STRATEGIES TO IMPLEMENT MOBILE HEALTH INTERVENTIONS FOR DIABETES MANAGEMENT IN ETHIOPIA

by

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DECLARATION

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DEDICATION

I dedicate this work to my wife, Mahdere Tsegaye, who has been there for me every step of the way and has ensured that I put forth all my effort to finish what I started. Further also to my sons Elab and Alador. They have been affected by my journey in different ways. There is no way to quantify my love for you.

I also dedicate this to my father, Tezera Zegeye, an exemplary father, for his continuous motivation and unreserved support and my mother, Almaz Tewelde, for her unconditional love. My Sister Ayda, you have been my most incredible supporter.

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ABSTRACT

Rapid mobile device penetration allows developing countries like Ethiopia to integrate Mobile Health (mHealth) technologies to improve healthcare delivery and diabetes management effectiveness. The high diabetes prevalence and the required quality of management necessitate enhanced interventions like mHealth. This study intended to investigate opportunities for the development of mHealth for diabetes management and design strategies for its implementation in Ethiopia.

The research was conducted in selected health centres in Addis Ababa, Ethiopia. A sequential exploratory mixed design was used to investigate mHealth opportunities and acceptance by healthcare professionals. An integrative literature review was conducted following the PRISMA-P protocol, and the findings were used to develop a second-phase quantitative data collection instrument. Multi-stage and purposive sampling techniques were used to select healthcare professionals and senior experts. Data were collected from articles, healthcare professionals, and experts using a data extraction form, questionnaire, and modified Delphi technique. A thematic analysis was used for qualitative data, and the Statistical Package for Social Sciences (SPSS) and AMOS software were used for quantitative data analysis. mHealth strategies were developed, revised, and validated using modified Delphi techniques.

The mHealth interventions domains were patient education, patient communication, and support for Diabetes Self-management (DSM), maintaining personal health records, screening, and using a clinical decision support system treatment/therapy plan. Most healthcare professionals (HCPs) accepted the identified mHealth domains and opportunities as practical, easy to use or less complex. The structural equation model analysis demonstrated that the perceived usefulness and ease of use or complexity of mHealth were predictors for the intention to use mHealth by HCPs for diabetes management. On the other hand, the attitude towards mHealth opportunities and capacity building in mHealth affected the intention to use by HCPs for diabetes management. Strategies were developed to highlight the opportunities for using mHealth for diabetes management and to address possible challenges that may hinder effective implementation.

The study concluded that there are opportunities for using mHealth in managing chronic conditions such as diabetes in Ethiopia. Successful implementation of mobile technologies requires a positive attitude and acceptance by HCPs to enhance the quality of diabetes management in primary health care settings.

Keywords: diabetes management, healthcare professionals, mHealth platform, mHealth strategy, technology acceptance, technology diffusion, primary healthcare setting.

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AES	Advanced Encryption Standard
API	Application Programming Interface
A2P	Application to Person
BCC	Behavioural Change Communication
CDSS	Clinical Decision Support System
CPD	Continuous Professional Development
DSM	Diabetes Self-Management
eHealth	electronic Health
EHR	Electronic Health Record
EMR	Electronic Medical Records
FHIR	Fast Healthcare Interoperability Standards
GSMA	Global System for Mobile Communications Association
JSON	JavaScript Object Notations
ICD	International Classification of Diseases
ICT	Information Communication Technology
IDT	Innovation Diffusion Theory
IEEE	Institute of Electrical and Electronics Engineers
HCP	Healthcare Professional (HCPs plural)
HIE	Higher Education Institute
HSTP	Health Sector Transformation Plan
I-CVI	Item-Level Content Validity Index
LMICs	Low and Middle-Income Countries
mHealth	Mobile Health
MMR	Mixed Methods Research
MNCH	Maternal, Neonatal, and Child Health
NCD	Noncommunicable Diseases
NGO	Nongovernmental Organisation
OpenHIM	Open Health Information Mediator
PCA	Principal Component Analysis
PEOU	Perceived Ease of Use
PHD	Personal Health Devices

PHR	Personal Health Record
PRISMA-P	Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols
PU	Perceived Usefulness
P2P	Person to Person
RCT	Randomised Controlled Trial
SEM	Structural Equation Model
SMS	Short Message Service (SMSes plural)
TAM	Technology Acceptance Model
TTM	Trans-Theoretical Model
T2DM	Type 2 Diabetes mellitus
WHO	World Health Organisation
XML	eXtensible Markup Language

CHAPTER 1

ORIENTATION TO THE STUDY

1.1 INTRODUCTION

Mobile health (mHealth) can be defined as the application of mobile devices and multimedia technologies in the healthcare system. According to the Global System for Mobile Communications Association (GSMA), there were more than 7.8 billion cellular prescriptions globally in 2017 (100% penetration rate), which are expected to reach 9 billion by 2025. 3.3 billion people were using mobile internet services (43% penetration) in 2017, and the penetration rate is expected to reach 61% in 2025 (GSMA Intelligence, 2018:6).

Rapid penetration of mobile devices is an opportunity for developing nations to integrate mHealth technologies to improve healthcare delivery and the efficiency and effectiveness of staff (International Telecommunication Union, 2015:3; Qiang, Yamamichi, Hausman & Altman, 2011:13). Successful implementation of technology requires careful anticipation of organisational challenges and healthcare professionals (HCPs) readiness. HCPs acceptances jointly or independently predict the successful implementation of technologies (Gagnon, Ngangue, Payne-Gagnon & Desmartis, 2016a:214; Garavand, Mohseni, Asadi, Etemadi, Moradi-Joo & Moosavi, 2016:2714; Kruse, DeShazo, Kim & Fulton, 2014:6). Thus, evaluating user acceptance and the reason for rejection is inevitable for the successful deployment of mobile technology.

In Ethiopia, The Health Sector Transformation Plan (HSTP), improving and integrating Information Communication Technology (ICT) in the healthcare system is a major strategy. mHealth is recognised as a key enabler in improving healthcare. In 2011 the mHealth framework was developed, focusing on the Health Extension Package (Vital Wave Consulting, 2011:12-13). Thus, Ethiopia has the political will to implement mHealth projects successfully. What needs to be established is the HCPs’ attitudes and acceptance of this technology in managing chronic ailments such as diabetes mellitus.

This chapter presents an overview of the research problem, the foundation of the study and a summary of the methodology adopted.

1.2 BACKGROUND TO THE RESEARCH PROBLEM

Diabetes mellitus has become a significant public health problem around the globe. The World Health Organisation identified diabetes as one of the four priority noncommunicable diseases (NCDs), along with cardiovascular disease, cancer, and chronic respiratory disease. Globally, more than 422 million adults lived with diabetes in 2014 (World Health Organization, 2016b:2-5); in 2019, this number was 463 million, according to the International Diabetes Federation (2019a:1). Without appropriate action, this number is expected to reach 578 million by 2030 (International Diabetes Federation, 2019a:4). It is also estimated that globally, around 4.2 million people are estimated to die due to diabetes and its complications (International Diabetes Federation, 2019a:54). The proportion increased in 2019: The prevalence of diabetes in Africa, Europe, South-East Asia, and the Region of America was 3.9%, 8.9%, 8.8%, and 13.3%, respectively (International Diabetes Federation, 2019a:38). The consequences and many health complications of diabetes can be prevented through structured healthcare programs (World Health Organization, 2016b:4).

Diabetes imposes a significant economic burden on patients and their families directly (medical costs) as well as indirectly (loss of work and wages) (World Health Organization, 2016b:6). It was expected to cost the world USD 760 billion in direct health spending in 2019, USD 825 billion by 2030, and USD 845 billion by 2045 (Williams, Karuranga, Malanda, Saeedi, Basit, Besançon, Bommer, Esteghamati, Ogurtsova & Zhang, 2020:4). Therefore, managing diabetes requires an integrated and holistic approach. Different interventions and approaches are suggested for diabetes management: self-management support and diabetes self-management (DSM) education have a significant impact on managing complications in diabetes (Badedi, Solan, Darraj, Sabai, Mahfouz, Alamodi & Alsabaani, 2016:5; Martín-Timón, Sevillano-Collantes, Segura-Galindo & Cañizo-Gómez, 2014:457). mHealth could have a significant impact on DSME.

The increased proliferation of mobile and wireless devices plays a significant role in designing and deploying mHealth initiatives. According to the WHO report by Kay and colleagues, 90% of the population could benefit from mobile-based health services (Kay, Santos & Takane, 2011:14). The introduction of mHealth is vital to overcoming known healthcare system constraints. It improves the health systems' equity, quality, effectiveness, and efficiency. mHealth also supports effective decision-making at all healthcare system levels (Labrique, Vasudevan, Kochi, Fabricant & Mehl, 2013:160; Latif, Rana, Qadir, Ali, Imran & Younis, 2017:11551).

The dominant mHealth initiatives are focused on Behavioural Change Communication (BCC) (Alghamdi, Gashgari & Househ, 2015; Latif et al., 2017:11548). These stand-alone applications mainly send short text messages to consumers to raise awareness and mobilize society as a change agent (Iribarren, Brown, Giguere, Stone, Schnall, Staggers & Carballo-Diéguez, 2017:37; Simone, 2015:1).

The purpose of mHealth projects is not limited to BCC and data collection and reporting. mHealth is also used for diagnosis, treatment, supply chain management, and other diverse healthcare services (Latif et al., 2017:11549). Most mHealth interventions in developing countries focus on maternal, neonatal and child health (MNCH) and communicable diseases. Thus, the WHO and Vital Wave recommend developing mHealth projects to prevent and manage NCDs like diabetes (Kay et al., 2011:14; Vital Wave Consulting, 2009:20).

Reports show that mHealth interventions produced positive outcomes on non-communicable disease (NCD) management. Specifically, text messaging significantly impacts supporting a healthy lifestyle (Iribarren et al., 2017:38). The potential of mHealth in developing countries for NCD includes an educational tool for lifestyle behaviour; efficient utilisation of resources; reminders and alerts for improving treatment adherence; overcoming geographical barriers; effective means of communication between healthcare providers and patients (Bloomfield, Vedanthan, Vasudevan, Kithei, Were & Velazquez, 2015:92; Nouetchognou, 2016:4; Rosskam & Hyder, 2017:2). Generally, mHealth has a crucial role in improving challenges of prevention, timely diagnosis, and self-management of diabetes. However, there is insufficient evidence to support the effectiveness of mHealth for NCD care in sub-Saharan Africa and other developing countries.

Successful implementation of mHealth initiatives depends on different factors, such as individual perceptions and ease of use (Garavand et al., 2016:2716; Kruse et al., 2014:6), usefulness (Gagnon et al., 2016a:214; Garavand et al., 2016:2716), social impact, attitudes and behaviour of users (Garavand et al., 2016:2716; Kruse et al., 2014:6) user computer anxiety, workflow impact, interoperability, technical support, expert support and communication among users (Gagnon et al., 2016a:214; Kruse et al., 2014:6), design and technical concerns, cost, time, privacy and security issues, familiarity with the technology and risk-benefit assessment (Gagnon et al., 2016a:214).

ICT is growing rapidly in Ethiopia. The penetration of mobile phones was around 25% in 2012 (Adam, 2012:9). In 2015, the country achieved a high subscription level by raising the number of mobile subscribers to 40 million, and the mobile service penetration rate was 44% (Reba, 2015:12). According to GSMA (2021:10), between 2020 and 2025 around 15 million peoples are expected to start using mobile technology. The mobile network coverage comprises 3G and 2G services, 4G LTE, and 5G technology deployment in Addis Ababa.

Ethiopia's government recognised the benefit of ICT for improving healthcare service delivery. As part of that, national eHealth, a strategy document, was prepared to integrate ICT into healthcare in 2013. mHealth was targeted as one application layer in the national eHealth strategy (Tilahuna, Zelekea, Kifle & Fritz, 2014:4).

This rapid increase in mobile phone subscriptions and the presence of a national eHealth (electronic Health) strategy is an opportunity for future work. Additionally, accurate data and information should be collected before designing and implementing an mHealth model for diabetes management. The mHealth system and strategy are already designed for Ethiopia's MNCH services. Expanding this system and strategies for the NCD domain would be effective. However, there is no current information on strategies to implement mHealth for NCDs like diabetes in Ethiopia. Therefore, based on the gathered evidence, this study was conducted to develop diabetes-related mHealth strategies in Ethiopia.

1.3 RESEARCH PROBLEM

Type 2 diabetes mellitus (T2DM) is a significant public health issue in Ethiopia, with an estimated prevalence of 3.2% in 2015. T2DM was projected to have a 7.5% prevalence (% of the population ages 20-79) in 2017, accounting for approximately 30,000 deaths (International Diabetes Federation, 2017:2). According to a study of T2DM patients admitted to large referral hospitals in Addis Ababa, one-third were admitted with diabetic foot ulcers, about 20% with diabetic cardiovascular disease/stroke and 10% with renal failure (Gizaw, Harries, Ade, Tayler-Smith, Ali, Firdu & Yifter, 2015:75). Tasew (2015:21-29) found that 49.6% of patients with T2DM did not receive information regarding their conditions. Only 28.1% of patients had access to blood glucose monitoring. Diabetic patients who had good self-care practices were found to be 52.3%. Additionally, 85% of the patients had poor glycemic control. These factors are modifiable. Behavioural Change Communication (BCC) and routine data collection and reporting supported by technologies could improve the management of diabetes (Rosskam & Hyder, 2017:2). However, HCPs need to have a positive attitude toward the usability of technology in managing diseases.

The increase in mobile users, the prevalence of diabetes and associated complications produce an appropriate local context for mHealth interventions. The healthcare provided for a diabetic patient is still routine, with less emphasis on diabetic management using mHealth technologies. Reports from the Congo MobilDiab mHealth initiative showed significant improvements in glycemic control. There is a need for research on the possibilities for developing diabetes-related mHealth strategies in Ethiopia.

1.4 AIM OF THE STUDY

1.4.1 Research Purpose

This study aimed to investigate opportunities for developing a mHealth intervention for diabetes management and design strategies for implementation in Ethiopia.

