeted on improving medication education and adherence of diabetes and hypertension patients. The literature review was conducted on PubMed and identified seven studies for evaluation. Studies were evaluated for the mHealth program, implementation, and program outcomes.

Following the literature review, this paper describes a program plan for diabetes and hypertension medication adherence program (INSTEP). INSTEP is a mHealth based program that will combine the use of medication education, improved medication communication strategies, and social support, to advance medication adherence and control of diabetes and hypertension. INSTEP will partner with the South African Department of Health, in addition to other key stakeholders, and launch an initial pilot program in Umlazi township primary health clinics. Program evaluation will be both quantitative and qualitative and both the training program for the primary health care clinics and patient program will be evaluation. Implementation evaluations and outcome evaluations will aim to provide data for quality improvement opportunities as the program continues to run.

## ACKNOWLEDGEMENTS

I would like to thank everyone who has assisted and supported in the writing of this paper. To Advance Access and Delivery and Tom Nicholson, who so kindly allowed me to complete my practicum with them in South Africa, which ultimately led to the development of the program in this paper. To my husband and family who have supported me through the process. To Michael Wilson, who has helped me to refine ideas and realize their potential, serving as second reader. Finally, to Professor Lori Carter-Edwards who has guided me through this journey, serving as first reader, and a great mentor.

# TABLE OF CONTENTS

## Table of Contents

<b>LIST OF ABBREVIATIONS AND DEFINITIONS.....</b>	<b>VI</b>
<b>INTRODUCTION.....</b>	<b>1</b>
<i>DIABETES AND HYPERTENSION</i> .....	1
<i>ACCESS TO QUALITY CARE</i> .....	2
<i>MEDICATION EDUCATION</i> .....	4
<i>MEDICATION ADHERENCE</i> .....	6
<i>MHEALTH</i> .....	8
<i>PROGRAM RATIONALE</i> .....	8
<b>SYSTEMATIC REVIEW .....</b>	<b>9</b>
<i>SEARCH STRATEGY</i> .....	10
<i>RESULTS</i> .....	11
<i>Review Process</i> .....	11
<i>Study Characteristics</i> .....	12
<i>Study Outcomes</i> .....	17
<i>DISCUSSION</i> .....	19
<b>PROGRAM PLAN.....</b>	<b>21</b>
<i>PROGRAM OVERVIEW</i> .....	21
<i>PROGRAM CONTEXT</i> .....	23
<i>PROGRAM THEORY</i> .....	27
<i>GOALS AND OBJECTIVES</i> .....	29
<i>Short Term Goals and Activities</i> .....	29
<i>Long Term Goals</i> .....	32
<i>PROGRAM IMPLEMENTATION</i> .....	34
<i>Partnerships</i> .....	34
<i>Training and Integration</i> .....	36
<i>Enrollment and Data Collection</i> .....	37
<b>EVALUATION PLAN .....</b>	<b>42</b>
<i>RATIONALE AND OVERVIEW</i> .....	42
<i>POTENTIAL CHALLENGES</i> .....	43
<i>EVALUATION DESIGN</i> .....	45
<i>INSTITUTIONAL REVIEW BOARD CONSIDERATIONS</i> .....	51
<i>DISSEMINATION PLAN</i> .....	52
<b>CONCLUSION .....</b>	<b>52</b>
<b>REFERENCES .....</b>	<b>53</b>

## LIST OF ABBREVIATIONS AND DEFINITIONS

BP	Blood Pressure
CHW	Community Health Worker
DOH	Department of Health
HBM	Health Belief Model
HIV	Human Immunodeficiency Virus
INSTEP	Diabetes and Hypertension Treatment Adherence Program
LMIC	Low- and Middle-Income Countries
NCD	Non-communicable disease
NGO	Non-governmental Organization
NDP	National Development Program
PHCN	Primary Health Care Nurse
SBP	Systolic Blood Pressure
SCT	Social Cognitive Theory
SMS	Short Message Service
WHO	World Health Organization

## INTRODUCTION

### *Diabetes and Hypertension*

Non-communicable diseases (NCDs) have been increasing in prevalence throughout the world, with diabetes and hypertension being two of the most common NCDs. The World Health Organization (WHO) reports that from 1980 to 2014, the rate of diabetes rose from 108 million to 422 million, with rates rising quickest in low- and middle-income countries.<sup>4</sup> An estimated 1.1 billion people in the world have hypertension, with nearly 2/3 living in low- and middle-income countries.<sup>5</sup> As of 2015, one in four men and one in five women have hypertension.

South Africa has been no exception to the rise of NCD's. The H3Africa QWI-Gen study evaluated the prevalence and awareness of hypertension across six sites in Sub-Saharan Africa (Nanoro in Burkina Faso, Navrongo in Ghana, Nairobi in Kenya, Agincourt, Dikgale, and Soweto in South Africa) and found the highest prevalence (54.1%) in Soweto, the largest township in South Africa.<sup>6</sup> The study also reports that of the three South African sites evaluated (Agincourt, Dikgale, and Soweto), all three had an average prevalence of hypertension greater than 40%.<sup>6</sup> Prevalence of hypertension has also been evaluated in Limpopo province and KwaZulu-Natal, reporting rates of hypertension to be 41% and 33%, respectively.<sup>7,8</sup> Increasing rates of hypertension are not confined to those outside the health care workforce. A study of hypertension prevalence among primary health care professional nurses in the Eastern Cape reported rates of 52%, revealing the depth and breadth of the growing problem in the country.<sup>9</sup>

The International Diabetes Federation estimates that in 2015, nearly 2.3 million people in South Africa had diabetes with 500,000 – 5 million possible undiagnosed cases<sup>10</sup> The Institute of Health Metrics and Evaluation reported Diabetes to be the 5<sup>th</sup> leading cause of death in South Africa in 2017.<sup>11</sup> More recently published studies on the impact of lifestyle and socio-economic

inequalities in diabetes prevalence within the country report that 39% of diabetes is undiagnosed, largely due to poor access to care in areas of low socio-economic status<sup>12</sup>, which also results in the inability to properly determine the true rate of NCDs in these areas of the country. Socio-economic variables are significantly associated with self-reporting of diabetes included living in rural areas and increasing age. Of those who self-reported diabetes in the study, there were findings of poor rates of treatment initiation (only 61% were being treated) and control (only 31% of those treated were controlled) attributed to poor diabetes education and medication adherence.<sup>12</sup> Studies have also shown that among older adults (61+), diabetes is associated with poorer quality of life and greater disability.<sup>12</sup>

#### *Access to Quality Care*

Access to care contributes to both the under diagnoses of NCDs as well as the proper management of those who are diagnosed. It can be impacted by factors such as distance to the treatment center, the quality of care provided once patients reach the treatment center, and patients' additional comorbidities.

To address the problem of the long distances that patients have to reach primary health care clinics, home-based services have been implemented in areas of South Africa. The evaluation of an integrated community home-based care service in Limpopo Province found that the most common gaps in services when visiting patient homes included health education, giving medications, managing hypertension, and patient counseling.<sup>13</sup> Home-based treatment groups were also implemented in KwaZulu-Natal, which included nurses and community health workers (CHW) conducting home visits, monthly follow up visits, and adherence support for the treatment of multi-drug resistant tuberculosis. Results of this home-based treatment group showed reduced



rates of needing to escalate care (referral to hospital) and a reduction of severe adverse events and mortality,<sup>14</sup> revealing promising results to expanding such care to include treatment for chronic diseases.

Patients who are able to travel to primary health clinics are often faced with inadequate care due to high patient volume and an overworked staff. A study investigating the role of primary health care nurses (PHCN) that were part of a chronic illness program at primary health clinics in Soweto found multiple nurse complaints.<sup>15</sup> PHCNs felt that they were given responsibilities to care for patients but were not given the authority to act and that they were not given appropriate access to patient information, and that they often felt they lacked sufficient knowledge and confidence and did not have physicians available to consult.<sup>15</sup> Additionally, they felt the chronic disease program was not properly integrated into the clinic – resulting in staff shortages and inability to properly care for the patients.<sup>15</sup> PHCNs in this program highlighted the need for training around chronic disease management which would improve their ability and confidence to support treatment and linkage to care programs across a range of diseases.<sup>15</sup> Interviews with PHCNs working in Umlazi, the second largest township in South Africa, reveal that many nurses lack the proper patient education materials to provide their patients, that they often do not have space to hold support groups for patients that have diabetes and hypertension, and they lack the knowledge to properly dose and titrate insulin, making it difficult to properly educate their patients on what they should be doing.<sup>16</sup>

Although resources are often stretched in primary healthcare clinics, and nurses have multiple responsibilities beyond NCD screening and support, advancement is possible. A study on a structured NCD service in KwaZulu-Natal found that nurses, when provided with proper protocols and tools, are able to make an impact in advancing hypertension control for patients.<sup>17</sup>

This NCD program emphasized the importance of identifying and tackling adverse effects, educating patients on the necessity of life-long therapy, simplifying treatment regimens, and ensuring the patient is involved in their own care.<sup>17</sup> Emphasizing these points, patients had significantly improved adherence to medications.

Access to care can also be influenced by more pressing co-morbid disease states. For example, patients who are Human Immunodeficiency Virus (HIV) positive are more likely to be diagnosed and treated for diabetes and/or hypertension because of the urgency of their co-morbid disease state.<sup>18</sup> This represents an opportunity for case finding when treating other communicable disease states for patients.