1.4.2 Research Objectives

The aim was extended through the following research objectives:

1) Conduct an integrative literature review on mHealth technologies for diabetes management in low and middle-income countries.
2) Identify potential barriers and facilitators for diabetes mHealth intervention in Ethiopia.
3) Design strategies for diabetes management mHealth interventions in Addis Ababa, Ethiopia.

1.4.3 Research Questions

1) What literature exists regarding the use of mHealth technologies in diabetes management in low and middle-income countries?
2) What are the potential facilitators and barriers to adopting mHealth interventions for diabetes in Ethiopia?
3) What would be the most appropriate mHealth strategy for diabetes management in Ethiopia?

1.5 SIGNIFICANCE OF THE STUDY

As discussed in the background, the mHealth application can potentially support chronic disease management, including diabetes. Thus, problems related to poor self-management, unhealthy lifestyles, and chronic complications could be addressed using mHealth platforms.

Studies reported that mHealth interventions increased patient-provider and provider-provider communication and satisfaction with care. The interventions include mobile-based health reminders, disease monitoring and management, and education which may significantly improve glycemic control (Wang, Xue, Huang, Huang & Zhang, 2017:459-460). Thus, developing diabetes mHealth significantly impacts disease management if factors for adoption and acceptance are identified and successfully addressed.

In Ethiopia, little evidence is available on mHealth applications for managing NCDs. Medhanyie and his colleagues (2015:3-6) reported that mHealth significantly improved data quality collected by health extension workers, but their focus was on MNCH services. Unpublished work by Serkalem (2013:20-52) evaluated the current mHealth initiatives in Ethiopia; none of the mHealth applications included in the study was designed for NCDs and diabetes. Moreover, there is no evidence regarding challenges, facilitators and strategies, or the users' perception of implementing mHealth for T2DM management.

This study identified barriers and facilitators for diabetes mHealth adoption in Ethiopia. Based on the gathered evidence, the strategies for effectively implementing mHealth interventions for diabetes management were outlined. The outputs of this study serve as a baseline framework for future interventions on mHealth. It also highlighted the possibilities of improved effectiveness and efficiency in the technology-enhanced management of diabetes. This thesis's original contribution is providing a structure or strategy to implement interventions for T2DM management using mHealth applications.

1.6 DEFINITION OF THE KEY CONCEPTS

Diabetes Mellitus: It is a chronic disease caused either by impairment in insulin production (the pancreas does not produce enough insulin) or body resistance to insulin, a hormone that regulates blood sugar or glucose (World Health Organization, 2016b:6). In this study, the focus is mHealth use for Type 2 diabetes mellitus. It is referred to as diabetes.

Diabetes management: Prevention, early diagnosis, and treatment of T2DM**.** This management includes data collection and reporting, health education and communication, self-management of diabetes and patient tracking (World Health Organization, 2016b:7).

mHealth: Defined as health practice supported by mobile devices. mHealth involves medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices (Kay et al., 2011:14).

mHealth applications: The mobile application includes but is not limited to communication between the clients and the healthcare system, a surveillance system, data collection, and analysis (Barton, 2012:1).

Strategy: The plan or blueprint chosen to bring about a desired future, such as achieving a goal or solution to a problem. This study refers to the term as an overall plan or series of activities for using mHealth to manage type 2 diabetes.

1.7 OPERATIONAL DEFINITIONS

Acceptance: In this study, the term refers to HPCs' perceived usefulness, perceived ease of use and behavioural intention to use mHealth for diabetes management.

Barriers: In this study, the term refers to challenges that hinder the implementation of mHealth in low and middle-income countries and the acceptance of mHealth applications for diabetes management.

Facilitators: In this study, the term refers to factors that influence the acceptance of mHealth applications for diabetes management positively.

Healthcare professionals (HCPs): In this study, HCPs refers to nurse practitioners, healthcare managers, and health information officials involved in managing diabetes.

Integrative literature review: In this study, integrative literature review refers to a systematic review of quantitative, qualitative, and grey literature to provide a comprehensive understanding of the use of mHealth applications in managing diabetes in low and middle-income countries.

mHealth strategies: In this study, mHealth strategies refer to interventions that employ mHealth applications for diabetes management.

1.8 FOUNDATIONS OF THE STUDY

1.8.1 Philosophical Paradigm

It is well understood that mixed methods and the overall methodologies used in this study rely on different philosophical assumptions: the ontological view (assumptions about world reality), the epistemological view (assumption on the quest of knowledge), axiology (assumptions on the nature of value and the role of the researcher, (Creswell & Creswell, 2018:45; Parvaiz, Mufti & Wahab, 2016:72; Saunders, Lewis & Thornhill, 2012:110).

The philosophical stance serves as a logical justification of research and is still an issue of debate among methodologists (Baškarada & Koronios, 2018:5). Paradigm can be defined as worldviews and stances about the nature of reality, knowledge and values (Morgan, 2018:269).

Paradigms are fundamental conceptions of research in a specific field with consequences on the levels of methodology and theory (Flick, 2014:540). These are assumptions upon which research and development are based. There are mainly four broad paradigms, namely, the constructivism, post-positivism, transformative and pragmatic paradigms (Creswell & Plano Clark, 2017:41). Creswell and Plano-Clark (2017:41) argue that in light of the still-developing norms and practices regarding mixed methods work, researchers ought to provide an explicit philosophical rationale for their methodological choices.

This study followed a single paradigm approach encompassing both qualitative and quantitative research methods, namely pragmatism (Bauer, 2017:71; Creswell & Plano Clark, 2017:41). Adopting pragmatism using a mixed methods approach provided the opportunity to address the problem from different angles. Pragmatism acts as a new paradigm to replace an older way of thinking about the differences between approaches to research by treating those differences as social contexts for inquiry as a form of social action rather than as abstract philosophical systems (Morgan, 2013:1049). As Creswell and Plano Clark (2017:42) explain, pragmatism involves combining qualitative and quantitative data and combining single and multiple realities, practicality, and stances. The authors further explained that pragmatism focuses on the consequences of research and the use of multiple methods for data collection to inform the problem under study (Creswell & Plano Clark, 2017:41).

The quantitative approach was originally derived from the positivist paradigm. In a positivist view, the goal is to observe, measure, and describe the phenomena experienced. A quantitative approach is used to deductively test theories by analysing the relationships among variables. The researcher does not influence the overall procedure of the research (Creswell & Creswell, 2018:21-22; Creswell & Plano Clark, 2017:35). The quantitative research in this study was used to categorize features, quantify behaviours, and construct a statistical model to explain what was observed regarding the possibility of a diabetes mHealth application. The search to understand the use of mHealth technologies for diabetes management guided the research approach that used qualitative research (Phase I). This study used mixed methods, a combination of qualitative and quantitative data, and allowed the researcher to use elements from both approaches in a complementary manner to strengthen the study (Creswell & Creswell, 2018:245). These methods were given equal status to avoid violating the quest for methodological diversity in mixed methods. The researcher selected from both worldviews what worked for the inquiry (Biddle & Schafft, 2015:326).

According to Creswell and Creswell (Creswell & Creswell, 2018:230), mixed methods reside somewhere between the qualitative and quantitative approaches because they contain elements from both approaches. Literature supports applying a mixed approach to investigate complex problems in healthcare (Weir & Fouche, 2015:15). Although Interface may occur at any phase of the research process, rigour is vital in mixed methods (Harrison, Reilly & Creswell, 2020:473).

MMR offers a methodology to explore complex issues in healthcare. MMR may have its roots in a single research paradigm rather than several different paradigms. Four fundamental concepts that constitute a philosophy of knowledge are discussed below:

1.8.1.1 Ontology

Creswell and Creswell (2018:60) define ontology as a philosophical stance on the nature of reality, an understanding of what is real and fundamental. According to them (Creswell & Creswell, 2018:44), postpositivism, constructivism, transformative thinking, and pragmatism are dominant views in research.

In the constructivist view, there is no single reality or truth, and individuals create reality in groups. Social entities are or could be created (constructed) by active insight and action of individuals in groups (Dieronitou, 2014:4; KIn, 2011:4). In contrast, a postpositivist argues that there is a single truth or reality. From this view, the social entity adheres to external objective reality (Bauer, 2017:72). A pragmatic perspective infers “what works.” Using diverse approaches, prime attention is given to the research problem and question while valuing both objective and subjective knowledge (Creswell

& Creswell, 2018). Pragmatism views reality as dynamic and fluid. In this study, this belief enabled the researcher to better understand what works and does not in implementing the mHealth application for diabetes management. The study assumed that the views of HCPs regarding mHealth for diabetes management are a social reality that will influence their intention to use the proposed strategy.

1.8.1.2 Epistemology

Epistemology draws on "How Can I know reality?," a quest for knowledge according to Creswell (2014:35). Epistemology is closely related to the choices of methodology. It can be defined as a claim of knowledge and understanding the nature of the knowledge (Creswell & Creswell, 2018:60). In this MMR study, a pragmatic approach was used to generate knowledge. Pragmatism was considered to be philosophically consistent with MMR. Pragmatism provides a basis for using mixed methods approaches as a third alternative to solve the research problem (Bauer, 2017:72-73). Epistemological assumptions are focused on the sources of knowledge concerning its nature.

The researcher combined the subjective and objective approaches for obtaining knowledge. Pragmatism offers an opportunity for selecting methodological mixes that can help researchers better answer multiple but related research questions (Morgan, 2018:271). It explains how mobile applications and their usability are determined by their predictability and applicability (Morgan, 2018:271). MMR offers to plug this gap by using quantitative methods to measure some aspects of the phenomenon in question and qualitative methods to strengthen knowledge acquisition (Bauer, 2017; Feilzer, 2009:8; Mitchell, 2018:106).

This study intended to examine what was known already in the field of mHealth on the use of diabetes in order to identify a suitable mHealth strategy for Ethiopia. According to Tariq and Woodman (2010:3), an interpretive framework is valuable for generating solid theory but lacks generalisability. Thus, quantitative evidence was sought deductively from a large group of health professionals to find generalisable findings regarding diabetes mHealth acceptance and adoption.

The rationale behind the choice of pragmatism epistemology in this study was: the practical value of the combined research methods (Morgan, 2018:270) and the technical concern of generating knowledge (Halcomb & Hickman, 2015:42; Morgan, 2018:272). Thus, the potential of Diabetes mHealth was generated subjectively; then, acceptance and possible adoption of such a system were generated objectively. This allowed the researcher to develop broad strategies for mHealth based on the combined findings.

1.8.1.3 Axiology

Axiology is another assumption of a research paradigm that deals with the nature of values and beliefs about the meaning of ethics and morals (Bauer, 2017:81). Pragmatism treats research as a human experience based on the beliefs and actions of the researchers; it focuses on beliefs that are directly connected to actions (Johnson, 2015:166). The mHealth opportunities, facilitators, and barriers were accessed and co-constructed through a careful synthesis of literature by the researcher and co-coder.

The researcher minimized personal bias by drawing upon studies from both qualitative and quantitative traditions in the integrated systematic review of literature, thus bringing a mix of worldviews. In Phase I, strict criteria were set for literature, thus avoiding biases. Phase II involved a quantitative phase where objective data were collected through structured methods.

1.8.1.4 Methodology

This study used mixed-method research. The researcher needed to choose the research process that would provide the best evidence.

Phase I of this study used an integrative literature review with the assumption that the use of criteria in the search strategy would strengthen internal trustworthiness; it is acknowledged that qualitative philosophy would argue that criteria could stifle the methodology. However, the multiple reality view is inadequate to observe usage situations and generalize the finding at a large scale (Cohen, Manion & Morrison, 2018a:37; Creswell & Creswell, 2018:240; Mitchell, 2018:105). Thus, a large-scale survey (quantitative) was conducted to garner empirical evidence that supports the qualitative inquiry. The assumption was that behaviours could be objectively measurable and generalizable.

The study employed qualitative research to investigate the application of mHealth for diabetes management and quantitative research to determine HCP acceptance of mHealth for T2DM management. These methods were given equal status to avoid violating the quest for methodological diversity in mixed methods. Mixed methods research (MMR) works in practice because it produces usable results that transcend the limits of mono-method research (Fetters, 2019:55).

1.8.1.5 Rhetoric

Firestone (1987:17) defined rhetoric as the art of writing effectively. In postpositivism, a researcher uses formal styles based on an agreed definition of variables. Conversely, in the constructivism paradigm, the researcher uses an informal style (Creswell & Plano Clark, 2017:41). The assumption was made that implementing mHealth in low and middle-income countries, facilitators and barriers would necessitate a description using words or narrative. In contrast, evidence from perceived usefulness, perceived ease of use/complexity and behavioural intention /acceptance was described in terms of objective numbers.

Scientific writing was maintained throughout the study. “Thick description” (Ponterotto, Mathew & Raughley, 2013:48) was provided for the qualitative component, and objective precision was pursued in the quantitative component.

1.8.2 Theoretical Framework of the Study

In recent times, mHealth has been seen as an opportunity to improve the efficiency and effectiveness of healthcare system delivery. However, its successful implementation is affected by different factors. Various investigators tried to identify predictors for the acceptance and adoption of mHealth technologies in the healthcare system (Abejirinde, Ilozumba, Marchal, Zweekhorst & Dieleman, 2018:79-80; Ayatollahi, Mirani, Nazari & Razavi, 2018:96; Harst, Lantzsch & Scheibe, 2019:12; Odnoletkova, Buysse, Nobels, Goderis, Aertgeerts, Annemans & Ramaekers, 2016:7). Acceptance and adoption measurement models were considered as an important tool for researching factors for successful implementation of the mHealth system. Especially the Technology Acceptance Model (TAM), the Innovation Diffusion Theory (IDT) and the unified theory of acceptance and use of technology (UTAUT) (Gagnon, Ngangue, Payne-Gagnon & Desmartis, 2016b:216; Garavand et al., 2016:2; Rahimi, Nadri, Lotfnezhad Afshar & Timpka, 2018:608) were considered.