### *Medication Education*

Medication education on managing diabetes and hypertension plays an important role in ensuring patients can adhere to their treatment regimen and thereby, successfully manage or control their conditions. Although both are important, medication education is distinct from health literacy, where the former refers to a patient's knowledge of why and how they are doing something and the latter refers to a patient's ability to read and understand instructions on taking medication.<sup>19</sup> A study evaluating the knowledge of symptoms and self-management of hypoglycemia in patients in a diabetic clinic in KwaZulu-Natal showed that of the 200 diabetic patients interviewed, the majority had fair to good knowledge about hypoglycemia; however, less than 25% knew what actions to take if they experienced an episode of hypoglycemia.<sup>20</sup> This knowledge can be lifesaving in instances when blood sugar is dangerously low and shows the need to improve education provided to patients with diabetes. A study evaluating 253 patients from 50 primary health clinics in the Limpopo Province revealed that less than a third of patients

knew what hypertension was, why blood pressure (BP) was recorded, and what normal BP should be.<sup>21</sup> The study also found that only 15% of the patients who received hypertension information received information specifically about the medications.<sup>21</sup>

Interventions to provide medication education to patients in South Africa has been met with conflicting results. A group diabetes education program was launched in Cape Town, offering four monthly education sessions in addition to routine care, reported that over 50% of recruited patients did not attend a single education session.<sup>2</sup> Additionally, the education sessions faced multiple barriers including the lack of space to hold session and lack of a guiding style (emphasis on collaboration, respect for choice and control, and empathetic listening) by the health promoters leading the session.<sup>2</sup> Despite its barriers and inability to replicate positive results from other group education interventions, the study did show that those who attended sessions showed an improvement in blood pressure, and a cost-effectiveness analysis revealed \$1862 per quality adjusted life year gained, indicating that such an intervention could be cost-effective.<sup>1,2</sup>

In another medication education intervention, the Take Five School group education program was launched for individuals with type 2 diabetes in the Western Cape.<sup>3</sup> Those who participated, staff and participants, felt that the groups enhanced social support and made some patients feel more comfortable to learn while appreciating the ability to learn from each other.<sup>3</sup> Constructive feedback also showed that patients would have wanted take-home materials to reinforce the information.<sup>3</sup> Further evaluation of the program revealed additional areas for improvement including healthcare staff feeling as if their patients did not take their advice and patients reporting that they did not always trust the advice of healthcare staff.<sup>3</sup> An exploration of patient experience in chronic care within Cape Town revealed useful information and opportunities for continued improvement in chronic disease care in South Africa.<sup>22</sup> Findings of

the study showed that patients often face multiple barriers to effective chronic disease management and the majority of patients reported not receiving adequate information, counseling, or support from their health care providers.<sup>22</sup> They felt the current method of care for treating their disease failed to meet their expectations,<sup>22</sup> indicating a need for a more patient-centered approach to managing NCDs.

### *Medication Adherence*

Patient knowledge of their chronic disease state(s) and the medication(s) they are taking is one link to the level of adherence for patients on NCD medications. Previously mentioned, several studies have reported low adherence rates among patients with chronic disease states, while highlighting the importance of understanding and accepting the medications prescribed.<sup>13,17</sup> A cross-sectional study in Limpopo province evaluated 137 patients with diabetes and found that younger age, current employment, and the ability to keep appointments were factors associated with improved medication adherence.<sup>23</sup> Poor adherence was often reported to be due to not having their pills, forgetting to take their medication, and travelling without taking enough pills with them to last their entire trip.<sup>23</sup> Those patients that were adherent to their medications recommended setting reminders, taking medications at meal times, and utilizing a treatment supporter.<sup>23</sup>

Methods have been utilized in an attempt to improve medication adherence for patients, some of which include next-generation electronic pill-boxes, adherence clubs, and medication pick-up points. The next-generation pillbox was tested for drug resistant tuberculosis and was found to be accepted and helpful for patients to remember to take their medications.<sup>24</sup> Patients who tested the electronic pill box made recommendations for the pill box to be able to set alarms

and reported that knowing someone was monitoring whether or not they were taking their medications made them feel special.<sup>24</sup> In an interview with a patient at a primary health care clinic in KwaZulu-Natal, the patient discussed a medication e-diary that was provided to him by a private physician which provides reminders for him to take his medication.<sup>25</sup> He reports that he always remembers his medications because an alarm goes off at 6:00 PM/18:00 and he has to answer a series of questions.<sup>25</sup>

Adherence clubs, which are medication pick up sites located closer to patient homes and are led by nurses, are another way to help patients become more adherent to their medications. A study on utilizing adherence clubs to improve antiretroviral therapy showed to be acceptable among patients, adoptable, appropriate and feasible.<sup>26</sup> Unfortunately, interviews with nurses in primary health care clinics in KwaZulu-Natal revealed multiple barriers with adherence clubs.<sup>16</sup> Due to the fact that nurses are tasked with transporting medications to adherence club locations, nurses often reported that transportation was lacking and therefore medications were rarely delivered to the areas that patients wanted to pick them up.<sup>16</sup> Nurses did report, however, that when transportation was available, the adherence clubs did work well to provide patients with medications closer to where they lived.<sup>16</sup>

The South African National Department of Health presented the Central Chronic Medication Dispensing and Distribution (CCMDD) model in 2014.<sup>27</sup> CCMDD provides medications for chronic disease states across many locations in South Africa, called pick up points.. Although these pick-up points work well for those patients who are enrolled, nurses at the primary healthcare clinics report that they would like more education on CCMDD because they do not understand how it really works.<sup>16</sup> Without nurses actively promoting patient enrollment into the CCMDD program, its impact and ability to improve medication adherence is limited.

### *MHealth*

South Africa is home to more than 76 million mobile phone subscribers, with an average of 156 mobile cellular telephone subscriptions per 100 people.<sup>28</sup> Mobile technology provides an avenue to develop innovative solutions for delivering healthcare to patients. The role of mobile health, also known as mHealth, has been studied in a variety of settings, including its role in care for patients with chronic disease states. MHealth has been found to be a promising tool for addressing access to care, coverage, and equity gaps in developing countries and low-resource settings.<sup>29</sup> It has been identified for use in aiding emergency response systems, disease surveillance, patient monitoring, health services reporting, and training and continuing professional development.<sup>28</sup>

Overall, mHealth has shown positive impact on chronic disease management in low and middle income countries (LMIC).<sup>29</sup> Within South Africa, however, previous systematic reviews of mHealth programs found insufficient evidence to prove the impact of mHealth on health outcomes.<sup>30</sup> Additional studies, beyond donor funded pilot programs launched in small regions of the country, are needed to determine the true impact of mHealth on the health care delivery process in South Africa. South Africa's mHealth strategy calls for strategies to explore change management, the return on investment/cost-benefit, and further evidence of success.<sup>28</sup>

### *Program Rationale*

As rates of diabetes and hypertension in South Africa continue to grow, methods to improve access to care, medication education, and medication adherence must be explored.

Current literature and interviews with PHCNs and patients provides much needed insight into methods, barriers, and opportunities for advancement.

The goal of the proposed program is to develop an effective, acceptable, resource-efficient, mobile application (app) method of improving medication education and adherence for patients, and when needed, for PHCNs. PHCN interviews report that regardless of whether patients have what they need for their health, they almost always have a cellular device.<sup>16</sup> The development of a mobile app that can meet the health care needs of South African patients with diabetes and hypertension may be useful in improving the care of these patients. Mobile applications can be inexpensive, implemented with minimal additional resources, and can be updated with new information when necessary. Vital to its success is the method in which it is incorporated into the workflow of PHCNs at the primary healthcare clinics and the lives of the patients that use it.

This paper will begin with a systematic review of current mobile applications aimed at improving medication education and or medication adherence and will highlight their outcomes within Sub-Saharan Africa. It will move into a program plan for the development and implementation of the mobile technology and its place in medication education and medication adherence. An evaluation plan for both the application and the implementation of its use in care will be presented and the paper will conclude with a discussion of the possible implications of the pilot project and its potential for scalability if successful.

## **SYSTEMATIC REVIEW**

MomConnect, launched in 2014 was the first large scale mHealth initiative provided by the South African Department of Health (DOH).<sup>31</sup> By 2017 the program had over 350,000 users

and has since reached over 1.5 million pregnant women.<sup>31,32</sup> The mHealth initiative allowed expecting mothers to subscribe to a messaging service that provided information and encouragement to register their pregnancy at the Ante Natal Clinic.<sup>32</sup> Shortly following the MomConnect mHealth program, the South African Government published a mHealth strategy in 2015 with a mission to utilize mHealth as an integral part of health care delivery and improve the health system in South Africa.<sup>28</sup> The aim of the strategy was to develop a single harmonized and comprehensive plan utilizing mHealth to support health sector priorities and meet the health needs of individuals, health care providers, managers, and policy makers.<sup>28</sup> Despite these aims, there has not been a large scale mHealth program implemented in South Africa and true understanding of how to target rising NCDs such as diabetes and hypertension through mHealth is still unknown.

With growing interest in the use and streamlining of mHealth interventions and the aims of South African mHealth strategy, the following research question was selected, “What mHealth interventions targeting diabetes and hypertension education and/or medication adherence have been utilized and accepted in Sub-Saharan Africa and what outcomes have they produced?”

### *Search Strategy*

A search strategy using PubMed was implemented to identify and critique current literature on the use of mHealth interventions in Sub-Saharan Africa target hypertension and type 2 diabetes management. Search terms included diabetes, hypertension, Africa, mobile, mHealth, medication, adherence, and medication education. PubMed search results were exported and imported into Covidence<sup>TM</sup>, software that is used for systematic reviews, with duplicate articles automatically removed. An abstract review was conducted, followed by a full-text review, and articles were included or excluded based on pre-specified inclusion and exclusion criteria (Table



1). Final full-text articles that were selected for inclusion were evaluated for intervention, methods, and outcomes/impact. Collectively, articles were assessed for limitations in the literature and gaps in knowledge.