This study integrated TAM with IDT theory to design strategies for successfully implementing an mHealth system for diabetes management.

1.8.2.1 Technology Acceptance Model (TAM)

The TAM, postulated by (Davis, 1989:319), was extended from the theory of reasoned action (TRA) (Ajzen & Fishbein, 1977:890) and offers a powerful explanation for user acceptance and usage behaviour of information technology.

The TAM is a widely used model in the studies of the determinant of mHealth acceptance. Many previous studies have adopted and expanded this model, which was empirically proven to have high validity in predicting user adoption of mobile technologies (Cilliers, Viljoen & Chinyamurindi, 2017 :1; Zhu, Liu, Che & Chen, 2018:23).

The TAM was based on two simple constructs: “perceived usefulness” and “perceived ease of use” for predicting technology adoption at an individual level.

Perceived Usefulness: Perceived usefulness (PU) is “the degree to which an individual believes that using a particular system would enhance his or her productivity” (Davis, 1989:320). PU was a valid construct for predicting an individual’s acceptance of mHealth (Kim, Gajos, Muller & Grosz, 2016:3). In previous studies, PU was a strong predictor for behavioural intention to use mobile devices for health-related services (Cilliers et al., 2017 :1; Zhu et al., 2018:27).

Perceived Ease of Use: Perceived Ease of Use (PEOU) is defined as “the degree an individual believes that using a particular system would be free of effort” (Davis, 1989:320). Similarly, PEOU was valid in predicting individuals’ acceptance of mHealth technology. PEOU also has a direct effect on perceived usefulness. According to two studies, PEOU positively predicts the intention to use mHealth technology (Cilliers, Viljoen & Chinyamurindi, 2018:1; Wang, Xiao, Sun & Wu, 2016:890)**.** While there are some convergent results from the technology acceptance research, the effects of some determinants remain debatable. Holden and colleagues have argued that the classic TAM is unsuitable for explaining contemporary health technology acceptance and urges for expansion. They also adopted and expanded TAM to incorporate social influences and a training system (Holden, Asan, Wozniak, Flynn & Scanlon, 2016:3). Kim and Park (2012:4-5) extended TAM into the Health Information Technology Acceptance Model (HITAM) to incorporate antecedents from the Theory of Reasoned Action (TRA) and Health Belief Models (HBM). Another study refined TAM to incorporate ICT knowledge and future demand as external variables (Melas, Zampetakis, Dimopoulou & Moustakis, 2011:554). This study used antecedents from the IDT to improve and extend TAM.

Behavioural Intention: Behavioural Intention (BI) is defined as the drive or capacity of an individual to engage in the desired behaviour. BI establishes how technology is used, which establishes the level of technology acceptance. BI is directly affected by perceived usefulness and ease of use (Holden et al., 2016:4).

1.8.2.2 Innovation Diffusion Theory (IDT)

Rogers' IDT theory is one of the most popular theories for studying the adoption of technologies. According to the IDT, innovation is perceived as an idea, process, or technology that is new or unfamiliar to individuals within a particular area or social context (Rogers, 1995:25).

According to Rogers (1995:28), five user-perceived attributes were consistently proven to be predictors of the success of ICT innovation: relative advantage, compatibility, complexity, trialability, and observability.

The relative advantage constructs assess the degree to which an innovation is perceived as being better than the idea it supersedes. Compatibility measures the level to which an innovation is perceived as consistent with existing values, past experiences, and the needs of potential adopters. Another construct is complexity which measures the degree to which an innovation is perceived to be difficult to understand, implement or use. Trialability measures the degree to which an innovation may be experimented with but on a limited basis. Observability measures the degree to which the results of an innovation are visible to others. In addition, the type of innovation (optional, collective, or authoritative), communication channel, the nature of social systems, and the extent of a change agent's promotion effort also affect I.T. adoption (Lee, Hsieh & Hsu, 2011:127-128; Pheeraphuttharangkoon, 2015:215; Rogers, Singhal & Quinlan, 2014:432).

IDT was used in rare situations to predict the adoption of mHealth technology. Pheeraphuttharangkoon (2015:262) found compatibility to be an important predictor for the adoption of smartphones. Another study on HCPs shows that task characteristics were positively related to HCPs' attitudes toward using a smartphone. Compatibility also showed a positive impact on both perceived usefulness and perceived ease of use (Damayanti, Hidayanto, Munajat, Meyliana & Negara, 2018:9). However, there is a lack of health technology adoption studies in literature solely based on IDT (Rahimi & Jetter, 2015:2485).

1.8.2.3 Combined TAM and IDT

The literature combined TAM and IDT to predict technology adoption (Rahimi & Jetter, 2015:2485). A study conducted in Taiwan using Combined TAM and IDT found that compatibility, complexity, relative advantage, and trialability on the perceived usefulness were significant in adopting the e-learning system (Lee et al., 2011:135).

Similarly, combined TAM and IDT were also used to measure health information technology adoption. Perceived usefulness, perceived ease of use, and compatibility were significant determinants of participants' intention to use mobile healthcare services. Similarly, perceived usefulness, perceived ease of use, relative advantage, compatibility, complicatedness, and trainability significantly affected physicians' attitudes toward using and accepting Electronic Medical Records (EMR) (Abdekhoda, Ahmadi, Gohari & Noruzi, 2015:178).

Combined TAM and IDT were used in this study to measure HCPs' intention to use mHealth technology for diabetes management (see Figure 1.1). Theoretically, the diffusion of an innovation perspective does not explicitly relate to the TAM, but both share some key constructs. Combined TAM and IDT improve the validity and credibility of this study.

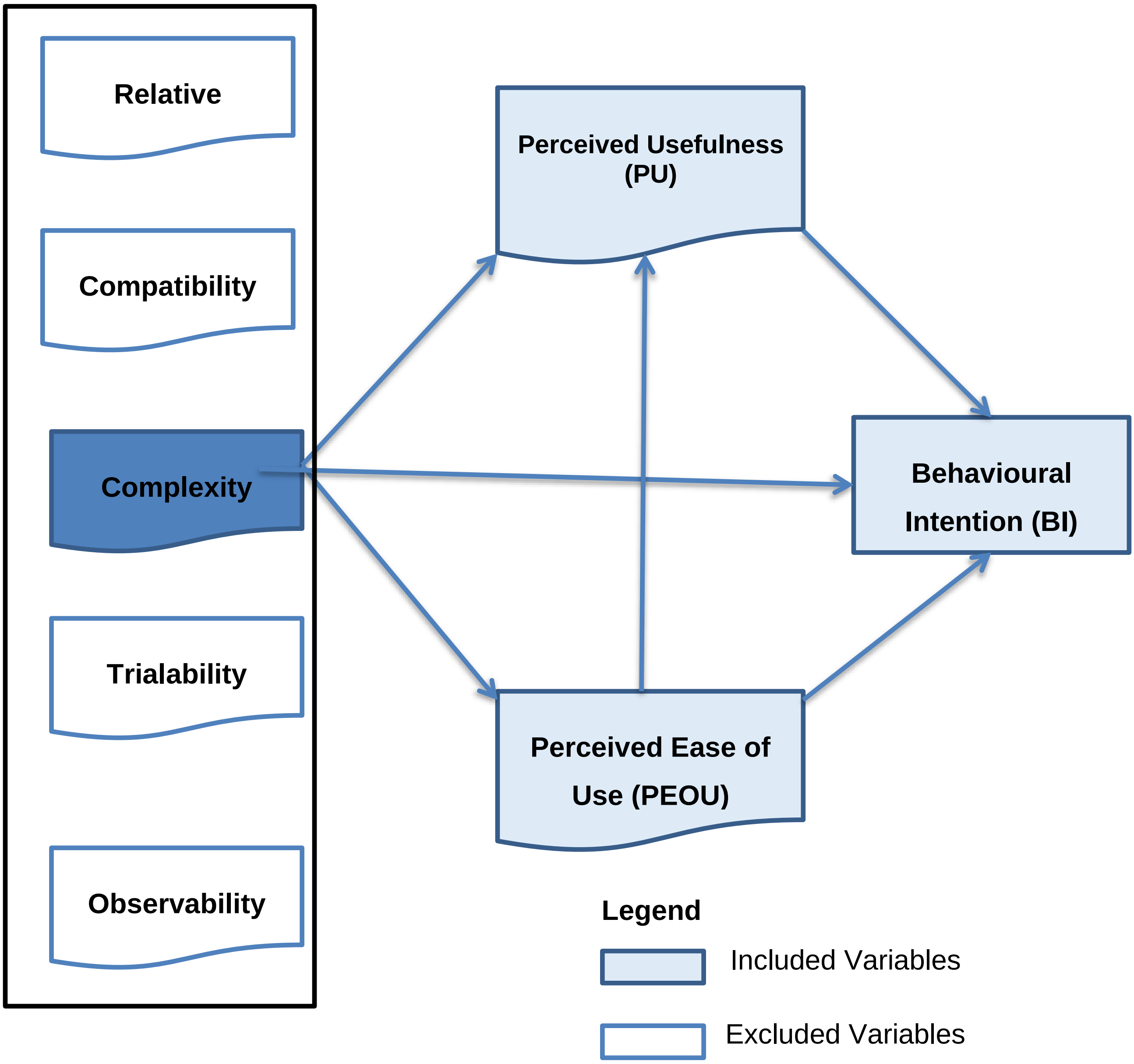

Figure 1.1: Theoretical Framework: Combined TAM and IDT (Lee et al., 2011:129)

1.9 RESEARCH DESIGN AND METHOD

The research design refers to a plan regarding the process to solve the research problem (Creswell, 2014:67). The study used a sequential, exploratory, mixed methods design, and both components were given equal stats. The first phase included the qualitative component to provide evidence on models of diabetes mHealth, types of diabetes mHealth applications and challenges and barriers to implementing diabetes mHealth.

From this initial exploration, the qualitative findings were used to develop assessment measures that could be administered to a large sample (Strudsholm, Meadows, Vollman, Thurston & Henderson, 2016:7). In the quantitative phase, data were collected from HCPs in Addis Ababa, Ethiopia. Table 1.1 provides a general summary of the research design and method. Details of the methodology are provided in Chapter 2.

Table 1.1: Summary of Research Design and Method

Phase One: Integrative Literature Review (Qualitative)	
Objective	Conduct an integrative literature review on using mHealth technologies for diabetes management.
Sub-objectives	Examine the models of mHealth initiatives for diabetes management in low and middle-income countries. Identify types of mHealth applications for diabetes management in low and middle-income countries. Identify outcomes and challenges of mHealth initiatives for diabetes management in low and middle-income countries.
Population	Empirical evidence, Gray Literature, and Documents.
Data Collection	Search Strategy: PRISMA-P Search Engines: ERIC, MEDLINE, PubMed CINAHL Plus, and PsycINFO
Data Analysis	Thematic synthesis.
Phase Two: Cross-sectional Survey	
Objective	Examine potential barriers and facilitators for diabetes mHealth intervention in Ethiopia.
Sub-objectives	Explore the perceptions of HCPs regarding the possibility of mHealth for diabetes management in Ethiopia. Identify factors that influence the acceptance of mHealth for diabetes management among HCPs. Determine the impact of perceived usefulness and ease of use on the intention to use diabetes mHealth.
Population	Healthcare Professionals (HCPs).
Data Collection	Self-administered questionnaire.
Data Analysis	Descriptive, SEM and inferential (using 95% CI).

Phase Three: Modified Delphi technique	
Objectives	Design strategies for diabetes-related mHealth interventions in Addis Ababa, Ethiopia.
Population	Health informatics experts, HCPs, and diabetes patients with T2DM.
Data Collection	Modified Delphi technique.
Data analysis	Descriptive (content validity index).

1.10 RESEARCH SETTING

Under the Addis Ababa City Administration, Addis Ababa Regional Health Bureau coordinates the city's overall healthcare activities. Under its administration are 11 hospitals, 96 health centres, one public health laboratory, and two health science colleges. There are also ten sub-city health offices directly accountable to their respective sub-city administrations.

Phase I included an integrative review of the literature. Therefore, the setting is not applicable. The setting for Phase II was outpatient departments in health centres. Clinical staff in Phase II included physicians, health officers, and nurses. In Phase III, health informatics experts, health managers, and patients were included from health centres, federal and regional health bureaus, and academic institutions.

1.11 ETHICAL CONSIDERATIONS

In every research, the primary consideration must be the participants' dignity, rights, safety, and well-being. As Guraya, London and Guraya (2014:125) note, it is essential that the study has merit, has justified benefits, minimal risk to participants is kept, and the participants are treated with respect and dignity, and their informed consent is given. Creswell (2014:139) points out accuracy and validates core ethical issues in research. This research adhered to the basic ethical principles of health research.

All study subjects gave complete information and informed consent. Participation was voluntary, and study subjects were informed of their right to withdraw at any time from the study. Anonymity was ensured, and confidentiality of information was always maintained. There were no anticipated risks to the participants. Additionally, ethical clearance was obtained from UNISA and the Addis Ababa Regional Health Bureau (AARHB). The detailed descriptions are provided in Chapter 2.

1.12 SCOPE OF THE STUDY

This study's scope was limited to mHealth applications for diabetes management. Thus, the researcher acknowledges that the findings may not necessarily apply to other NCDs. This study focused on human perspectives, including acceptance and adoption of mobile technology for diabetes management. While acknowledging the patients' perspective in Phase III, patients were not included in the large-scale survey in Phase II.

1.13 STRUCTURE OF THE THESIS

Chapter 1 Orientation to the study: The chapter introduces mHealth applications in healthcare, especially managing chronic diseases such as diabetes. It outlines the background of mobile health-related policy in Ethiopia. It provided the general aims of the research with objectives and sub-objectives. It outlines the justification for the importance of this research, and gaps are indicated. It outlines the background of research philosophy, especially on the study's ontological, epistemological, axiological, rhetoric, and methodological stand. It also outlines the research design used in each phase of the study. Additionally, it presents the ethical considerations and scope of the study.