**Table 1: Systematic Review Inclusion and Exclusion Criteria**

<b>Inclusion Criteria</b>	<b>Exclusion Criteria</b>
English Language	English language not available
Located in Sub-Saharan Africa	Located elsewhere or includes too many geographic areas
Intervention involves the use of mobile technology	Intervention is not mobile technology related or includes use of additional technologies and methods
Intervention focused on diabetes and hypertension management	Intervention focused on diagnoses, case detection, or is not focused on NCDs
Intervention does not require significant additional human resources	Intervention requires significant additional time from healthcare staff or additional staff to be hired
Intervention must report outcomes	Literature that publishes only protocols without outcomes

## *Results*

### Review Process

A total of 115 studies were identified with 42 duplicates removed. Seventy-three studies were screened by abstract and 24 full-text studies were assessed for eligibility, with 7 studies

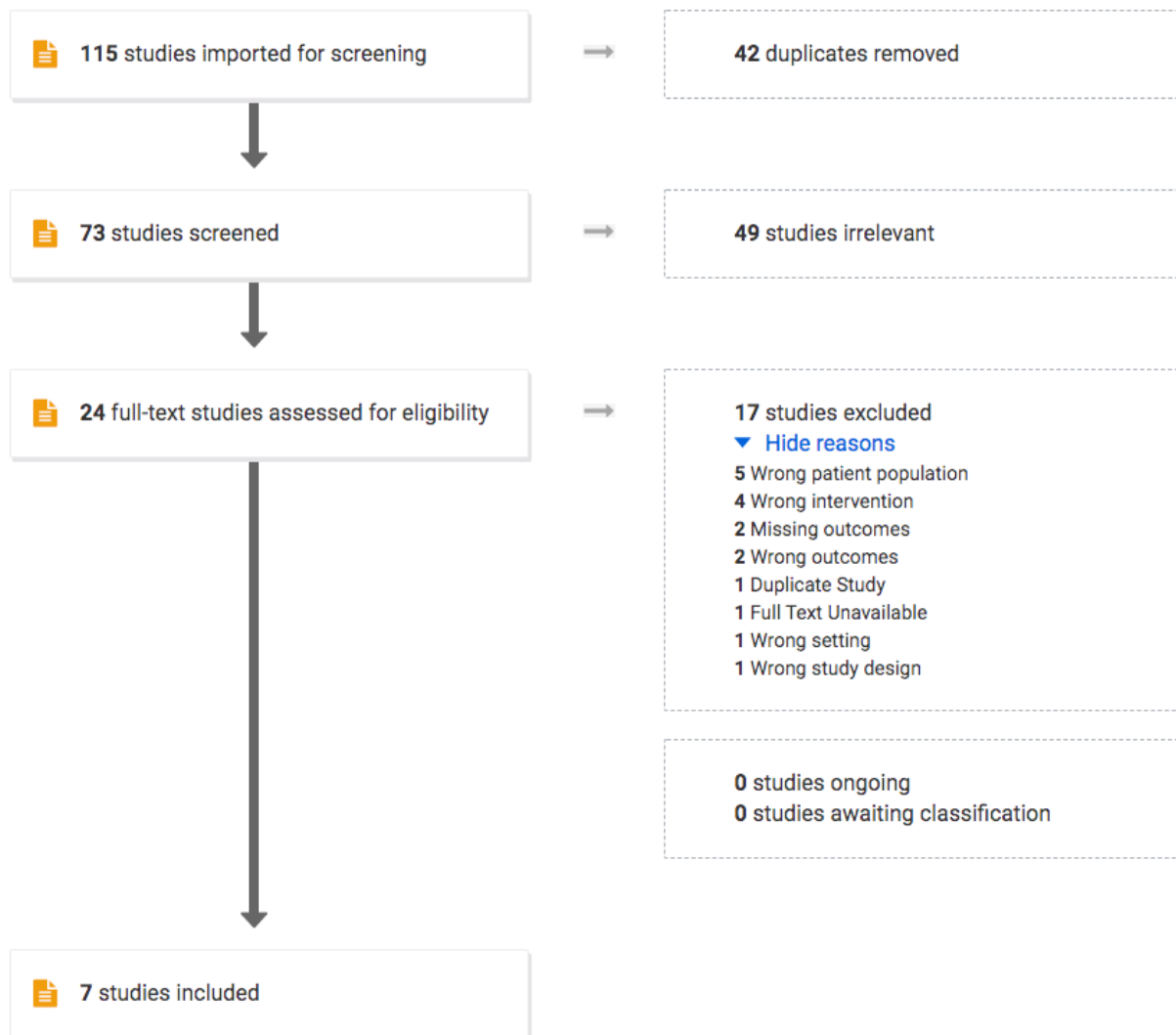
being included in the final review (Figure 1). During abstract review, a number of studies appeared to qualify, but on full-text review, were excluded based on a participant population outside of Sub-Saharan Africa or an intervention that was not centered around implementation of an mHealth intervention. MHealth interventions that included a mix of participants from different geographic regions, including Sub-Saharan African, were excluded due to increased heterogeneity of results and reduced external applicability of outcomes. Two articles were excluded due to only publishing the intervention protocol and lacking any intervention outcomes and two additional articles reported outcome results on the implementation of the mHealth intervention without any outcomes on health care, and were therefore also excluded. Additional reasons for exclusion after full text review can be found in figure 1. A total of 7 articles were included in the final systematic review and a brief summary of each can be found in Table 2.

### Study Characteristics

Of the seven included articles, three were reports regarding the same mHealth intervention describing process outcomes, quantitative program outcomes, and qualitative program outcomes. The remaining four articles described unique mHealth interventions.

The intervention setting of included articles were relatively homogenous. One intervention occurred in Ghana, and six were conducted in South Africa. Of the six articles focused on South Africa, four of the six articles described interventions that occurred in Cape Town, one study was in Mpumalanga province, and one was unspecified.

**Figure 1: PRISMA Diagram generated by Covidence™.**



The majority of mHealth interventions focused on short message service (SMS) text messaging interventions and evaluated the impact of those messages on controlling chronic disease states. One intervention provided advance Bluetooth monitoring technology paired to a provided mobile phone. One study evaluated “bottom up” phone interventions which was defined as informal ways that patients and health care staff were utilizing their mobile phones for health care. Additionally, one study, in addition to SMS text messaging, utilized a buddy system as peer support for improved health.

Study participant demographics were variable across studies. Smaller studies included 20-30 participants whereas larger studies included as many as 1372 participants. Studies which fell in between had enrolled 60, 156, and 223 participants. The majority of studies included both men and women participants, with only one study concentrating on women participants only. One study that chose to conduct focus groups with stakeholders regarding the mHealth intervention included primary health care professionals (physicians, nurses, pharmacists, allied health professionals, and reception staff) as well as third party providers of off-site pre-packaged prescriptions and health care system service providers. Another study that evaluated the “bottom-up” approach interviewed patients and health care workers.

All studies focused on improving care for chronic diseases. Five studies focused on improving hypertension medication adherence, one study focused on improving diabetes management for women, and one study focused on “chronic diseases” in addition to pregnant women.

**Table 2: Review Summary of Included Articles**

<b>Author</b>	<b>Population</b>	<b>Intervention</b>	<b>Methods</b>	<b>Results</b>
Anstay Watkins, J <sup>33</sup>	Patients with chronic disease, nurses, and physicians in Mpumalanga province, South Africa	Determination of how mobile phones are currently being used from the “bottom-up” by patients and health workers	Interview study to examine the current use of health-related digital mobile communication among patients and health workers	40% of patients, 60% of nurses, and all doctors reported using their mobile phones more than once per week for health-related purposes. Over half of the patients used their mobile phones to help set reminders and alarms to manage their own chronic disease.
Bobrow, K <sup>34</sup>	General adult population attending	Parallel, three group (1:1:1)	Personalized SMS text-messages,	SBP decreased from baseline to 12 months for all

Author	Population	Intervention	Methods	Results
	outpatient chronic disease services in a single public clinic in Cape Town, South Africa.	randomized controlled trial	interactive message group messages	groups. The mean adjusted difference in change for the information-only groups compared to usual care was -2.2 mm Hg (p = 0.046 and for the interactive message group compared to usual care -1.6 mm Hg (p = 0.16)
Bobrow, K <sup>35</sup>	South African health care workers and patients with high blood pressure or NCDs	Theory-based behavior intervention to support adherence to high blood pressure treatment delivered by mobile phone text message	Utilization of the Medical Research Council Framework for the development of complex interventions to create a mobile application that provides reminders for clinical appointments, medication adherence, health information, and how to navigate the health care system.	The MRC framework is useful for developing mobile health interventions in low resource settings. Treatment adherence can be supported by well-regarded messages that are polite, credible, contextualized, and endorsed by a member of the primary health care facility staff.
Hacking, D <sup>36</sup>	223 hypertension clinic patients in Cape Town, South Africa	90 mobile text messages over 17 weeks	Participants were randomly assigned to intervention or control groups. Baseline questionnaires were given to both groups to gauge health knowledge, the intervention	No statistically significant changes in health were observed between groups. The intervention group reported increase in behavior changes.

<b>Author</b>	<b>Population</b>	<b>Intervention</b>	<b>Methods</b>	<b>Results</b>
Leon, N <sup>37</sup>	General Adult Population attending the outpatient chronic disease services in a single large public sector clinic in Cape Town, South Africa	12-month adherence support intervention delivered via SMS-text message (in local language) on blood pressure and treatment adherence compared	Three-armed (usual care, one-directional SMS, interactive SMS) randomized controlled trial, combination of convenience and purposive sampling. Focus groups and individual interviews explored perceptions and experiences of participants	Most participants had a positive experience with the SMS-text intervention, however, not all reported that it helped improve adherence behavior. 1/3 reported the intervention highly beneficial resulting in improved attitude, development of a sustainable routine, improved health condition, and improved adherence behavior
Rotheram-Borus, M.J <sup>38</sup>	Women with Diabetes in Cape Town, South Africa	12-week program linking women with a buddy via a mobile phone for support. SMS messaging about health behavior	3-component intervention, series of 12-psycho-educational group session, mobile phone probes that asked about health daily, text messaging to a buddy to support lifestyle changes. Weekly sessions with participants	22 participants. Hours slept each night increased between baseline and three months. No other statistically significant changes.
Sarfo, F <sup>39</sup>	Stroke survivors at a single tertiary medical system in Ghana	2-arm cluster pilot randomized controlled trial.	Subjects received a blue-toothed UA-767Plus BT BP device and smart phone for monitoring and reporting BP measurements and medications intake for 3 months compared with standard care	Systolic BP <140 mmHg at month 3 was found in 20/30 subjects in the intervention arm vs 14/30 in the control arm (p=0.12)

## Study Outcomes

Study outcomes were mixed in showing effectiveness of mHealth interventions on improving control of chronic disease states and described both qualitative and quantitative outcomes.