Chapter 2 Research Methodology: The chapter addresses the research approach and methodology used in this study. It highlights the design, study population and sample, instruments used and data collection and analysis methods. Detailed information was presented for each research phase, including the theoretical framework that guided this study. In addition, measures to ensure the study's trustworthiness, validity, and reliability, including ethical considerations, are presented.

Chapter 3 Analysis, Presentation, and Discussion of Findings of Phase I: this chapter presents results, analysis, and description of results and discusses Phase I. Major themes are identified to guide data collection in Phase II.

Chapter 4 Analysis, Presentation, and Discussion of Findings of Phase II: this chapter presents results, an analysis and a description of the results and a discussion of Phase II. It gives details of descriptive and inferential analysis and interpretation of the data gathered to address the set research.

Chapter 5 Integration, interpretation, and a discussion of combined findings: This chapter presents a description, analysis and interpretation based on the learning curve from the studied literature in Phase I and the knowledge generated throughout the study in Phase II.

Chapter 6 Development and discussion of the strategies for implementing mobile health: This chapter discusses diabetes mHealth strategies in Ethiopia. It presents an analysis and interpretation of data gathered to set strategies for diabetes mHealth.

Chapter 7 Conclusions, recommendations, and limitations: The chapter presents conclusions from the results. Recommendations and suggestions for further studies are presented regarding mHealth for diabetes management in Ethiopia.

Each of the subsequent chapters closes with a summary of key points that emerged in the chapter.

1.14 SUMMARY

This chapter provided a brief introduction regarding mobile penetration and health services. An overview was provided regarding diabetes: The illness' epidemiology, risk factors, complications, management, mHealth interventions, and current evidence. The problem led to research questions, and research purposes were stated. The theoretical framework which guided the proposed research was identified and discussed. The research paradigm was presented, and the research designs were discussed in each phase used to collect and analyse data. The next chapter presents the research methodology.

CHAPTER 2

RESEARCH METHODOLOGY

2.1 INTRODUCTION

The previous chapter dealt with the overview and orientation of the study. This chapter gives a detailed description of the research design and methodology and its implementation. Population, sample size, sampling technique, data collection, and data analysis are discussed for each study phase. Measures relating to the trustworthiness, validity, and reliability of instruments and ethical considerations are also described in this chapter.

2.2 RESEARCH DESIGN

The study design is a specific blueprint or protocol for conducting the study, which allows the investigator to translate the conceptual hypothesis into a practical one (Bloomfield & Fisher, 2019:28; Peters, Tran & Adam, 2013:10). According to Creswell and Creswell (2018:49), a research design is the process of inquiry within qualitative, quantitative, and mixed methods that serves as a roadmap during the overall research process. The research design demonstrates the value and rigour of the study. The research design of this study was constructed based on the established relationship between the research problem and the theoretical framework (Kivunja, 2018:45). MMR was chosen to answer the question: What literature exists regarding the use of mHealth models and applications in diabetes management in developing nations? What are the potential facilitators and barriers to adopting mHealth interventions for diabetes in Ethiopia? What would be the most appropriate mHealth strategy for diabetes management in Ethiopia? These are separate but related study questions.

Successful implementation of diabetes mHealth requires a detailed investigation of opportunities, challenges, user acceptance, and health technology adoption. Because it necessitates different methods and evidence integration, there is a growing interest in using MMR on mHealth for T2DM management (Matthew-Maich, Harris, Ploeg, Markle-Reid, Valaitis, Ibrahim, Gafni & Isaacs, 2016:2). As a result, in this study a sequential, exploratory, mixed methods design employing qualitative and quantitative methods was best suited to obtaining comprehensive evidence to investigate the opportunities for developing mHealth interventions for diabetes management in Ethiopia. The mixed-research design is appropriate and effective for investigating complex health problems. It improves the quality and credibility of empirical evidence (Creswell & Plano Clark, 2018:35; Strudsholm et al., 2016:1).

A sequential, exploratory, mixed methods design was initialised by qualitative exploration of existing literature on the implementation of diabetes mHealth applications, followed by a quantitative approach (Creswell & Plano Clark, 2018:122; Harrison et al., 2020:492; Toraman & Clark, 2019:181). At first, qualitative data were collected and analysed, and these findings were used for developing the subsequent quantitative data collection tool (Fetters, 2019:111; Plano Clark, 2019:107).

This type of study aims to collect different but complementary data on the application of mHealth for diabetes to better understand the challenges and barriers to local implementation and to bring together differing strengths and non-overlapping weaknesses of quantitative methods with those of qualitative methods. It is used when the researcher intends to triangulate the methods by directly comparing and contrasting quantitative statistical results with qualitative results (Creswell & Plano Clark, 2018:77; Plano Clark, 2019:107).

Data were integrated at the interpretation level. Intentional integration of data sets maximises the strength and minimises the drawbacks of each data type (Creswell & Plano Clark, 2018:77; Fetters, 2019:111). The qualitative data from the integrated literature review informed the generation of questions on the models, applications, outcomes, and challenges of diabetes mHealth, contributing to the successful adoption by HCPs. These findings were used to build a quantitative survey administered in a cross-sectional study of HCPs.

Generally, this study was developed in three phases: Phase I qualitative, Phase II quantitative, and Phase III integration of findings, development and validation of the strategies using the Modified Delphi technique. Figure 2.1 presents the phases of the study.

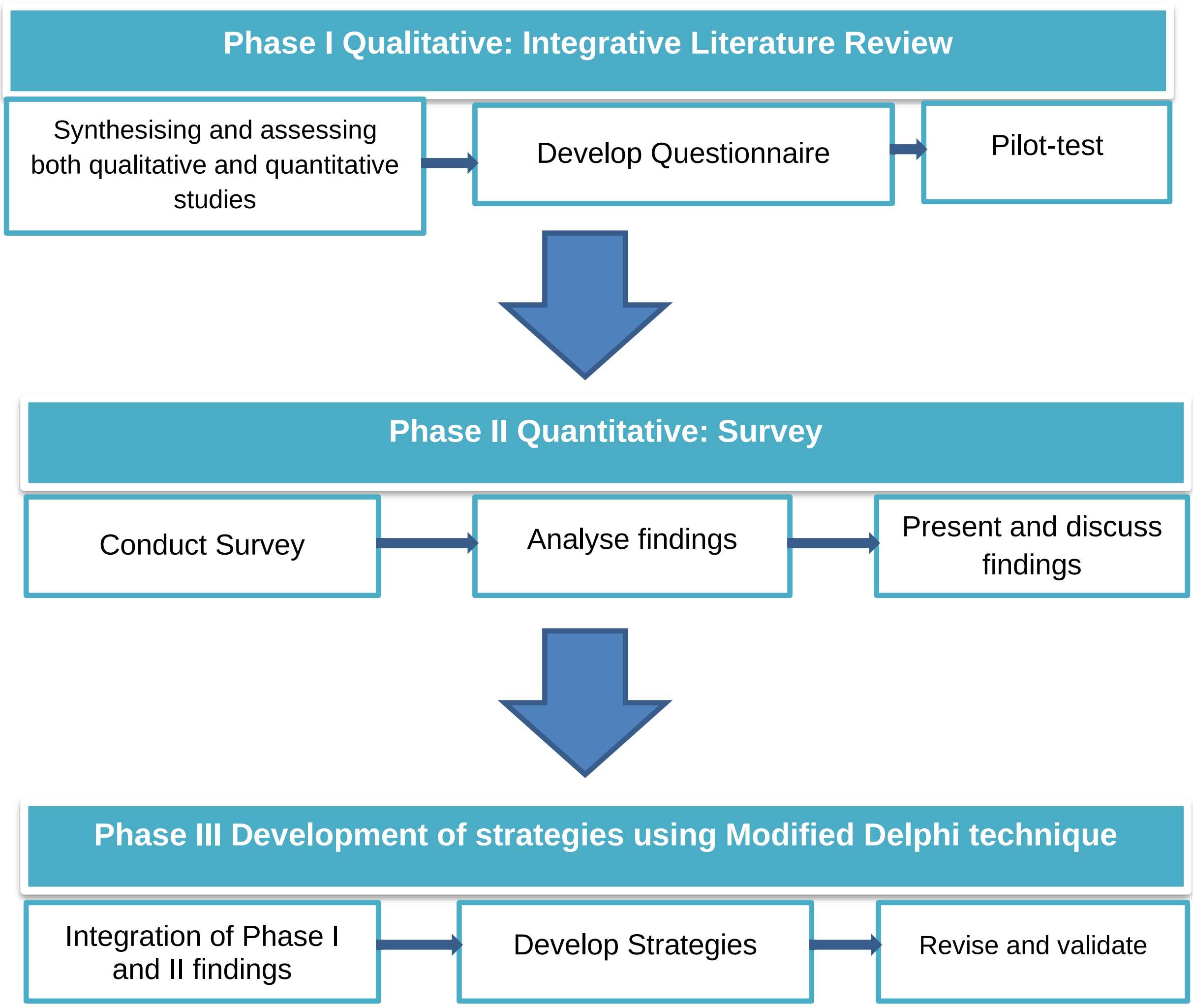

Figure 2.1: Research Phases of the Study

2.2.1 Phase I: Qualitative: Integrative Literature Review

An integrative review is the most comprehensive methodological approach that combines theoretical and empirical evidence (Souza, Silva & Carvalho, 2010:103; Whittemore & Knafl, 2005:547). Including various pieces of evidence from interventional and non-interventional literature makes an integrative literature review more appropriate and complete for investigating complex health problems (Souza et al., 2010:103). The strength of an integrative review's distinctive and rigorous methodology concludes the current state of knowledge among diverse studies (Russell, 2005:2; Whittemore & Knafl, 2005:546).

Different reviews were conducted to evaluate the effectiveness of mHealth for diabetes management (Holmen, Wahl, Småstuen & Ribu, 2017:1-16; Hou, Xu, Diao, Hewitt, Li

& Carter, 2018:2009-2013; Sarah J. Iribarren et al., 2017:28-40; Kitsiou, Paré, Jaana & Gerber, 2017:1-16; Latif et al., 2017:11540-11556; Matthew-Maich et al., 2016:1-18). Thus, this study conducted an integrative literature review on theoretical and empirical evidence as experimental and non-experimental literature to investigate diabetes mHealth application for diabetes management. This integrative literature review was focused on evidence from developing countries.

The integrative literature review was developed based on the research problems. The basic stages of integrative literature were employed rigorously. These included problem identification, literature search, data evaluation, data analysis and presentation (Russell, 2005:3; Whittemore & Knafl, 2005:549).

2.2.2 Phase II: Quantitative: Cross-sectional Survey

According to Creswell and Creswell (2018:49), a cross-sectional survey provides a numeric description of opinions or facts of a target population by studying a sample of that target population. The major strengths of cross-sectional studies are quick, simple, and cheap to perform. They are often based on self-administered or interview-administered questionnaires (Spector, 2019:7). Inference can also be made from the sample to the target population (Creswell & Creswell, 2018:49-50).

In this context, a cross-sectional study was employed based on the purpose of this study, which was the implementation strategies of the diabetes-related mHealth application. The cross-sectional survey in this phase was based on a random and representative sample to provide reliable population estimates. This also enabled this study to gather essential sources of information for evidence-based mHealth technologies for diabetes management and the acceptance of mobile technologies by the HCPs.

The primary aspect of a cross-sectional study is the measurement tool. The measurement tool in this study was connected to the qualitative study in Phase I. Major findings from the qualitative phase were used to refine and develop a new tool administered at a large scale.

2.2.3 Phase III: Development and Validation of Strategies: Modified Delphi Technique

The results from both phases were integrated to develop meta-inferences, which were used to develop the strategies for mHealth for Type 2 Diabetes Mellitus (T2DM) management. The integration was conducted at the interpretation level by a joint display of qualitative and quantitative findings using a table. Thus, strong evidence was gathered for developing strategies for effectively implementing a diabetes-related mHealth system (Creswell & Plano Clark, 2017:26; Guetterman, Fetters & Creswell, 2015:556). The draft strategies were revised and validated by the Modified Delphi method.

The Modified Delphi method is a consensus-building technique that seeks expert judgment on pre-determined contents in an organised and iterative manner. The Modified Delphi technique is the most widely used method for gathering data from experts. In terms of iteration and intent, the Modified Delphi technique is similar to classic Delphi (Avella, 2016:311). The only difference is that the Modified Delphi begins with pre-determined content drawn from various sources, and iteration can be extended until consensus is reached among experts. The main advantage of Modified Delphi is that it provides a solid foundation in previously developed evidence and improves the Round 1 response rate (Avella, 2016:306; McMillan, King & Tully, 2016:660).

In this study, three rounds of the Modified Delphi technique were employed. In the first round, a discussion was held with a purposively selected panel of experts on the draft strategies developed based on Phase I and integrated findings. Based on the comments and contributions of a panel of experts, strategies were converted to data collection tools for Round One. In Round Two of the Modified Delphi, the same experts rated each strategic activity's relevance and or importance, and the strategies were modified based on the experts' consensus level. In Round Three, different experts rated the relevance and appropriateness of the modified strategies to validate the final set of strategies based on the experts' consensus level.

2.3 RESEARCH METHODOLOGY

Research methods outline how data collection, analysis, and interpretation are conducted during the research process (Creswell & Creswell, 2018:41). Both emerging and pre-determined methods were incorporated. In the following sub-sections, the population, data collection methods, sampling and sampling procedure, data collection tools and procedures and data analysis methods are discussed in detail.

2.3.1 Research Setting

The study was conducted in public health centres under the Addis Ababa Regional Health Bureau in Addis Ababa, Ethiopia. Addis Ababa is the capital city of Ethiopia, located in the central highlands, with a land area of 527 km^2 (Berhanu, Raghuvanshi & Suryabhagavan, 2016:15). The city is organized into ten sub-cities (Figure 2.2). The Addis Ababa Regional Health Bureau, part of the Addis Ababa City Administration, coordinates the city's overall healthcare activities. It oversees ten sub-city health offices, 13 hospitals, 98 health centres, one public health laboratory, and two health science colleges (Federal Ministry of Health Ethiopia, 2016:73). 5721 HCPs work in the Addis Ababa Regional Health Bureau (Federal Ministry of Health Ethiopia, 2016:65).

Health centres were selected for this study based on their services to diabetes patients with Type 2 Diabetes Mellitus (T2DM). The service is not only limited to curative activities; preventive services were considered in this study. The integration of T2DM and hypertension prevention care and treatment service into primary healthcare were also launched and mainly implemented in AARHB (Federal Ministry of Health Ethiopia, 2016:41). Around 47 health facilities provide early detection and integrated management of diabetes (Federal Ministry of Health Ethiopia, 2016:45). Another important aspect is the accessibility and adequacy of mHealth services. According to the Ethiopian ICT strategy, Addis Ababa has the highest mobile and internet penetration. Additionally, 3G and 4G mobile network services are available in Addis Ababa (Reba, 2015:19). Figure 2.2 depicts Addis Ababa's map.

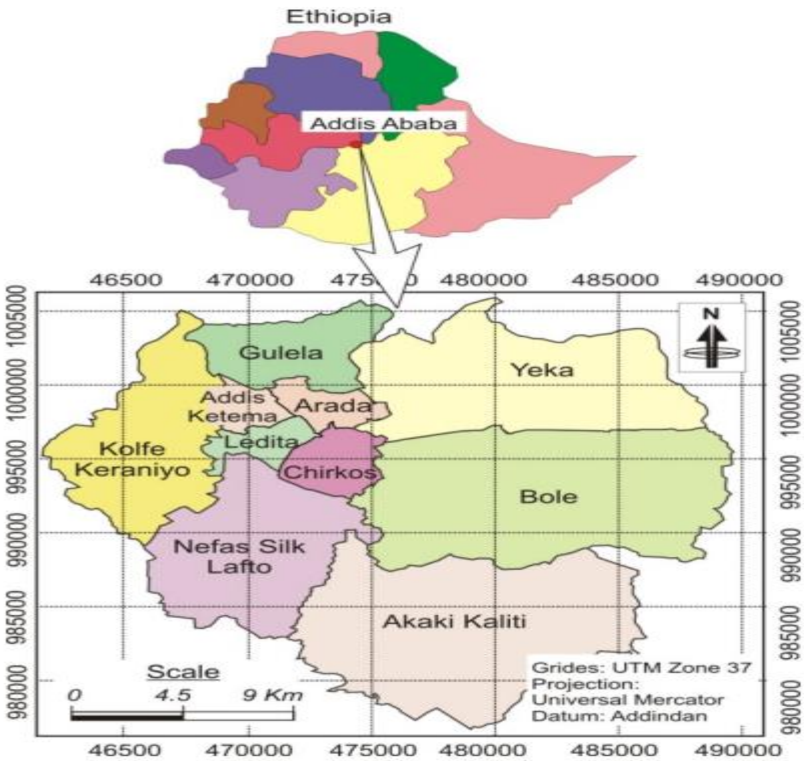

Figure 2.2: Map of Addis Ababa City (Berhanu et al., 2016:15).

2.3.2 Phase I: Qualitative: Integrative Literature Review

Phase one used an integrative literature review. It is the only approach that combines diverse methodologies (Whittemore & Knafl, 2005:547). The integrative review builds on meta-ethnography and imports some concepts from critical interpretive synthesis (Lubbe, ten Ham-Baloyi & Smit, 2020:2). Integrative literature was appropriate for this study as the researcher intended to go beyond original data to fresh interpretations of mHealth for diabetes management, which are not yet implemented in Ethiopia. The advantage of this approach in graduate studies is that it uses clear and thorough methods to identify and critically appraise relevant studies to address the research question and establish a more rigorous research foundation.

The qualitative approach in integrative literature review has the potential value to inform policy and practice (Thomas & Harden, 2008). Qualitative research involves emerging questions and procedures that inductively build from particulars to general themes. It generates a theory, a pattern, or a generalisation that emerges inductively from data collection and analysis (Creswell & Creswell, 2018:42).

According to Whittemore and Knafl (2005:152), an integrative literature review follows comprehensive and rigorous methods for reviewing the literature. An integrative literature review facilitates the inclusion of multiple perspectives and diverse methodologies that support developing strategies in emerging practice areas. The five steps in an integrative literature review are problem identification, literature search, data evaluation, analysis, and presentation. This study employed clear and precise search and selection criteria, which are discussed here.

2.3.2.1 Search Strategy and Study Selection

An integrative literature review requires thorough, objective, and reproducible data. According to Cumpston et al. (2019:11), data search is conducted in predefined resources. Such a system enhances the possibility of reliable effects and relieves preventable bias. The search strategy was developed in consultation with the UNISA librarian. First, the researcher divided the research questions into two main concepts: mHealth and diabetes. Then the main concepts' synonyms, abbreviations, and alternative spellings were listed in two combinations:

Combination I: "mobile Health," "mHealth," "telemedicine," "telecare," "SMS," "telemonitoring."

Combination II: "diabetes mellitus," "diabetes management," "diabetes monitoring" Diabetes Monitoring, "T2DM", "DM," "Diabetes."

These words were used in conjunction with using AND/OR appropriately.

The initial electronic search for primary studies was undertaken with the UNISA librarians. The retrieved databases include ERIC, MEDLINE, PubMed CINAHL Plus, and PsycINFO using the following keywords and expanded MeSH: "mobile health" and "mHealth. These terms were used in conjunction with diabetes mellitus. According to Whittemore & Knafl (2005:152), electronic database searches lead to between 10 and 50 per cent of articles in an exhaustive review. Reference lists of relevant reviews and studies were reviewed, and hand searches were also conducted in relevant journals of the field in addition to studies.

A search strategy was followed according to the preferred reporting items for systematic review and meta-analyses protocols (PRISMA-P) format. The PRISMA-P checklist primarily aims to prepare protocols for systematic reviews and meta-analyses that summarize aggregate data from studies, particularly evaluations of intervention effects (Moher, Shamseer, Clarke, Ghersi, Liberati, Petticrew, Shekelle & Stewart, 2015:2-3). The PRISMA-P detailed description is used to include and exclude studies. PRISMA-P was also used to identify relevant data for extraction and mapping.

Purposive sampling combined with a comprehensive search was employed to identify published and grey literature from various databases. Purposive sampling was based on predefined criteria.

2.3.2.2 Inclusion Criteria

Tentative inclusion criteria were established for the studies. It was open and substantive changes were made when findings from the integrative literature review informed it. The inclusion criteria for this integrative review were:

- The study evaluated mHealth interventions targeting diabetes management.
- All types of evidence were included (Grey literature, empirical, reports and guidelines).
- The study was implemented in low- and middle-income countries.
- The study was a peer-reviewed article.
- It was available in English.
- It was published between January 2006 and December 2018.

The criteria were selected to ensure the inclusion of all studies examining mHealth interventions' outcomes.

2.3.2.3 Exclusion Criteria

Studies were excluded from the review if they:

- Evaluate the willingness or intention to use mHealth without interventions.
- Were conducted in high-income nations due to resource disparities.

PRISMA2015 Flow Diagram

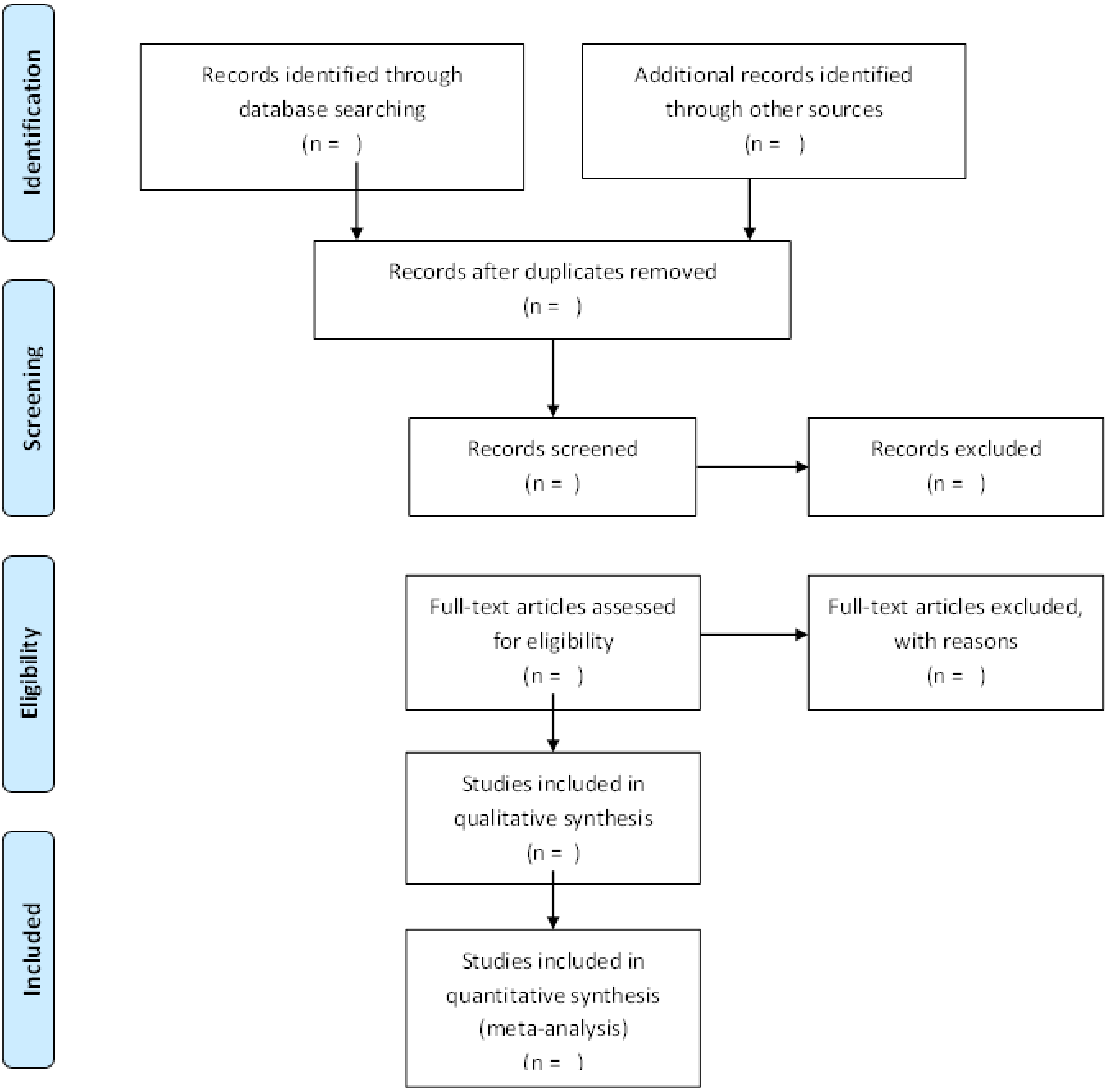

Figure 2.3: Search Strategy: Models and mHealth Applications for Diabetes Management

2.3.2.4 Data Extraction

In the integrative literature review, the data collection was mapped based on the PRISMA-P framework. Two experts extracted data. The two experts were doctoral students with experience conducting a literature review, and their role was limited to extracting data from selected articles. Any discrepancies between the two experts were resolved by discussion until a consensus was reached. A coding scheme was constructed to guide the extraction of information from each of the included studies. Major topics and sub-topics mapped included studies using flowchart boxes or data extraction formats (Russell, 2005:3; Whittemore & Knafl, 2005:549).

The information extracted included: the study's aim, the study design, the unit of analysis, the methods, the number of participants, the findings, the purpose of the technology mHealth platform or application, the theoretical framework, the location, the information architecture, the interoperability, strategies for strengthening diabetes management, outcomes of diabetes management and conclusions (see Annexure A).

2.3.2.5 Quality Assessment

The Joanna Briggs critical appraisal checklist for Randomised Controlled Trials (RCT), quasi-experimental/interventional studies, and qualitative studies was used in this study to determine the risk of bias (see Annexure B). The checklists are based on four responses: yes, no, unclear, and not/applicable. The Joanna Briggs critical appraisal checklist for RCT studies contains 13 questions about intervention, methods and analysis (Tufanaru, Munn, Aromataris, Campbell & Hopp, 2017:3-10). Similarly, the Joanna Briggs checklist for quasi-experimental/interventional studies contains nine questions related to intervention, methods and analysis (Tufanaru et al., 2017:3-10). The other tool used is the Joanna Briggs critical appraisal checklist for qualitative studies, which contains ten questions related to the congruence of methodology with philosophical perspective, research question, data collection method, and interpretations of results. The questions also address the researcher's influence (Lockwood, Munn & Porritt, 2015:179-187).

The risk of bias was rated as high when the "yes" scores of the study reached 49%, moderate when the "yes" scores of the study reached 50% to 69%, and low when the "yes" scores of the study reached 70% (see Annexure B).

2.3.2.6 Trustworthiness and Integrity of the Qualitative Phase

Integrative literature reviews are considered research methods and should meet the same standards of rigour. Different approaches are recommended to enhance validity during the review's data collection stage. These include: using an exhaustive data collection strategy; clearly defining sources of information, years included in the review and keywords used for searching; using data extraction formats; communicating all selection biases; and summarising and presenting characteristics of studies included in the samples (Russell, 2005:4; Souza et al., 2010:104; Whittemore & Knafl, 2005:549).

The review was begun with a formulated research question and specific objectives. The balance between the specific objectives and methodological approach was maintained throughout the study. Clearly defining the search question to determine the studies to be included is the most important stage in the integrative review, which defines the participants, interventions to be evaluated, and results to be measured (Souza et al., 2010:103).

An exhaustive data collection strategy was applied during data collection. A data collection/search strategy was developed with the assistance of the health research librarian. Samplings of the papers were made explicit to allow transferability, credibility, dependability, and confirmability using the PRISMA-P format. Data extraction was developed to extract information from selected studies and literature systematically. Two independent reviewers conducted the data extraction to ensure integrity. Any discrepancies between the two experts were resolved by discussion to reach a consensus.