Three related articles described the process outcomes for developing a mHealth SMS text messaging intervention,<sup>35</sup> qualitative feedback from its participants,<sup>37</sup> and quantitative outcomes on improving blood pressure control using the mHealth intervention.<sup>34</sup> In developing an mHealth SMS text messaging intervention, semi-structured interviews and focus groups with different stakeholders revealed the importance of developing messages that were polite in tone, contained credible information, was context based, and was endorsed by a known member of the primary care staff.<sup>35</sup> Participants more highly valued SMS text messages that included a named provider at their clinic and would be more likely to respond to such a message.<sup>35</sup> Participants also reported they valued being able to select the time of day that messages were sent so as not to disturb other commitments and being sent a follow SMS text message if a scheduled appointment was missed.<sup>35</sup> The feedback collected during the development process was utilized to create the mHealth application.

Quantitative and qualitative outcomes were evaluated using the above mentioned mHealth application. To evaluate quantitative outcomes related to management of blood pressure using the mHealth intervention, participants were randomized in a 1:1:1 fashion into one of three groups, usual care, information only SMS, or interactive SMS and the primary outcome was change in systolic blood pressure at 12-months from baseline.<sup>34</sup> At 12 months, participants in the information only SMS leg had average systolic blood pressure (SBP) 2.2 mm Hg lower than the

usual care leg, and participants in the interactive SMS leg had average SBP 1.6 mm Hg less than the usual care leg.<sup>34</sup> Neither of these results were of statistical significance.<sup>34</sup> To evaluate qualitative outcomes, two focus groups and 15 individual interviews were conducted.<sup>37</sup> The majority of participants reported they were comfortable with the SMS text messaging technology. Those that benefitted the most from the intervention had previously been struggling with adherence due to high personal stress and the intervention was able to provide the practical and emotional support needed to help them improve their behavior.<sup>37</sup>

Other studies also focused on improving hypertension care. A mixed-methods study enrolled 223 hypertension clinic patients to receive either SMS text messages with hypertension health information or usual care.<sup>36</sup> All participants were administered a baseline knowledge questionnaire at the beginning and end of the 17 weeks mHealth intervention and no between group differences were noted in overall health knowledge.<sup>36</sup> Sarfo et al conducted a 2-arm cluster pilot randomized controlled trial for 60 recent stroke survivors with the intervention arm receiving a blue-toothed UA-767Plus BT BP device and smart phone for monitoring and reporting BP measurements and the control arm receiving usual care. Based on reported medication adherence (evaluated by medication possession at month three) the smart phone app sent tailored motivational text messages to participants.<sup>39</sup> After three months, they found that 66.7% of subjects in the intervention arm achieved SBP < 140 mm Hg compared with 46.7% of patients in the usual care arm ( $p=0.03$ ).<sup>39</sup> Adherence to medications was also reported to be 10% higher in the intervention arm.<sup>39</sup>

One study focused on improving diabetes care among women. Twenty-two women with diabetes from Cape Town were enrolled in a 3-month program focused on improving health knowledge to better manage diabetes through text messages.<sup>38</sup> The program included 3



components, 12 psycho-educational group sessions, mobile phone probes that asked about daily health, and text messaging to a randomly assigned buddy to support lifestyle changes.<sup>38</sup> Results evaluated diabetes specific measures such as body mass index, blood pressure, emotional distress, coping styles, and blood sugar were evaluated.<sup>38</sup> The intervention did not show improvements in body mass index, blood pressure, or blood glucose, however, participants did report higher levels of social support, positive actions, and reduced depression withdrawal.<sup>38</sup>

Lastly, Anstey-Watkins and colleagues (2018) evaluated current mHealth interventions that were informally occurring in the health care setting when caring for patients with chronic disease (including hypertension and diabetes) and pregnant women.<sup>33</sup> They interviewed 113 patients and 43 health workers in Mpumalanga province and found that 40% of the patients and 60% of the nurses reported using their mobile phones more than once per week for health-related purposes.<sup>33</sup> Health workers most commonly used their phones to gather health information and patients most commonly used their phones to support management of their chronic disease.<sup>33</sup> Despite the high use of “bottom up” mHealth, many health care staff interviewed expressed frustration and discontent at having to pay for their own airtime to use their mobile phone for work purposes and patients often expressed that they simply do not have the money to buy airtime.<sup>33</sup>

### *Discussion*

A review of current mHealth interventions and their outcomes provide valuable insight into the development of future mHealth related activities. Although there were minimal studies that could be evaluated, insight into the “bottom-up” use of mHealth/mobile phones informs

program planners that the use of mobile phones to improve health is already occurring and is accepted by both health care workers and patients.

The use of mHealth to improve control of hypertension could be promising as interventions both low cost and high cost seem to have shown improvements in SBP in just a few months. Alternatively, mHealth interventions using SMS text messaging solely targeted at improving health knowledge seemed to be ineffective in educating patients about their chronic disease. Utilizing mHealth SMS text messaging to provide social support for improving health seemed to be effective and could be further explored as an opportunity to improve medication adherence.

A review of the current literature also identifies a number of gaps in knowledge surrounding mHealth. Important to note is that a number of these interventions were pilot programs and had a small number of participants. It is unknown whether these programs would produce similar results if scaled up or if scale up is even possible, feasible, and/or sustainable. Additionally, none of the current reports of mHealth interventions for chronic disease management indicated any cost-effectiveness outcomes and therefore, it is unknown whether or not these programs are worth the investment of already limited resources. Lastly, these pilot mHealth programs were all developed and created independent of any involvement from the South African Department of Health, leaving a gap in knowledge on how the department of health could influence or advance such programs to reach their ultimate mHealth goals. Partnership and collaboration with the South African Government is a crucial step in ensuring mHealth programs can be sustainable in the long term so, based on currently literature, it is hard to determine whether or not these programs could be 1) scalable and 2) sustainable.

## PROGRAM PLAN

### *Program Overview*

The National Health Act of 2003 required the South African Department of Health to develop a framework and structure for a uniform health system.<sup>40</sup> Since then, the DOH has launched programs such as CCMDD and MomConnect to address access to care for patients in even the most rural areas.<sup>27,32,41</sup> Despite these efforts, an evaluation of the South African health care system still reveals several issues about public institutions including insufficient health care workers, highly preventable adverse events, and poor-quality of healthcare delivery.<sup>42</sup> Increasing disease burden due to rising rates of NCDs further strains the insufficient health care workforce.

The South African mHealth strategy aims to utilize mHealth as an integral part of health care delivery in the country.<sup>28</sup> South African has over 76 million mobile phone subscribers and an average of 146 mobile cellular telephone subscriptions per 100 persons.<sup>28</sup> Among low-income populations, 75% of mobile phone owners are 15 years or older.<sup>28</sup> MHealth can be used to remotely monitor patients and serve as an extension of health care services, health promotion, health services reporting.<sup>28</sup>

Although supported by the government, there are still a number of barriers that prevent fully incorporating mHealth into the health care routine of the country. Major challenges have included, but are not limited to, the lack of alignment and integration of interventions into health plans, strategies, and systems, an absence of government leadership and coordination, poor documentation and learning of best mHealth practices, and an absence of practical approaches to privacy and security.

The diabetes and hypertension medication adherence program (INSTEP) is a mHealth based program that will target medication adherence and social support for patients with

hypertension and diabetes. INSTEP will be incorporated into the workflow of primary health care clinics and serve to augment patient care around diabetes and hypertension management. Patients with diabetes and hypertension will be educated by nurses about the program and use of care through their mobile device and if they agree to participate in the program, initial health information will be asked and electronically recorded by the nurse. INSTEP will utilize Unstructured Supplementary Service Data (USSD) technology and the computer framework generating and receiving the information will serve as a secure interactive platform for communication to remind patients to take medications, inform patients about appointments, send informational messages, and connect patients with others nearby for social support. With the use of USSD technology, INSTEP will not be limited to patients with phones that can connect to the internet, or require patients to purchase airtime.

INSTEP's initial target population will be patients with diabetes and hypertension in Umlazi township. INSTEP will partner with the South African Department of Health to develop 1) agreed upon process and outcome measures that are of importance to both the program team and the Department of Health, 2) agreed upon cost-effectiveness evaluations and 3) a projected sustainable funding model, and in this way, will work towards addressing major gaps in mHealth knowledge and implementation. At least 50% of INSTEP's 12-member program team will be local public health professionals, nurses, physicians, pharmacists, and patients. INSTEP hopes to make a long-term impact in the health of its users by providing a low resource solution to improving management and control of diabetes and hypertension, thereby preventing morbidity and mortality from disease complications.

## *Program Context*

### Political Environment and Consistency with National Priorities

South Africa held its first democratic election in 1994, electing President Nelson Mandela, and was subsequently divided into its nine provinces (replacing the previously existing four provinces and ten black homelands).<sup>43</sup> Challenged with poverty, unemployment, and inequality, in 2011, the government developed the National Development Plan: Vision for 2030 (NDP).<sup>43</sup> The NDP recognized the deficient workforce, poor infrastructure, and poor quality of public services and set an approach to change that would improve opportunities, increase employment, and reduce poverty. The NDP stated the need for South Africa's rural community to have better opportunities to participate fully in the economic, social, and political life of the country.<sup>44</sup>

The NDP, currently still underway, is comprehensive and addresses advancement in multiple areas, including, but not limited to, reducing greenhouse gas emission to prevent climate change, using science and technology to revolutionize services, establishing effective and affordable transportation, and making high-speed broadband internet universally available at competitive prices.<sup>44</sup> Critical actions mentioned within NDP related to health care include phasing in national health insurance with a focus on advancing public facilities, increasing the health care workforce, and reducing the relative cost of private health care.<sup>44</sup>

Mhealth utilizes widely available technology that works alongside goals and critical actions set forth in the NDP. INSTEP is well aligned with national priorities focused on health care and compliments its emphasis on advancing technological innovations that can aid in providing better services to South Africans.

## Acceptability to Providers and Recipients

As previously mentioned, South Africa is home to more than 76 million mobile phone subscribers.<sup>28</sup> In a study evaluating patient use of mobile devices, all 113 interviewed patients owned their own mobile phone, of which half of the phones had internet connection capabilities.<sup>33</sup> Qualitative studies evaluating the acceptability of SMS text-messaging as a method to improve patient care and outcomes reported findings that patients as well as health care workers felt that use of mobile phones as a way to follow up were acceptable, and in many instances, were already being used in this manner even without a formal program.<sup>33,35,37</sup> Providers even reported that they were comfortable with SMS text-messages including their name as long as the messages were in compliance with the Department of Health guidelines.<sup>35</sup> To ensure nursing staff and physicians are open to participating INSTEP and are clear on what the program will require and how it will be run, both informational and training sessions will be held at each primary healthcare center.

## Financial Resources

INSTEP will be in line with many of the strategic initiatives of the South African Government. A partnership with the South African Department of Health will explore opportunities for government funding to be a sustainable financial contributor to the program, ensuring that process and outcomes monitoring for cost-effectiveness is in place and is projected to show an overall cost-savings once the program is successfully integrated into public health care.

MHealth grants are increasingly available from a number of different institutions. The US National Institutes of Health offers mHealth grants for individuals with chronic conditions to

promote effective patient-provider communication, adherence to treatment and self-management (\$125,00 per year for R21, \$200,000 per year for R33) that require partnerships between at least one institution from the United States and one from a LMIC institution.<sup>45</sup> Such partnerships are certainly possible and are already planned for within INSTEP. Importantly, application to this grant is feasible within the current time frame (letter of intent due August 24, 2020, application due date September 24, 2020) making it a possible funding mechanism for the INSTEP program over a longer period of time.

### Technical Feasibility

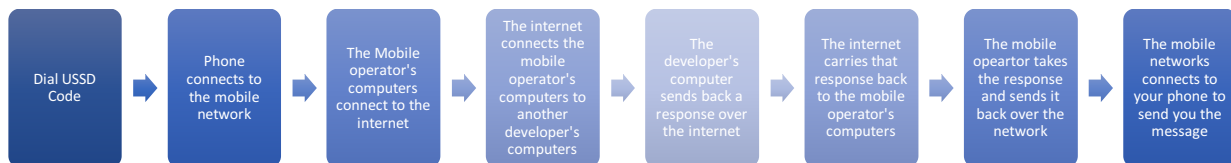
The prevalence of mobile phones among the South African population make it technically feasible to utilize mHealth as a solution to delivering health care support and information between health care providers and patients. The largest barrier to overcome is the limited ability for many patients to afford airtime and connect to the internet. Additional points to consider in developing an mHealth based intervention and pairing it with the concept of producing a mobile application is the fact that although mobile phones are highly prevalent, not all phones have the capability to connect to the internet, and therefore, could not download a new application even if the patient could afford it.

USSD is a method of communication highly utilized within Africa. Despite a mere 18% penetration of internet connectivity on the continent, there is still nearly 80% penetration of mobile phones, many of which has users that rely heavily on USSD use within phones that may not have the processing power of android and iOS devices used in developed nations.<sup>46</sup> USSD allows the user to dial a USSD code in their phone which connects their phone to a mobile network. The mobile operator then uses its computers to connect to the internet (Figure 2).

MomConnect utilized USSD to enroll pregnant women into the national pregnancy register.

INSTEP would utilize USSD to communicate with patients regarding adherence of medications and social opportunities.

**Figure 2: Modern USSD Workflow**<sup>46</sup>



### Engagement of Key Stakeholders

Stakeholder buy-in and program acceptability to nurses and patients will be crucial to the success of INSTEP. Partnering with the Department of Health and gaining their support will be vital in successfully reaching long-term goals and scaling up of the program. Additional stakeholders include, local non-profit non-governmental organizations, the physicians, and the nurses within the primary health care facilities. In a setting where staff is already insufficient, launching new programs that require additional training and possibly additional time is often not appealing to health care staff. Ensuring that the implementation of INSTEP is in line with the priorities of health care staff in the primary health care clinics is a necessity. Appropriate training and resources must be provided to the entire clinic staff to ensure the program is clearly understood and can be incorporated seamlessly into the daily workflow of the staff. Patients are another stakeholder group, and often one of the most important ones. Their understanding, acceptability, and willingness to participate in INSTEP will be the only way that the program can be impactful. Lastly, in an effort to ensure INSTEP is well aligned with the NDP, another stakeholder that will be brought to the table for open discussion when developing and launching INSTEP include individuals from the South African Government.



### *Program Theory*

It has been shown that health programs, including mHealth programs, are most successful when developed alongside a set of health behavior theories. INSTEP's development and implementation will be rooted in concepts from the Health Belief Model (HBM), the Social Cognitive Theory (SCT), and the Social Network Theory (SNT)

HBM was initially developed in the 1950's to help with identification of why people do or don't utilize preventive services offered by public health departments.<sup>47</sup> HBM focuses on six constructs of individual behavior, risk susceptibility, risk severity, benefits to action, barriers to action, and cues to action.<sup>47,48</sup> INSTEP will work towards addressing each of the six HBM areas at different points within the program. Due to the fact that chronic disease states such as diabetes and hypertension can be non-symptomatic for a number of years, patients may believe that they will be ok and that the disease may not impact them too much. To address individual perceptions of risk susceptibility and risk severity, after initial enrollment, participants, through their mobile device, will be asked questions about perceived risk of susceptibility to complications from diabetes or hypertension and their perceived severity of those complications. Additionally, patients will be asked about their perceived self-efficacy in being able to take action to prevent complications from their disease. This information will be stored and utilized to send occasional relevant informational messages to the patient alongside their medication reminders.

To address modifying factors of barriers and cues to action, INSTEP will send adherence messages to patients based on their current medication regimens. Lastly, to ensure patients understand the value of medication adherence, messages regarding benefits of adherence will be sent to patients throughout the month, and especially when adherence is reported to be high.

SCT is an interpersonal model of health behavior and is built on the theory that the interaction between behavior, personal cognitive factors, and socioenvironmental influences shapes a person's actions, a term called reciprocal determinism. Major constructs within this model include personal cognitive factors (an individual's ability to self-regulate behavior), Socioenvironmental factors (an individual's perceived physical environment), and behavioral factors (an individual's actions that are either health-enhancing or health-compromising).<sup>47,49</sup>

INSTEP's main focus within this model will be on the socioenvironmental factors and supporting behavioral factors. INSTEP will focus on social support within the socioenvironmental construct and provide opportunities for patients to engage with other patients in their nearby area that have the same disease state. Patients will be given opportunities to message each other, and if they wish, to meet with each other on a voluntary basis to provide support for each other as they work towards improving their health. Social support through INSTEP will be aimed at providing emotional support, information support, and esteem support.<sup>49</sup> Social support can aid adherence to new behaviors but also improve perceived self-efficacy. To support behavioral factors associated with medication adherence, patients who utilize INSTEP and report at least 85% medication adherence to their medicines each month will be provided with transportation money to their primary health clinic to receive a refill of their medications, when needed. This will be a positive reinforcement reward for improving behavior in taking their medications.

SNT, for purposes of INSTEP, is described as the influence of the relationships among people. SNT posits that network environmental influences are powerful determinants of behavior. Along these lines, INSTEP will intentionally work towards developing social networks through social support that can promote medication adherence behaviors. Ideally, data on

medication adherence rates can be utilized to provide social support in a 2:1 ratio, two patients that have relatively high rates of medication adherence with one patient that has a lower rate of adherence.

These three health behavior models target both individual and interpersonal behaviors. INSTEP will strategically utilize each of these theories to develop participant's personal beliefs in self-efficacy, improved self-motivation to improve their health and prevent disease complications through medication adherence, and reduce barriers to medication adherence through education and reminders.

### *Goals and Objectives*

The overall goal of the diabetes and hypertension medication adherence program (INSTEP) is to reduce complications from diabetes and hypertension by improving medication therapy adherence for patients in Umlazi township through use of mHealth as a readily available communication, adherence, and education resource.

Short Term Goals and Activities (for further details, please see Figure 3 and Figure 4.)

1. By month 3 establish a working partnership with a local non-governmental organization and the Department of Health.
  - Activities: INSTEP program director to conduct stakeholder meeting first with a local prominent non-governmental organization and then with the Department of Health to establish partnerships with Howard University College of Pharmacy. INSTEP program concept will be presented with opportunity for feedback.

Interests from the Department of Health (cost-effectiveness evaluations, sustainability and scalability evaluations, etc) will be built into the program.

2. By month 5, secure necessary funding for development and management of mHealth messaging technology and platform.
  - Activities: INSTEP program director to secure funding through agreements with the Department of Health to supplement transportation costs for participants who are 85% (take medications 26/30 days) adherence to their medications. INSTEP program director to apply for NIH funding grants.
3. By month 6, establish INSTEP's 12-member program team, including six local members from Umlazi.
  - Activities: INSTEP program director will visit Umlazi Primary health clinics and recruit two nurses, one physician, one pharmacist, and two patients, to be a part of the program team. INSTEP program director will also hire one local program manager, one local information technology specialists, one program developer, one local administrative assistant, one pharmaco-economics research specialist (from any location), and one public health specialist (from any location).
4. By month 6, establish a working relationship with the Primary Health Clinics in Umlazi Township.
  - Activities: INSTEP's six program team members (nurses, physician, pharmacist, patients) will visit Umlazi's tertiary care hospital (Prince Mshiyeni) and each primary health clinic. The team will meet with the hospital/clinic directors as well as health care staff to explain the program, how the program can benefit the

hospital/clinic, and the minimal resources it will require from each clinic to be a part of INSTEP.