2.3.2.7 Qualitative Data Handling

The qualitative data were extracted using the data extraction format. As discussed earlier, data extraction was conducted by two experts.

Finally, the two formats were combined in one Excel sheet after resolving disagreement by discussion. All the information extracted from the included literature was recorded and stored in Microsoft Excel. The two experts rechecked the completeness and accuracy of the data. The data were arranged by topic and sub-topics to make it more convenient for data analysis which is discussed later.

2.3.2.8 Qualitative Analysis

There are different analysis mechanisms in qualitative data analysis (Christmals & Gross, 2017:8; Hopia, Latvala & Liimatainen, 2016:5). The choice of data analysis depends on several factors, including the research question and purpose of the synthesis, the nature of the evidence, and outcomes (Torraco, 2016:419). A systematic review that explores or conceptualises an issue might be best addressed through an interpretive synthesis (Christmals & Gross, 2017:8; Elsbach & van Knippenberg, 2020:8-9).

As the emphasis is on interpretive synthesis, thematic synthesis was used because it relies primarily on using words and texts to summarise and explain the synthesis's findings (Elsbach & van Knippenberg, 2020:8-9; Torraco, 2016:1284). First, data reduction was conducted using tables and figures (Whittemore & Knafl, 2005). The quantitative findings were converted into qualitative (qualitising) to facilitate data reduction and analysis (Noyes, Booth, Moore, Flemming, Tunçalp & Shakibazadeh, 2019:7). Then, the textual description of the quantitative studies and qualitative description are all displayed for comparison and analysis. The findings are presented in tables and described using texts (Souza et al., 2010:104; Whittemore & Knafl, 2005:549).

The general framework for synthesis comprised:

Development of Framework: After reading the literature, the framework was developed on mHealth models and applications to interpret and understand the implementation processes.

Development of Preliminary Synthesis: preliminary synthesis of findings was conducted to identify contextual factors that may influence results. A textual description was created for the included studies. The textual description was used to create a cluster, and the findings identified recurrent themes. Attention was given to the heterogeneity of study methods.

Exploration of the relationship: the relationship between the findings was explored. The cross-literature comparison allows patterns to emerge. Cross-comparisons were used to explore factors that may explain differences, including variances in health technology user experiences, the effects of diabetes mHealth interventions and the implementation of diabetes mHealth applications. It also identifies opportunities and challenges for implementing diabetes mHealth applications.

2.3.3 Phase II: Quantitative

Quantitative methods provide a numeric estimation of population variables and test objective theories by investigating the relationship between variables. Among the numerous quantitative methods, surveys and experiments are the most distinguished design in quantitative research. According to Creswell and Creswell (2018:183), surveys provide a numerical description of a population's attitudes or perceptions by studying a population sample.

Depending on whether the outcome variable is evaluated for potential associations with exposures or risk factors, cross-sectional studies can be classified as descriptive or analytical. The analytical cross-sectional is used to investigate the associations between variables (Wang & Cheng, 2020:S66). These variables can then be measured with instruments, and the resulting numbered data can be analysed statistically to summarise and investigate associations (Creswell & Creswell, 2018:162). The quantitative method, analytical cross-sectional design, was appropriate for Phase II of this study since the objective was to quantify the mHealth acceptance of HCPs and investigate the relationship between the theoretical model variables. The statistical analysis is also crucial to determine the factors that predict acceptance of mHealth by HCPs.

The information was gathered at a single fixed point in time. Self-administered surveys, interviewer-administered surveys, mail surveys, and online surveys are all options. Data were collected from randomly selected HCPs using a self-administered questionnaire. Although it takes more time and money, the self-administered questionnaire has a high response rate (Safdar, Abbo, Knobloch & Seo, 2016:1273; Sedgwick, 2014:2).

2.3.3.1 Population

The quantitative phase's target populations were Health Care Professionals (HCPs) working in the outpatient department of health centres in the Addis Ababa Regional Health Bureau who were exposed to daily diabetes management in the outpatient department.

HCPs' acceptance of mHealth is critical to providing technology-enhanced clinical care and improving the quality of clinical care (Brzan, Rotman, Pajnikihar & Klanjsek, 2016:210). Additionally, it would be a challenge to implement diabetes-related mHealth effectively if it is not accepted and adopted by HCPs (Garavand, Samadbeik, Kafashi & Abhari, 2017:403; Graffigna, Barello, Bonanomi & Menichetti, 2016:5; Okazaki, Blas & Castañeda, 2015:207).

2.3.3.2 Sampling and Sample

The study utilised a random sampling method, which is used in quantitative research to select participants. Probability sampling is appropriate for quantitative research to ensure that the samples are representatives of the population because each individual has a known chance of being selected from the population (Creswell & Creswell, 2018:334). Using a random sampling method enhances the representativeness of the research findings (Creswell & Creswell, 2018:212). The study used a multistage sampling method, which involved successive random sampling of units progressing from a geographic area to a specific sample per the eligibility criteria. Multistage is ideal if the population is dispersed in a large geographical area and when it is impossible or impractical to compile a list of the constituents of the population. The multistage sampling techniques allowed this study to begin by selecting a cluster of health centres because it was difficult to construct a sampling frame of HCPs for all health centres. The number of health centres and HCPs working in outpatient departments in selected health centres were sought for sampling from the Human Resources department, Addis Ababa Regional Health Bureau.

In total, 98 health centres are in Addis Ababa in ten sub-city administrations. The first stage involved creating geographic clusters of health centres, and out of 98, 30 health centres (30%) were randomly selected using cluster sampling techniques, using the proportionate formula:

$$ni = (Ni/N) * n$$

ni= cluster size for each sub-city; Ni= total number of clusters in each sub-city (health centres); N= total number of clusters (98 health centres); n= total size of cluster or sample (30 health centres).

Then, a sampling frame was constructed based on the type of professionals involved in clinical care and managing diabetic patients in the selected health centres. In the second stage, stratified sampling techniques were employed to select HCPs based on their profession types randomly using the proportionate formula:

$$nsi = (Nsi/N) * n$$

nsi= sample size of each stratum; Nsi= size of each stratum, N= total population (685), n=total sample size (272).

Figure 2.4 presents the scheme of the sampling procedure.

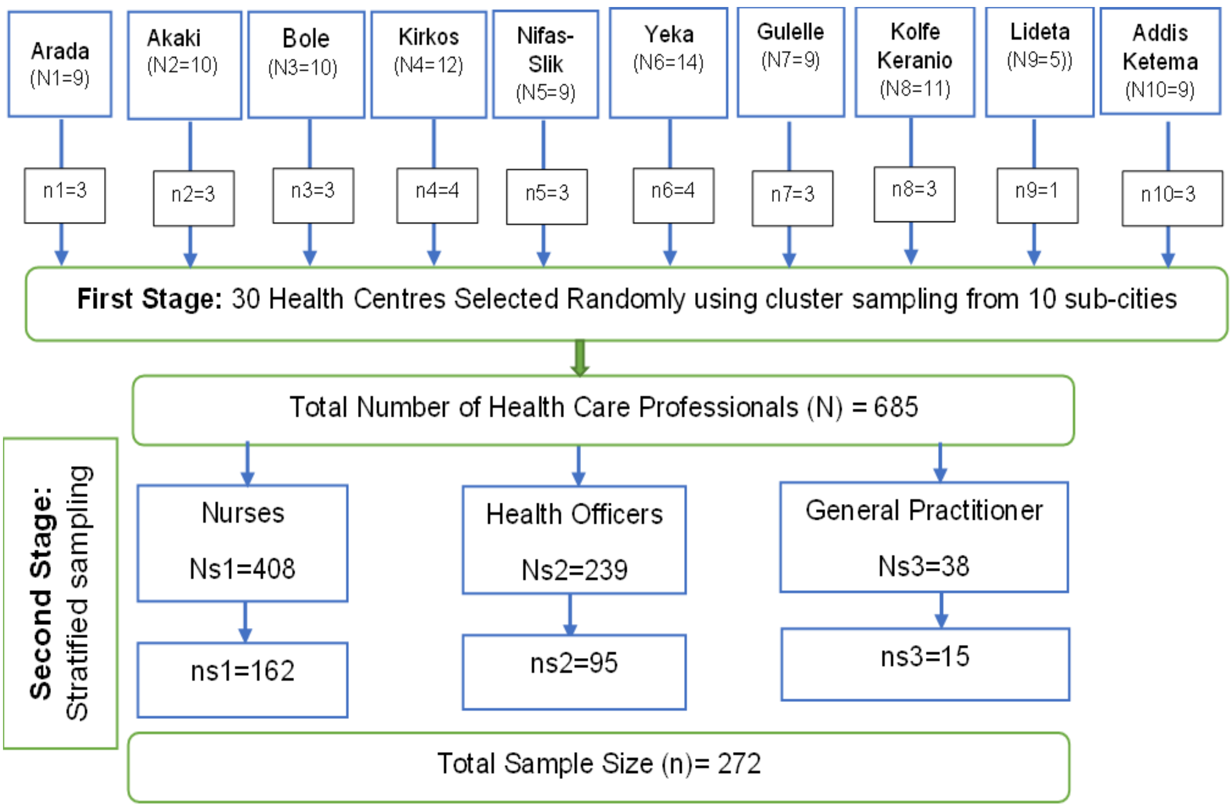

Figure 2.4: Sampling Procedure

2.3.3.2.1 Inclusion Criteria:

1) HCPs who are working in outpatient departments such as diabetes clinics in health centres, and

2) HCPs who have been involved with day-to-day diabetes management for over a year.

2.3.3.2.2 Exclusion Criteria:

1) HCPs not directly involved with diabetes management.

Sample size determination is not an arbitrary process. According to Creswell and Creswell (2018:213), the sample size should not be assumed by some random fraction or adopted from previous studies. Instead, it should be aligned with the analysis plan of the study. In quantitative research, sample size depends on the significance level, power, and magnitude of the difference (effect size) (Creswell & Creswell, 2018:210; Wang & Cheng, 2020:S67). The Raosoft sample size calculator considers these three functions of sample size: 95% Confidence interval, 5% margin of error, and 50% response distribution. Thus, the sample size was calculated using Raosoft online sample calculation formula based on the data obtained from the human resource department. The number HCPs workings in the outpatient department were around 685.

x=Z(c/100)2r(100-r)

n=N x/((N-1)E2 + x)

E=Sqrt[(N - n)x/n(N-1)]

By adding a 10% non-response rate, the total sample size was 272 HCPs.

2.3.3.3 Data Collection Methods

In this second phase, quantitative data were collected through a self-administered questionnaire. Self-administered questionnaire refers to a data collection tool that has been explicitly created for completion by a respondent without support or minimal support of the data collector (Cheung, 2020:1). The quantitative data collection in

Phase II and qualitative data collection in Phase I collections are related to each other and not independent. One builds on the other. The quantitative data collection in this phase was built on the qualitative findings in Phase I (Hitchcock & Onwuegbuzie, 2022:25).

Four data collectors were involved in the data collection process. The principal investigator trained the data collectors one week before the actual data collection so that the process could be followed consistently (Creswell & Creswell, 2018:216). The researcher closely supervised the data collection process. Before the start of data collection, informed consent was sought from the participants (see Annexure C).

2.3.3.4 Data Collection Instruments

A self-administered questionnaire was used to collect quantitative data (see Annexure D). As described earlier, the data collection instruments in Phases I and II were not independent. The questions for the second phase were derived from the themes generated from the first phase. A self-administered questionnaire is less expensive and can be used effectively with many participants. It enables data collection from many participants quickly while maintaining respondent anonymity. In removing the interviewer from the equation, survey quality can be improved by eliminating interviewer error (Jong, 2016:1). Self-administered questionnaires are the primary measuring instrument in survey research (Cheung, 2020:1). A structured self-administered questionnaire was used because of the quantitative nature of the research and the fact that the respondents had a high level of literacy.

2.3.3.5 Development of the Instrument

The following variables were derived from the study's theoretical framework: perceived usefulness, perceived ease of use, critical features of the mHealth applications, perceived complexity, and behavioural intention to use diabetes mHealth. The data collection instrument was developed based on the research objectives, findings of Phase I, and literature review (Ahlan & Ahmad, 2015:30; Frandes, Deiac, Timar & Lungeanu, 2017:260; Humble, Tolley, Krukowski, Womack, Motley & Bailey, 2016:33).

The questionnaire had the following sections (see Annexure D):

Section A General Information: This section has two parts. The first part contains sociodemographic information, including gender, age, education level, working positions, mobile phone possession and type, internet access, education and training related to mHealth. The information was used to investigate the relationship with mHealth acceptance by HCPs.

Section B Perception regarding the use of mHealth: This section assesses the attitude of HCPs on the opportunity of mHealth for T2DM management identified from Phase I.

Section C Perception of the usefulness of diabetes mHealth application: This section was part of the theoretical model and assessed the perceived usefulness of mHealth uses for T2DM management by HCPs.

Section D Critical features of the mHealth applications: This section assesses the views of HCP on the criticality of mHealth features identified from Phase I of this study.

Section E Perceptions on complexity/ease of use of mHealth applications: This section was part of the theoretical model and assessed the perceived complexity/ease of use of mHealth for T2DM management by HCPs.

Section F Health professional intention to use diabetes mHealth system: This is the theoretical framework's outcome or its dependent variables, and it assessed the acceptance of mHealth for T2DM management by HCPs.

After the tool development was completed, it was converted to a mobile digital data collection tool using KoBoToolbox software. The Harvard humanitarian initiative developed KoboCollect, a free, open-source, simple, robust, and powerful tool for mobile data collection. Data can be entered using a web browser or KoBotoolbox's Android app, KoBoCollect. On both Android phones and tablets, KoBoCollect supports offline data entry. This study used KoBoCollect to collect data using mobile phones and tablets. KoBoToolbox offers researchers 10,000 submissions per month, 5 GB of data storage and unlimited projects (Pandey & Surachna, 2021:5553).