5. By month 8, develop mHealth messaging platform and have it ready for use.
  - Activities: INSTEP's program manager, information technology specialist, program developer, and administrative assistant, will purchase necessary hardware and software to develop USSD platform. Program developer will work towards building messaging logic to account for messages that must be sent to participants for adherence, social support, and education. Program developer will develop a secure data platform to record patient responses to messages to track adherence and attendance at clinic appointments.
6. By month 12 conduct INSTEP trainings for all nurses and physicians in each of the Primary Health Clinics in Umlazi Township.
  - Activities: INSTEP's six program team members (nurses, physician, pharmacist, patients) will visit hospitals and primary health clinics in Umlazi that agreed to run the INSTEP program and conduct onsite trainings.
7. By month 13, ensure all primary health clinics in Umlazi are actively recruiting and participating in the INSTEP program.
  - Activities: After each training, INSTEP's seven program team members (nurses, physician, pharmacist, patients, public health specialist) will visit hospitals and primary health clinics in Umlazi that agreed to run the INSTEP program and conduct focus groups with the nurses and physicians to determine how the program is running and identify any barriers or opportunities to provide clarity on the program. Public Health specialist will evaluate present state of program and

determine if any adjustments/quality improvement changes need to be made before proceeding.

8. By month 22, enroll at least 200 participants into the INSTEP program
  - Activities: Information Technology specialist and program manager will track enrollment statistics at 10, 13, 16, and 17 months. If enrollment is low, visits to primary health clinics will be made to determine current barriers to enrollment.
9. By month 24, increase self-efficacy and medication adherence of participants who have been enrolled in the program for at least 6 months by 15%
  - Activities: Baseline survey will be administered via USSD messages upon enrollment to establish participant self-perceived efficacy. Survey will be re-administered 6 months after enrollment into the program. Interactive USSD messages will track medication adherence rates.
10. By month 24, have at least 50% of program participants meeting with a social support network of other patients with the same disease state
  - Activities: Train nurses to emphasize the value of meeting with others that have similar disease states so that you can help and support each other. Utilize messages to help organize social opportunities for participants.

#### Long Term Goals

1. By month 36, at least 50% of all patients being seen at primary health clinics in Umlazi for diabetes or hypertension will be enrolled in INSTEP.

- Activities: Enrollment feedback will be elicited from primary health clinics every 6 months to identify opportunities to increase enrollment and to help resolve any barriers that may be present.
2. By year 4, reduce A1c levels of at least 30% of INSTEP participants with diabetes by 3% or reach target goal of <7%.
    - Activities: A1c levels will be measured at least once every 6-12 months for 3 years, for all INSTEP participants with diabetes. This will be provided free of cost to participants using A1c Point of Care machines provided through the INSTEP program.
  3. By year 4, reduce blood pressure of at least 30% of INSTEP participants with hypertension by 20/10 mmHg or reach target goal of <130/80 mm Hg for 3 or more months.
    - Activities: Blood pressure will be measured at every monthly visit to the clinic. Automatic blood pressure machines (two per clinic) will be provided to chronic disease nurses in each primary health clinic. Training will be provided on how they are used.
  4. By year 5, Complete cost-benefit evaluations to determine cost-savings of improved diabetes and hypertension control for enrolled participants.
    - Activities: INSTEP's pharmaco-economics research specialist will be evaluating data for A1c, blood pressure, and adherence for INSTEP participants and developing up models for cost savings for each participant where blood pressure or A1c was able to be lowered through improved adherence. Based on data,

simulation models of cost-benefit if INSTEP was scaled up to additional cities will be developed.

5. By year 5, complete monitoring and evaluation of INSTEP to determine possibility for scaling up to additional locations.
  - Activities: INSTEPs public health specialist will establish both process and outcome measures for evaluating the program. Quality improvement initiatives will be carried out throughout the implementation of the project using PDSA cycles. Based on data gather during implementation in Umlazi, lessons learned will be used to create strategies to scale up the program.

### *Program Implementation*

Implementation of INSTEP will occur in three phases, first with partnership development, second with a brief pilot program and then training and integration into primary health care workflow in all Umlazi clinics, and third with enrollment and data collection. All phases are in an effort to achieve the main goal of the program: to reduce complications from diabetes and hypertension by improving medication therapy adherence for patients in Umlazi township.

### *Partnerships*

Initiating and establishing all partners will occur through stakeholder meetings, either with individual organizations or as a large group. All stakeholder meetings will prioritize trust, transparency, and respect so that all those that are present feel comfortable speaking.



Establishing a partnership with an influential non-governmental organization in South Africa, Interactive Research and Development (IRD), and the Department of Health will be vital to the success of INSTEP. A stakeholder meeting will be called in the initial weeks to discuss the program concept and its implementation with key leaders in IRD to gain buy in. Stakeholders will have an opportunity to respond with their concerns, comments, and any requests for additions or changes to the program to more appropriately meet needs. The same process will be conducted with the Department of Health after support from IRB is obtained. Within the capabilities of the program and if requests are in line with 1) projected budget and 2) the ultimate goal of the program, changes or additions could be made to ensure stakeholders are accepting and in support of the program. Establishing a partnership with prominent local non-governmental organizations and the Department of Health will be the first action items for the program as it will aid in implementation of other aspects.

A separate stakeholder meeting will be held with key leaders at Prince Mshiyeni (after meeting with IRD and the Department of Health) to garner support for INSTEP. Points of emphasis during this meeting will be the support of the program from IRD and the Department of Health (presentation of relevant paperwork as proof), and the benefit to the patients and health care centers that will be enrolled in this program. An opportunity for hospital leadership to voice their concerns during this meeting will be provided and the program director will try to address all concerns or order to gain support from the Hospital. Additional stakeholder meetings on a quarterly basis to ensure stakeholder needs and concerns are being addressed.

Lastly, once partnerships are established with both the Department of Health, Prince Mshiyeni, and IRD, meetings with the director of each Primary Health Clinic in Umlazi will be

set to explain the program and the role of the clinic in enrolling participants and assisting with monthly or yearly monitoring of the patient.

### Training and Integration

An extensive training program will be developed and implemented at each Primary Health Clinic that agrees to be part of INSTEP. The training program will be repeated twice for each Clinic so that those who must work during the time of the training have an additional opportunity to attend. While all nurses and physicians are welcome to attend the training, the training will be required for nurses and physicians managing the chronic disease program at the primary health clinics. The training will consist of an introduction to INSTEP, a simulated training session showing the workflow of enrolling a patient into the INSTEP program, a practice component where nurses and physicians can get hands on opportunities to enroll their first patients under the guidance of program staff as well as use the A1c point of care machines and measure blood pressure, and will conclude with a question and answer session. Once trained, nurses and physicians will be asked to begin enrolling patients into the program and that INSTEP program staff would be occasionally stopping by to gather feedback on the patient enrollment process. Health care staff will be encouraged to enroll as many participants as possible into the program.

The trainings will occur first at nine prespecified Umlazi primary health clinics and those clinics will begin recruitment as a pilot program for a period of seven months. During this time, refinements will be made to the training program based on experiences in the nine clinics and training will be rolled out to the remaining clinics in Umlazi township. For the seven months, the program will run with a limited number of participants to determine opportunities for

improvement before expanding to all Umlazi clinics. Expanded recruitment of participants will begin upon completion of the seven month pilot program and any necessary adjustments have been made to INSTEP.

Nurses responsible for enrollment will be trained to complete three steps before the patient leaves the appointment. First, to ask the patient to sign an electronic consent form for the program, which will include a separate consent to provide a name and phone number to patients who may also live nearby to connect to social support. Second, the nurse will ask the patient to text “enroll” to a pre-specified clinic number, which will allow the program team to determine what patients are enrolling from which clinics. Third, the nurse will review with the patient when to take each of his/her medications so that the patient can correctly respond to the medication regimen questions being asked.

Nurses responsible for follow up of each of the participants will see them on a monthly basis per usual care. During each of these appointments, blood pressure will be taken, and the nurse will text the results to a prespecified number. Additionally, the nurse will ensure that the date of the next appointment is entered into the INSTEP system so that reminders for appointments can be made to the participant.

#### Enrollment and Data Collection

INSTEP’s mHealth based program will be designed to assist the patient with adhering to medication therapy for diabetes and hypertension in three different ways: Reminders, Education, and Social Support. Messages will be sent to the patient through USSD and users will be able to interact by sending messages back. All information received will be secured and only visible to

program team members. Enrolled members will be assigned a generated participant ID which will be provided for the participant in the event of a phone number change.

Upon enrollment, participants will first) be asked if they have diabetes and/or hypertension, second) be asked how often they are scheduled to take their medications during the day for each disease state in order for the program to setup message reminders about daily medications, third) be asked a series of likert scale questions to better understand their current perceptions of self-efficacy, risk of complications due to diabetes and/or hypertension, and severity of complications due to diabetes and/or hypertension, fourth) when they prefer to receive educational related messages, and fifth) what area of Umlazi they live in. Message reminders for adherence will not include specific medication names, but will politely remind patients to take their diabetes or hypertension medications with a brief description of what the pill looks like (for easier identification by the patient). When received, patients will have the opportunity to message back (y) to confirm the medications have been taken or (n) to confirm that they were not able to be taken. A lack of response will be recorded as (n). Incentives to respond and be adherent to medications include a transportation voucher provided to the participant if he/she was 85% compliant to medications throughout the month, determined based on participant responses to adherence messages sent daily. Participants who are actively participating on a weekly basis in the program may also be eligible to receive travel vouchers if deemed necessary by the chronic disease nurses at the primary health clinics, but would be required to come to monthly clinic meetings to continue receiving the vouchers. Message reminders for appointments will also be sent two and one day before the appointment. In order to protect participant privacy in case a phone is misplaced or lost, participants who fail to interact

with the program after one week will be placed on hold until a message from the participant is received.

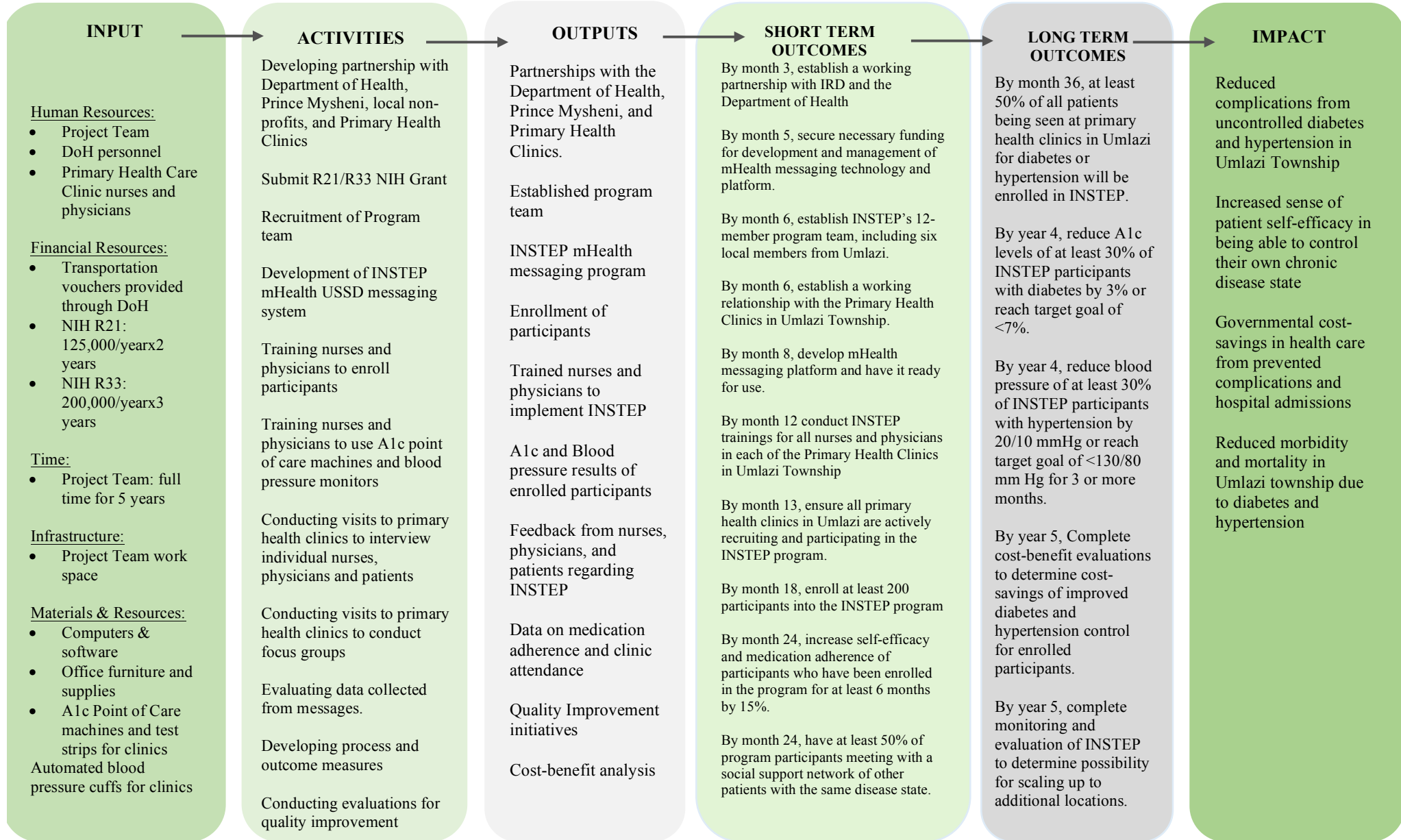
In addition to the message reminders to take medications, messages regarding the risk of developing complications due to diabetes or hypertension, education about the disease state, and encouraging messages to improve compliance will also be sent, no more than once a day, at a pre-specified time that the patient requests. Educational messages will include named physicians from the primary health clinic.

Lastly, when participants enroll into the program and indicate where they live, the participant will be informed that there are other program participants that live in nearby surrounding areas and if they would like to get in contact with them. If the participant indicates (y), contact information for two participants will be provided. Subsequent messages will encourage the participant to meet with the new contacts and solicit feedback on whether he/she did.

Through messages a large amount of data will be collected. Information will be collected on participant demographics, adherence to medication therapy, HbA1c, blood pressure, and attendance at primary health care appointments. All data will be utilized to reach long-term goals of evaluating cost-benefit of the program over the five-year period. Additionally, through periodic visits (where interviews and brief focus groups will be conducted) to the primary healthcare clinics every six months, information on how the program is running, barriers that have been met, what is working well will be collected for continuous quality improvement opportunities and to aid the monitoring and evaluation process.

**Figure 3: INSTEP Logic Model**

Assumptions: Department of Health is in support of this program, NIH Grants are successfully awarded, messaging platform is technically feasible



**Figure 4: GANTT Chart of INSTEP’s first two years**

ID	Task Name	Start	Finish	Duration	Q1 20			Q2 20			Q3 20			Q4 20			Q1 21			Q2 21			Q3 21			Q4 21											
					Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec									
1	Establish Partnership with NGOs and DOH	1/1/2020	3/31/2020	65d	█																																
2	Secure funding (short and long term)	4/1/2020	9/24/2020	127d				█																													
3	Establish 12 member program team	4/1/2020	5/29/2020	43d				█																													
4	Establish partnerships with Primary Health Clinics	4/1/2020	5/29/2020	43d				█																													
5	Develop mHealth messaging platform	6/1/2020	7/30/2020	44d						█																											
6	Run INSTEP Pilot program	6/1/2020	12/31/2020	154d						█																											
7	Conduct INSTEP trainings at primary health clinics	8/3/2020	12/31/2020	109d								█																									
8	Enrollment of participants at Primary Health Clinics	1/1/2021	9/30/2021	195d													█																				
9	Monitoring and Evaluation	9/1/2020	12/31/2021	349d										█																							

## EVALUATION PLAN

### *Rationale and Overview*

INSTEP is a multicomponent program and will require evaluation of both program implementation as well as program outcomes. Process evaluations will be necessary for both the training programs launched in the primary care centers to ensure that nurses and physicians understand the purpose of INSTEP, how it will run, and what they need to do for it to be successful, and for the running of the mHealth program with participants to ensure the program is being carried out with participants as planned. Outcome evaluations will be necessary to determine whether the combined interventions in the program are able to improve control and management of patients with diabetes and/or hypertension. Successful outcomes of the program will be vital to gain further support (both human and financial) from the Department of Health to scale the program to additional parts of the country.

Internal and external stakeholders will be involved in the evaluation process at different stages of the program. Within the training program portion of INSTEP, internal stakeholders will evaluate implementation and outcomes and external stakeholders will evaluate only implementation. Evaluation of the training program at the primary health care clinics will be essential in ensuring the training is appropriate to begin enrolled patients. Insufficient training of those directly involved in the program will result in poor implementation of the INSTEP program, impacting outcomes. Internal evaluators will be necessary to ensure that the program is running as intended. External evaluators will be vital to continuous quality improvement measures and will evaluate implementation from a perspective of improvement, providing a strengths, weaknesses, opportunities, and threats (SWOT) analysis for each implementation



phase, based on their observations and data collected. The results of the implementation evaluation will provide much insight into opportunities to improve the INSTEP program.

The patient program, both implementation and outcomes, will be evaluated by external evaluators. External evaluators will be less likely to have bias in evaluating outcome results, providing a report on the true impact of the program. External evaluators will be from the South African Department of Health and partnering local non-profit non-governmental organizations. Results will inform on the true impact of the INSTEP program in improving the management of diabetes and hypertension.

### *Potential Challenges*

INSTEP's evaluation plan will be complex with two phases of implementation and outcomes evaluations. One major barrier will be ensuring that the evaluation remains within the estimated budget, as feedback for improvements from evaluations will inevitably require additional funds to ensure those aspects are addressed. The program team will have to ensure that limited resources are used to make the most impactful improvements to the program.

Due to the resource constrained settings of the primary health clinics, ensuring that the health care workforce at each clinic will have the time and resources needed to properly enroll and follow up with INSTEP participants will be difficult. In many of these settings, nurses are overworked and short on time, which could result in a rushed enrollment into the program where nurses have not collected or completed all the steps needed for the patient. Due to the many competing responsibilities they face in any given day and to ensure the nursing staff is receiving the appropriate support to fully carry out the duties in INSTEP, observations of their work will be made periodically to determine opportunities where support can be provided. It will be vital to

stress the importance of the enrollment and follow up process with the nurses during the training, and equally important to make sure that the enrollment process is as streamlined and quick as possible, taking no more than an additional 5-7 minutes. Nurses must feel comfortable and trust that by providing truthful answers, that the only outcome could be improvement or assistance rather than negative consequences.

An outcome evaluation challenge is the social support component of the program. INSTEP's current mHealth program does not formally organize local gatherings for its participants, only putting them in touch with each other. It will be difficult to ensure impact of this portion of the program if participants are not acting on the contact information and meeting those in their local area for further support. To alleviate this potential barrier, overtime, the INSTEP program may identify highly compliant participants to serve as diabetes and hypertension champions that volunteer to be present on certain days at the primary health clinics to meet INSTEP participants and build supporting social relationships with them. This opportunity to recruit champions will occur overtime, and the initial champions can be recruited from the pilot program. Additionally, if the technology allows and if it is feasible, INSTEP may look into improving the program after launch and determining the possibility of providing meet-up points and times within communities that participants reside in. Tackling this improvement would depend on the outcomes of this first phase of the program.

Barriers to patient adherence in low-socioeconomic areas often include losing their phone and acquiring a new number, or moving away from their current location, affecting the outcomes this program could have. Due to this, ensuring proper patient follow up may be challenging since INSTEP is based on mobile messaging to a registered number, and providing social support within the originally registered place of residence. The program will need to ensure there is an

easy way for participants to update their number and address while enrolled. To do so, at each primary health clinic visit with an enrolled participant, nurses in the program will be trained to ask about any changes in accommodation arrangements and text any changes in contact numbers or accommodation. They will also inform participants that they have the ability to text to update those changes if they want to. Although these updates will be in place, the program will anticipate to lose approximately 15% of its participants to loss to follow up.

Lastly, program evaluation, particularly for the outcomes of the program, exposes patients to a risk of breaching patient confidentiality. Evaluation will have to be completed very carefully without any patient identifiers to ensure privacy of patient data.

### *Evaluation Design*

The evaluation will be completed using a mixed-methods approach, utilizing both quantitative and qualitative methods to gather implementation and outcomes data. Methods will be geared towards answering the following implementation and outcome questions (Table 3). Questions are categorized to either be quantitative or qualitative, evaluated by either an internal or external evaluators, and evaluating either the training portion of the program or the enrollment/patient portion of the program. Quantitative evaluations specify a unit of measurement that should be produced from that evaluation.