2.3.3.6 Reliability of the Data Collection Instrument

Reliability refers to the consistency of a measure. The most important type of reliability for multi-item instruments is internal consistency, the degree to which groups of items on an instrument behave consistently (Creswell & Creswell, 2018:215; Souza, Alexandre & Guirardello, 2017:86-87). Developing an instrument is primarily focused on reducing errors in the measurement phases. There are different means of estimating the reliability of any measure that identify the sources of measurement error. This includes stability, equivalence, and homogeneity (Cohen, Manion & Morrison, 2018b:268; Souza et al., 2017:87).

The instruments were designed based on literature and study objectives to ensure reliability. Additionally, the tool was piloted on a population not part of the main study. Pretesting or pilot testing an instrument allows for identifying such sources and taking corrective actions. Cronbach's alpha was used to measure the tool's internal consistency (homogeneity). This test determines the average of all correlations in every combination of split halves (Mohajan, 2017:13). Cronbach's alpha was appropriate to test internal consistency because the quantitative instruments had more than two responses (Creswell & Creswell, 2018:215; Mohajan, 2017:16).

During the pilot study, data were collected from 40 HCPs who were different from the sampled subjects for the actual study. Data collected from the pilot test were analysed using SPSS software to determine Cronbach's alpha. Cronbach's alpha result is a number between 0 and 1. An acceptable reliability score is 0.7 or higher (Creswell & Creswell, 2018:119; Pallant, 2020). The internal consistency of the tool was also checked using the actual research data. The Cronbach's alpha of the pilot study is presented in Table 2.1. The detailed result of component factor analysis is presented in Chapter 4.

Table 2.1: Construct Reliability of the Data Collection Instrument (n=40)

Construct	Number of items	Cronbach's alpha
Perception (attitude)	12	0.87
Perceived usefulness	6	0.79
Perceived complexity/ease of use	7	0.96
Intention to use	10	0.84

2.3.3.7 Validity of Quantitative Data Collection Instrument

Validity refers to the extent to which a questionnaire purports to measure (Creswell & Creswell, 2018:215). It is the extent of built‑in error in the questionnaire (Cohen et al., 2018b:245). A drafted questionnaire was first developed to establish validity.

Content validity refers to the instrument's ability to measure what it is designed to measure (Almanasreh, Moles & Chen, 2019:2). The procedures to establish content validity comprise an exhaustive literature review and consultation with content experts (Cohen et al., 2018b:262), which were used in this study.

Face validity is a subjective assessment of a construct's operationalization by a researcher, expert, or non-expert. In this study, the face validity of the data collection instrument is addressed through subjective assessment by the researcher, supervisor, experts, and pilot study participants (Taherdoost, 2016:29).

The extent to which an instrument measures the characteristic or theoretical construct it intends to measure is known as construct validity. Confirmatory factorial analysis was used to evaluate the model's overall goodness of fit using the model-fit measures (2 /df, GFI, NFI, CFI, RMSEA). Incremental fit indices with higher values indicate greater fit improvements over the baseline model. Values in the .90s (or more, recently 0.95) and a 2 /df below 3.0 are typically considered a good fit. Reliability, composite reliability, and average variance extracted were used to test the convergence validity of the scale. Additionally, discriminant validity was obtained by contrasting the average variance extrapolated from each factor with the shared variance between factors (Newman & Constantinides, 2021:94). The findings of the confirmatory factorial analysis are presented in Chapter 4.

2.3.3.8 Data Management

The principal investigator handled all data, and they were inaccessible to anyone. Data collected through self-administered questionnaires using the KoBoCollect android application were cross-checked after every day's fieldwork. The data collected in the KoBotoolbox software were exported to Statistical Package for Social Science (SPSS) version 24 using CSV format. The use of digital collections ensures that data are accurate, consistent, and complete. When digital data collection is designed with quality attributes, data cleaning activities are significantly reduced (Pandey & Surachna, 2021:5551).

2.3.3.9 Quantitative Data Analysis

A quantitative analysis goal is to analyse the collected numerical data to investigate underlying patterns, trends, and relationships to draw conclusions from the study. The quantitative data analysis was conducted using SPSS version 24, including descriptive and inferential statistics (Leech, 2021:355). The AMOS software was used for Structural Equation Model (SEM) analysis.

Descriptive statistics are used to organise and summarise collected sample data. It allowed the researcher to organize the variables and summarise the mHealth acceptance of HCPS. Descriptive statistics such as frequencies, percentages, measures of central tendencies and dispersions were used to explain the selected characteristics of the HCPs (Pallant, 2020:69). Means and standard deviations were determined for perceived usefulness, perceived ease of use and behavioural intention (acceptance) to use constructs. The findings of descriptive statistics were presented using standard tables following statistical principles (Holcomb, 2016:2).

Inferential statistics are analysed to generalise the sample to the population and draw a conclusion from the study. In this study, component factor analysis, SEM, and multiple regression were conducted to investigate the relationship among variables and draw a conclusion from the study (Holcomb, 2016:2). In the component factor analysis, a principal component analysis (PCA) starts with a large data set and tries to summarise the data using a smaller set of components. PCA was conducted for perceived usefulness, perceived complexity/ease of use, and the intention to use constructs of the theoretical framework (Pallant, 2020:202).

Before performing PCA, the suitability of the data for analysis was determined using correlation coefficients and the Kaiser-Meyer-Olkin sampling adequacy measure. Many correlation coefficients greater than 0.3 and KMO values greater than 0.6, with statistical significance for Bartlett's Test of Sphericity (p0.05), are the eligibility criteria for further analysis in the PCA. Another criterion for suitability is uni-dimensionality. A construct is one-dimensional if its constituent items represent the same underlying trait (Pallant, 2020:205). In this study, uni-dimensionality is analysed by an eigenvalue and eigenvalue of 1 or more using Kaiser's criterion to declare items used for measurement appropriate to explain one component. Another criterion is convergent validity which tests the relationship between measures that ought to be related. Loading factors, composite reliability, and average variance extracted are examined to determine the measurement's convergent validity, and a value greater than 0.7 is an acceptable range. Another suitability feature is discriminative validity which tests the level of mutual exclusion between the items used to measure the various constructs. Discriminate validity is tested by comparing the correlation matrix with the calculated square root of the AVE, and the criteria are that the square root of the AVE should be higher than the corresponding correlation (Mertens, Pugliese & Recker, 2017:49-50; Pallant, 2020:213-215).

After the PCA, SEM was used to test the relationship between perceived usefulness, perceived ease of use/complexity, and behavioural intention (acceptance). The summated scale was used in SEM. The results of the analysis of the structural model included path coefficients, path significances, and variance constructed (R^2 values) for each dependent variable. Confirmatory factorial analysis using the model-fit measures was used to assess the model's overall goodness of fit, including goodness-of-fit index (GFI), adjusted goodness-of-fit index, comparative fit index (CFI), normal fit index (NFI), incremental fit index (IFI), and root mean square error of approximation (RMSEA). Higher incremental fit indices indicate a larger improvement over the baseline model in fit. Values in the .90s, values less than 0.08 for root mean square error of approximation (RMSEA), and $\chi 2$ /df less than 3.0 are generally accepted as indications of a good fit (Mertens et al., 2017:50; Newman & Constantinides, 2021:94).

Additionally, a multiple linear regression was conducted to identify factors affecting the intention to use mHealth by HCPs. Regression is an inferential statistic that investigates the relationship between several independent variables and a dependent variable (Mertens et al., 2017:28). Before conducting the multiple linear regression, multicollinearity, outliers, normality, linearity, homoscedasticity, and independence of residuals assumptions were checked. The first assumption is the absence of multicollinearity, which exists when the independent variables are highly correlated (r=0.9). Multicollinearity was checked for a correlation value greater than 0.7. The Variance inflation factor (IVF) less than ten and tolerance level greater than 0.1 were used to declare the absence of multicollinearity. The linearity was checked using a Normal P-P Plot, and linearity was considered when a reasonably straight diagonal line was observed. Another assumption is homoscedasticity, in which all predicted scores should have the same variance of the residuals about predicted dependent variable scores. A scatter plot was used to check homoscedasticity, and the plot should look like a reasonably "boxed" cloud with most of the scores grouped in the middle (along the 0 points). Outliers are checked by inspecting the Mahalanobis distances (Mertens et al., 2017:28-30; Pallant, 2020:177-180).

The adequacy of the sample size is checked by using the formula given by Tabachnick and Fidell (2013:123): $N > 50 + 8m$ (where m = the number of independent variables). A total of 17 independent variables, including the constant, were tested in the regression model, and based on the formula, the required sample size is 186, which is smaller than the sample size of this study (Pallant, 2020:170).

Overall model fitness of the regression was checked using F statistics, associated degree of freedom, and R^2 coefficient. The 5% significance level was used to guide the decision of statistical significance of the overall model fitness. Further, the β estimates, t-value, p-value and VIF are presented in a table. The 5% significance level was used to guide the decision of statistical significance.

2.4 INTERNAL AND EXTERNAL VALIDITY OF THE STUDY

Validity and rigour (trustworthiness) address decisions during research inquiry and impartiality of research findings. This sequential, exploratory, mixed methods design reviewed validity for quantitative and qualitative research because of the requirement of multiple validities (Onwuegbuzie & Abrams, 2021:253).

2.4.1 Internal (Contextual) Validity

Internal (contextual) validity is one of the essential indices of validity. In quantitative research, it is called internal validity; in qualitative, it is expressed as contextual validity (Creswell & Plano Clark, 2018:367)

Internal validity or lack of bias in quantitative research aims to identify proper selection criteria and groups of study subjects (Onwuegbuzie & Abrams, 2021:253). There are different threats to internal validity, including inadequate knowledge of the research area, poor instrumentation, and bias in data analysis. Statistical analysis was done by adjusting variables to control confounding variables to enhance internal validity. Additionally, the data collection process was well supported by the literature. Instrumentation issues occurred when scores yielded from a measure lacked the appropriate level of consistency (as a result of inadequate content, criterion and/or construct validity) (Creswell & Creswell, 2018:242).

In the contextual validity of qualitative research, the truth value is assessed by credibility. Credibility refers to our ability to capture the multiple realities of those we study (Leung, 2015:325). Contextual validity was addressed using the following strategies (Creswell & Creswell, 2018:245):

Triangulation of data: Data were collected through multiple sources and evidence (observational, interventional, qualitative, and non-empirical evidence).

Repeated data extraction: Data extraction was conducted by two experts independently, and the difference was resolved by consensus.

Clarification of researcher bias: The researcher's role was well articulated and communicated in the thesis.

2.4.2 External Validity (Generalizability and Transferability)

External validity in quantitative research determines whether one can draw more general conclusions based on the model used and whether results may be generalised to other samples (Cohen et al., 2018b:276). The literature search was conducted from different ecological settings. In addition, a representative sampling technique was employed in Phase II to enhance the generalisability of the finding to the target population (Creswell & Creswell, 2018:247).

In qualitative research, generalisability concerns whether the research results are transferable. In the qualitative phase, rich, thick, detailed descriptions were provided so that anyone interested in transferability could have a solid framework for comparison (Creswell & Plano Clark, 2018:326).

2.4.3 Reliability (Consistency)

Reliability in quantitative research generally refers to the extent to which a variable or set of variables is consistent in what it is intended to measure. Cronbach's alpha test was used to enhance the internal consistency of the instrument (Souza et al., 2017:86).

In qualitative research, reliability is related to consistency, typically meaning that another person should be able to examine the work and come to similar conclusions. Two important procedures were followed to address reliability. First, a data extraction examination was conducted by two experts, and an inter-coder agreement was determined (triangulation). The second peer examiner was recruited during the qualitative data analysis process.

2.4.4 Content Validity

Content validity looks at whether the instrument adequately covers all the content that it should concerning the variable. After the data were developed by reviewing important literature, expert judgment was sought and included to ensure the content validity of the quantitative instruments in Phase II and Phase III (Souza et al., 2017:87-88).

2.5 PHASE III DEVELOPMENT AND VALIDATION OF STRATEGIES: MODIFIED DELPHI TECHNIQUE

In Mixed Method Research (MMR), integrating qualitative and quantitative data signifies the importance and relevance of mixed methods. A study cannot be categorised as using "mixed methods" simply because it uses qualitative and quantitative data collection techniques. MMR is defined and shown to have value by integrating or linking the two data strands (Fetters & Molina-Azorin, 2017:427; Guetterman et al., 2015:554; Oliveira, 2020:1).

Integration can occur at various study levels, including the design, methods, and interpretation. Connecting, constructing, merging, or embedding are different ways to integrate (Oliveira, 2020:2; Onwuegbuzie & Johnson, 2021:14-15). The intent of integration at the design level in the exploratory mixed method is to build from the qualitative phase of the study so that a quantitative feature can be established. As discussed previously, the Phase I findings were integrated at the design level to develop the data collection instrument for Phase II. However, integration is also conducted at the interpretation level to explore the connection between Phase I and II findings. The integration at the interpretation level is important to connect the qualitative and quantitative findings.

The integration of this study aimed to demonstrate how the opportunities for mHealth interventions for diabetes management identified in phase-I are connected to HCPs' perception of these identified opportunities. The integration aimed to determine the mHealth use in developing countries and challenges and connect how these were perceived and accepted by the end users to guide the development of strategies for diabetes-related mHealth interventions in local settings (Onwuegbuzie & Johnson, 2021:15).

This study used a joint display to integrate Phases I and II findings at the interpretation level. A joint display analyses integration data by arranging quantitative and qualitative data in a single table or graph, allowing a more straight and nuanced comparison of the findings (Creswell & Plano Clark, 2018:330; Guetterman et al., 2015:554). Both Phases I and II findings are displayed side by side in a table to aid the drawing of meta-inferences that could be used to guide the development of strategies for diabetes-related mHealth. The meta-inference generated was presented in narration and used to develop the draft strategies. After the draft strategies were developed based on the integrated findings, a Modified Delphi Technique was conducted to revise and validate the developed strategies.