The primary health care training program will be conducted by six members of the program team, of which three will be local to the town. Internal evaluators will be those who are not directly running the training program. Two internal evaluators will accompany the training team to each training session to record 1) time it takes to run the program, 2) whether trainers had all materials needed to run the training program, 3) number of nurse and physician attendees

(out of all of the nurses and physicians in the clinic), 4) if the training session was being conducted similar to ones given prior, and 5) any major barriers faced while implementing the training program. Additionally, these two evaluators will provide a training exit survey to physician and nurse participants that includes a demographic section (including first name and last name initial for tracking purposes), and questions that assess whether they feel comfortable implementing INSTEP after the training program and what feedback they may have about the training program. The two evaluators will also update the count on how many primary health clinics completed training for the week. Internal evaluators will remain consistent for the entire training program to ensure consistency in the evaluation methods.

External evaluators will take on a relatively observational role in evaluating implementation of the training program. Two external evaluators, one from the Department of Health and one from a local non-profit, non-governmental organization partner, will attend at least two training sessions each week and observe the training program. They will be free to ask questions to trainers or participants as needed before or after the program, but will not interrupt the program while it is being given. They will also have access to data gathered by internal evaluators, as needed. Their goal will be to evaluate the implementation of the program to provide a SWOT analysis after the training programs have been provided for six weeks.

External evaluators will be paired with at least one internal program team member and together, they will complete the implementation and outcome evaluation of the INSTEP program after the training and pilot program is completed. Six evaluators will be needed, three from the department of health, and three from a local non-profit, non-governmental organization partner. Evaluators will work in triplets consisting of one evaluator from each institution and an internal evaluator from the program team, and will be responsible for 1/3 of the primary health clinics in

Umlazi Township. To collect relevant qualitative data, evaluators will conduct survey evaluations at each of their assigned primary health care clinics at least once a month, surveying at least two nurses and two patients at each visit. The survey will include demographic data of the person completing the survey (first name + last name initial, role of either nurse/physician/patient, name of the primary health clinic), and questions on acceptability of the program and barriers faced. Questions will be formatted in both five-point Likert scale questions and open-ended questions that require written feedback. During the scheduled visits every two weeks, evaluators will also observe nurses enrolling patients into the program to gather data on the SWOT analysis and the quantitative analysis.

Focus groups will be held with primary health clinics once every quarter and with patient participants within Umlazi township once every six months. Focus groups will inquire about topics similar to those asked in the evaluation surveys given every two weeks, but will allow deeper conversation among participants and the ability to further elaborate and ask follow up questions. In the primary health clinics, focus groups will be held separately with nurses and then physicians, to prevent any fear of sharing due to hierarchy. Focus groups with patients will be held within areas of Umlazi township that are accessible to participants. There will not be a set number of focus groups for patient participants as the requirement will be to hold sessions in as many areas as needed to capture at least feedback from 25% of the participants. Questions about how INSTEP has or hasn't improved patient care, the acceptability of the program, barriers faced, and any feedback about the INSTEP program will be asked.

Quantitative data needed to answer evaluation questions will be collected from the messaging database by the information technology specialist and provided to all of the evaluators on a monthly basis. Evaluators can ask for data at any point if it is necessary for their evaluation,

even if outside of the monthly report. Data will be provided on the following, which should provide sufficient data to answer the majority of quantitative implementation and outcome evaluation questions:

- Number of patients enrolled each week at each primary health clinic
- Total number of enrolled participants at time data was pulled,
- Number of patients that have provided baseline HbA1c and blood pressure results
- Current HbA1c and blood pressure results for each enrolled participant compared to baseline (if available)
- Number of participants that have responded at least once to medication adherence messages via the USSD messaging system.
- Number of participants that have reported yes to meeting up with a social contact provided through INSTEP
- Number of times participants have attended their clinic visit within a six-month period

To assess for improvement in self-efficacy once every six-months, INSTEP will send questions on assess self-perceived self-efficacy through the USSD messaging system. All questions can be answered with a yes or no, and data will be provided to evaluators one month after the data is gathered. Lastly, evaluators will be allowed to ask questions of the program when as needed to assess progress in program implementation and any quality improvement initiatives that have been implemented. Using all of the data collected both quantitatively and qualitatively, a SWOT analysis of the program will be provided to the program team once every year for further quality improvement opportunities.

<b>Table 3: Evaluation Questions for INSTEP</b>				
			<b>Implementation Questions</b>	<b>Outcome Questions</b>
Training Program	Internal Evaluator	Quantitative	How long, on average, does the training program take? (in hours)	Have 100% of the primary health clinics in Umlazi township received at least two training sessions? (Yes/No)
			How many training sessions have trainers had insufficient resources to complete the training as planned (%)	Have 100% of chronic disease nurses and physicians in Umlazi township primary health clinics completed a training session? (Yes/No)
			How many primary health clinics complete training each week? (#)	What % of nurses report they feel comfortable implementing INSTEP after the training program (%)
			How many nurses and physicians are being trained each week? (#)	What % of nurses report they want additional training or are uncomfortable implementing the INSTEP program after completing the training program? (%)
		Qualitative	What feedback do the nurses and physicians have about the training program?	
			Is each training session being conducted in the same way?	
	What major barriers have been faced in completing the training program for each primary health clinic?			
	External Evaluator	Qualitative	What are the major strengths of the training program?	
			What weaknesses are there to the training program?	

<b>Table 3: Evaluation Questions for INSTEP</b>				
			<b>Implementation Questions</b>	<b>Outcome Questions</b>
			What opportunities are there for improving the training program?	
			What threats are there to the training program?	
Patient Program	External + Internal Evaluator teams	Quantitative	How many patients are being enrolled each week? (#)	By month 13, what % of primary health clinics are actively recruiting participants into the INSTEP program? (%)
			What % of nurses are following the complete enrollment protocol for patients enrolling into INSTEP? (%)	Have at least 200 patients enrolled by month 18 of the program? (Yes/No)
			What % of enrolled patients are reporting their baseline HbA1c, blood pressure on enrollment? (%)	At month 24, what % of enrolled participants in INSTEP for at least 6 months reported improved self-efficacy in taking medications? (%)
			What percent of enrolled participants each month respond to medication adherence messages through the USSD messaging platform? (%)	At month 24, what % of enrolled participants in INSTEP for at least 6 months show data with improved medication adherence from baseline? (%)
			How many quality improvement initiatives are undertaken for the program each year? (#)	By month 36, what % of patients being seen for chronic diseases at an Umlazi primary health clinic has enrolled into INSTEP? (%)
			What percent of participants report having met up with a social support contact provided through INSTEP? (%)	By year 4, what % reduction, on average, in HbA1c is seen in enrolled INSTEP participants who have diabetes? (%)



<b>Table 3: Evaluation Questions for INSTEP</b>			
		<b>Implementation Questions</b>	<b>Outcome Questions</b>
		What % of participants have increased clinic attendance from baseline? (%)	By year 4, what % of enrolled patients have reduced blood pressure by at least 20/10 mmHg or reached a blood pressure goal of 130/80? (%)
	Qualitative	How acceptable is INSTEP to patients, patient's families, nurses and physicians?	Do patients, nurses, and physicians feel that being a part of INSTEP has improved patient care?
		What barriers have patients, nurses and physicians faced in being part of the INSTEP program?	What feedback do patients, nurses, and physicians have about the INSTEP program?
		What are the major strengths of INSTEP?	
		What weaknesses are there to INSTEP?	
		What opportunities are there for improving INSTEP?	
		What threats are there to the INSTEP?	

*Institutional Review Board Considerations*

Due to the fact that patient identifiers and medication information will be collected during the implementation and evaluation portion of the program, it will be necessary for the program team to apply for Institutional Review Board approval if any of the data or if the program is going to be published through any avenue. To ensure this program abides by regulations for research in South Africa, the program team will apply for investigational review board approval at the start of the program, in which the submitted information will include a

copy of the consent form that participants will sign when they enroll into the program. The goal will be to get approval for the program prior to the enrollment of the first participant, which provides eight months for the program to acquire this approval.

### *Dissemination Plan*

INSTEP is planned to launch within Umlazi Township under the approval of the South Africa Department of Health. As the program will be enrolling participants through the primary health clinics, which are highly attended by many patients in the township, dissemination of the program will be mainly focused within the primary health clinics. Signs (in isiZulu) for the program will be posted within the patient rooms for chronic disease nurses and patient brochures in isiZulu and English will be provided to the nurses to give to patients.

### CONCLUSION

The diabetes and hypertension medication adherence program's (INSTEP) ultimate aim is to reduce complications from diabetes and hypertension by improving medication therapy adherence for patients in Umlazi township. This program builds off knowledge gained through current literature and is developed to address two major NCD's contributing to morbidity and mortality in South Africa. It combines three different strategies of improving diabetes and hypertension management through improving communication between health care workers, providing reminders for medication adherence, and providing an avenue for social support. The program's technology is made to be accessible to those who may have limited access to airtime, breaking down a barrier to effective mHealth programs.

Unique to any other publication about mHealth, the INSTEP program will undergo a cost-benefit analysis, conducted by a pharmaco-economics specialist, to evaluate the overall benefit of the program and estimated cost-savings. This data will be incredibly useful in better understanding the impact that INSTEP can have, and potentially create greater buy-in to expand the program to other areas of South Africa. Additionally, this will be the first mHealth based program that has partnered closely with the Department of Health, ensuring governmental support.

INSTEP is meant to be a sustainable program beyond the duration of grant funding. If cost-benefit analysis is positive, costs-savings could certainly outweigh the costs to maintain and scale up the program. Additional costs to continue the program and scale up would include training of additional health care workers in primary health clinics, a small monitoring and evaluation team, provision of travel vouchers, and maintaining the messaging platform. Overall, successful implementation of INSTEP could lead to the provision of a mHealth based program that serves as a tool for health care workers to prevent major complications of un-controlled diabetes and hypertension.

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