2.5.1 The Modified Delphi Techniques

According to Avella (2016:311-313), there are two types of Delphi panels: conventional and modified methods. The Modified Delphi technique was utilized to develop strategies for implementing mHealth for diabetes management in Ethiopia. Modified

Delphi Techniques is a formal group consensus procedure that quantitatively and methodically combines expert judgment and evidence (Avella, 2016:306). It allows panel members to augment the possible answers based on their experiences (Strudsholm et al., 2016:9). The main advantage of Modified Delphi is that it provides a solid foundation in previously developed evidence and improves the Round 1 response rate. The Modified Delphi method also allows experts to reach a consensus without meeting face-to-face, which significantly reduces the bias introduced by group interaction (Avella, 2016:311; Fink-Hafner, Dagen, Doušak, Novak & Hafner-Fink, 2019:16). It was used in this study to seek consensus on the appropriateness of the proposed strategies. Key findings from both phases were integrated to derive meta-inferences.

2.5.2 Recruitment of Experts

The type and number of participants are crucial in designing the Modified Delphi panel. There are two types of samples: Homogeneous and Heterogeneous (Fink-Hafner et al., 2019:16). In Rounds One and Two, heterogeneous senior experts were selected purposively from governmental organisations, nongovernmental organisations (NGOs) and Higher Education Institutes (HIEs) based on the following criteria:

- Profession: Health Informatics/Health information system expert/eHealth expert/software developer/Networking expert.
- Qualification: Second degree and above.
- Experience: Experts with five years and above experience in the design and development of mHealth and familiarity with digital health policy and strategies.

There is no agreement on the panel size for the Modified Delphi technique nor recommendations or unequivocal definitions of “small” or “large” samples (Humphrey-Murto, Wood, Gonsalves, Mascioli & Varpio, 2020:165). A panel with ten experts is adequate for revising and validating the content relevance before large-scale validation (Nasa, Jain & Juneja, 2021:119). For Rounds One and Two, ten experts were selected purposively using the above criteria.

For Round Three, the researcher contacted the digital health department at the Federal Ministry of Health, Addis Regional Health Bureau and ten sub-city health offices to identify and construct a list of experts that included senior health informatics specialists, HCPs, and patients who fulfil the selection criteria. The researcher also contacted the Addis Ababa University Information System schools and non-governmental organisations. The selection criteria were:

- Health Informatics/ICT experts (second degree and above working in the Ministry of Health, regional health bureau, Higher Education institutes, Woreda Health Office, and health centre).
- HCPs (more than five years working experience in NCD centre at the health centre, previous experience in mHealth).
- Adult Patients with T2DM: literate and who have experience in mHealth.

Despite there being no consensus on the number of participants for Modified Delphi, it is recommended to increase the sample size to heterogeneous experts (Nasa et al., 2021:119). In Round Three, a panel of 100 experts was selected purposively using the above criteria.

The purpose of the study was explained to all experts who participated in the Modified Delphi and who provided informed consent (see Annexure E).

2.5.3 Development and Validation of Strategies

Iterative approaches with multiple rounds and feedback are the classical features of the Modified Delphi panel. Originally, Dalkey and Helmer (1963:460) used five rounds of the Delphi panel. However, there is no scientific evidence or rules on the number of rounds. The most commonly used number was three rounds (Davidson, 2013:56). Three rounds of the Modified Delphi technique were employed to revise and validate the developed strategies based on the integrated findings.

2.5.3.1 Preliminary Stage

Draft strategies were developed using the meta-inference generated from combined findings. A presentation based on the draft strategies was also prepared to facilitate discussion with the panel of experts during Round One of the Modified Delphi.

2.5.3.2 Round One

In Round One, the researcher telephoned the selected ten experts to outline the goals of the study, the Delphi process, and ethical considerations. After the verbal agreement, the consent form was emailed to experts (See Annexure E).

The purpose of round one is to present the draft strategies and hold discussions. After presenting the strategies, a discussion with experts to gather additional information, comments, and suggestions. The comments and suggestions the experts agreed on were used to revise the draft strategies. Participants were also invited to add additional strategies, which were incorporated after an agreement was reached. All ten experts participated in the virtual discussion, which was held using the Google Meet platform. The discussion lasted for 60 minutes. The revised strategies were converted to a data collection instrument for validation and revision in Round Two (see Annexure F).

2.5.3.3 Round Two

The purpose of Round Two was to validate and revise strategies. The data collection instrument was developed after Round One, and it contained strategies with a four-point rating scale: 1=Not relevant, 2=Somehow relevant, 3=Relevant and 4=Highly relevant (see Annexure F).

The experts who participated in Round One were invited through email to rate the relevance/importance of mHealth strategies for diabetes management. The experts were requested to return the data collection instrument within three weeks. A reminder email was sent twice at the end of weeks one and two. The instrument was returned by 8 out of 10 experts by the end of the third week.

After data collection, each strategy's level of consensus among panel experts was analysed. Thus, an item-level content validity index (I-CVI) was computed using a Microsoft Excel sheet to determine the level of agreement and guide the decision to validate the studies. I-CVI is defined as the proportion of content experts who gave a 3 or 4 on the relevance of each strategy (Shrotryia & Dhanda, 2019:4). The formula used to compute the I-CVI was (Yusof, 2019:51):

$$\text{I-CVI} = (\text{agreed strategy}/\text{number of experts}) \times 100\%$$

The I-CVI greater than 82% was used to determine the panel of experts' consensus to validate each strategy (Yusof, 2019:51).

2.5.3.4 Round Three

After Round Two, the strategies (data collection instrument) were revised by removing items with based I-CVI values. The data collection instrument was consisting revised strategies with a 5 points Likert Scale: 1=Strongly disagree, 2=Disagree, 3=Neutral, 4=Agree and 5=Strongly agree (see Annexure G).

For Round Three, 100 selected experts were invited by email; experts who did not respond to the email were contacted by telephone. The consent form was emailed to the experts following the verbal agreement over the phone (see Annexure E). Like Round Two, three weeks were given for experts to return the data collection instrument. A reminder email was sent twice at the end of weeks one and two. The instrument was returned by 91 out of 100 experts by the end of the third week.

The purpose of Round Three was to determine the level of consensus among panel experts in each strategy and finalise the strategy. Thus, like the previous round, an I-CVI was computed to determine the level of agreement and guide the decision to validate the studies using a Statistical Package for Social Science (SPSS) Version 24. An I-CVI greater than 80% was used to determine the panel of experts' consensus to validate each strategy (Yusof, 2019:51).

2.6 ETHICAL CONSIDERATION

Ethical principles are defined by Polit and Beck (2012:727) as a system of moral values that is concerned with the degree to which research procedures adhere to professional, legal, and social obligations to the study participants. The study was conducted according to the ethical guidelines described by the National Research Ethics Review Committee of Ethiopia at the Ministry of Science and Technology of Ethiopia (2014:1-95) and the research ethics code of the University of South Africa Health Studies department.

The researcher observed the following ethical principles:

2.6.1 Obtaining Ethical Clearance

Ethical clearance was sought from the Department of Health Studies ethics committee, UNISA, and the Addis Ababa Regional Health Bureau, research ethics review committee (see Annexure H). Then, before the commencement of the study, permission was sought from the respective Health Institutions.

2.6.2 Obtaining Informed Consent

The Declaration of Helsinki (World Medical Association, 2001:2) states that each potential participant must be adequately informed about the study and its implication to them as individuals before agreeing voluntarily to participate. Informed consent consists of three phases: First, the researcher provides adequate information about the proposed study; then, the researcher makes sure the prospective participant understands the information that is being provided; and finally, the potential participant decides based on the information provided on whether to join the study. These phases were strictly followed in this study.

All the participants were older than 18 years. The study subjects were given complete information about the nature and purpose of the study and their full rights to protection from harm and risk and were participating in the survey only after they had provided consent (see Annexure C). Participants were informed that participation is voluntary and of their rights to withdraw from the study at any time without penalty. All the explanations were done systematically in a language the individual could speak or understand. Then, written consent was obtained from all participants (see Annexure C). The informed consent process was conducted considering cultural sensitivity and local appropriateness.

2.6.3 Beneficences

Beneficences are an obligation to do good and not harm; beneficiaries may include individuals and/or communities, whether or not they are directly participating in the proposed initiative (Willison, Ondrusek, Dawson, Emerson, Ferris, Saginur, Sampson & Upshu, 2014:4).

There were no intended benefits and no anticipated risks to the participants. However, to address any unanticipated risks, information gathering, and documentation were done in a manner that presented the least risk to respondents, was methodologically sound, and built on current experiences and good practices.

2.6.4 Non-maleficence

Harm associated with evidence generation in public health frequently arises from collecting, using, or disclosing information; potential consequences include stigmatisation, discrimination, psychological distress, or economic loss. Other harm, such as threats to health, may also occur (Willison et al., 2014:4).

For all research involving human subjects, the investigator must ensure that potential benefits and harm are reasonably balanced and to minimise risks. Risk is the probability and magnitude of some future occurrence of harm. The risks to which research subjects may be exposed have been classified as physical, psychological, social, and economic.

Adequate risk assessment was conducted in this study. Participants had no anticipated significant physical, psychological, social, or economic risks. Different mechanisms were implemented to ensure minimal risks for participants. Data were not individually identifiable, and adequate measures of protection against breaches of confidentiality of data were in place. Nothing in applicable laws, institutional rules, or the local cultural context suggested that conducting the study in a particular environment would pose higher risks to the participants. Risks to subjects were reasonable concerning the knowledge that was expected to result. The only risk anticipated was minimal discomfort during the completion of the data collection instruments; participants were instructed to skip questions or stop the interview if they became distressed. This study did not involve vulnerable people as potential research participants (Ethiopian Ministry of Science and Technology, 2014:21).

2.6.5 Respect for Human Dignity and Autonomy

According to the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1976:4), respect for human dignity in research combines two ethical convictions: Individuals should be considered autonomous subjects and protection should be provided for subjects with diminished autonomy. These are the right to self-determination and the right to full disclosure.

In this study, respect for human dignity was considered the primary principle, and it was ensured that subjects entered the research voluntarily and with adequate information. All participants were capable of self-determination and could act independently.

2.6.6 Principles of Disruptive Justices

In research ethics, justice is fair treatment for all subjects. An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1976:8-9).

Participants were selected fairly and justifiably, and both individual and social justice were considered. The following points were observed to ensure justice. First, the selection, exclusion, and inclusion of categories of research participants were fair and accurately described in the research results. Second, the process of recruiting participants was fair and scientific. Third, there was no unfair burden of participation in research on particular groups. Fourth, there was no exploitation of participants in the research. Finally, research outcomes would be made accessible to research participants promptly and transparently.

2.6.7 Privacy and Anonymity

Privacy refers to persons and their interest in controlling the access of others to themselves, and no participant should ever be forced to reveal information to the researcher that the participant does not wish to reveal (Oates, Kwiatkowski & Coulthard, 2010:22).

Participants were informed that participation was voluntary and that they had the right to withdraw at any time from the interview. The participants' names were not collected to protect the anonymity of the respondents. The participant's data were analysed and presented in groups. The presented result data did not reveal the identity of participants and health facilities (Creswell & Creswell, 2018:152).

2.6.8 Confidentiality

Confidentiality is the process of protecting an individual's privacy. It pertains to the treatment of information that an individual has disclosed in a relationship of trust, with the expectation that this information is not divulged to others without permission (Oates et al., 2010:22).

The appropriate measures were taken to ensure the security and confidentiality of data. A password protected all data collected from participants, and backup data were created and encrypted. The researcher used coded information by replacing the identifying name of the individual with a number. No individual was at risk of disclosing their private information due to their participation in research. Adequate information was provided on the confidentiality of data to establish trust between the research participant and the researcher.

2.6.9 The Culture

The researcher had adequate experience in respecting the cultural values, traditions, or taboos valued by the informants. The researcher ensured no culturally sensitive items were in the data collection tool.

2.7 SUMMARY

This chapter briefly described the study's theoretical foundation, framework, and research design. This study's qualitative, quantitative and Modified Delphi phases were discussed in the research design. In the research methodology, research setting, population, sampling, and sampling procedures were well addressed. Data collection instruments, the data collection process, pre-testing of the data collection tools, and the validity and reliability of data collection instruments were also well addressed. Additionally, ethical principles for undertaking this study were considered.

The next chapter presents the results, analysis, a description of the results and a discussion on Phase I.

CHAPTER 3

ANALYSIS, PRESENTATION, AND DISCUSSION OF FINDINGS OF PHASE I

3.1 INTRODUCTION

This chapter presents an analysis, a description of the results and a discussion of the integrative literature review (Phase I). The integrative review methodology outlined by Whittemore and Knaff (2005:549) adopted for this study included the following activities: a literature search, data reduction, data synthesis and presentation. This review considered evidence from both qualitative and quantitative studies, followed the reporting requirements of the PRISMA-P guidelines, and used an aggregative narrative synthesis approach to summarize the results (Pope, Mays & Popay, 2006:28). The details of the literature search data reduction strategy, and data synthesis are provided in Chapter 2.

Detailed descriptions of the insights that emerged from empirical and nonempirical articles are included in this review. The Phase I study reviewed the use of mHealth for diabetes management in developing countries. A thematic analysis is provided on models of mHealth initiatives and types of mHealth applications for diabetes management in developing nations. Potential outcomes and challenges are also identified and described in detail. Categorical codes were used to mediate between various forms of data. Generating these codes provided a move to higher levels of abstraction utilized in qualitative analytical methods to synthesize findings from multiple studies (Harden & Thomas, 2005:268).

3.2 FINDINGS OF PHASE I

In this paragraph, the findings of Phase I are presented. The findings presented here include descriptions of included studies, overall study quality, models of mHealth, types of mHealth applications, outcomes, and challenges of mHealth initiatives.

3.2.1 Literature Retrieval

The electronic search identified 2186 articles after excluding duplications, of which 234 were considered potentially eligible. Of these, 215 were excluded because they were conducted in upper-income countries (n = 115), did not address m-health (n = 28), were focused only on communicable diseases (n = 69), or because of a lack of an English language version (n=3). Only 19 articles fulfilled the study selection criteria, including 14 empirical studies and five reviews and reports. Figure 3.1 shows the flow diagram for the papers selected from the databases.

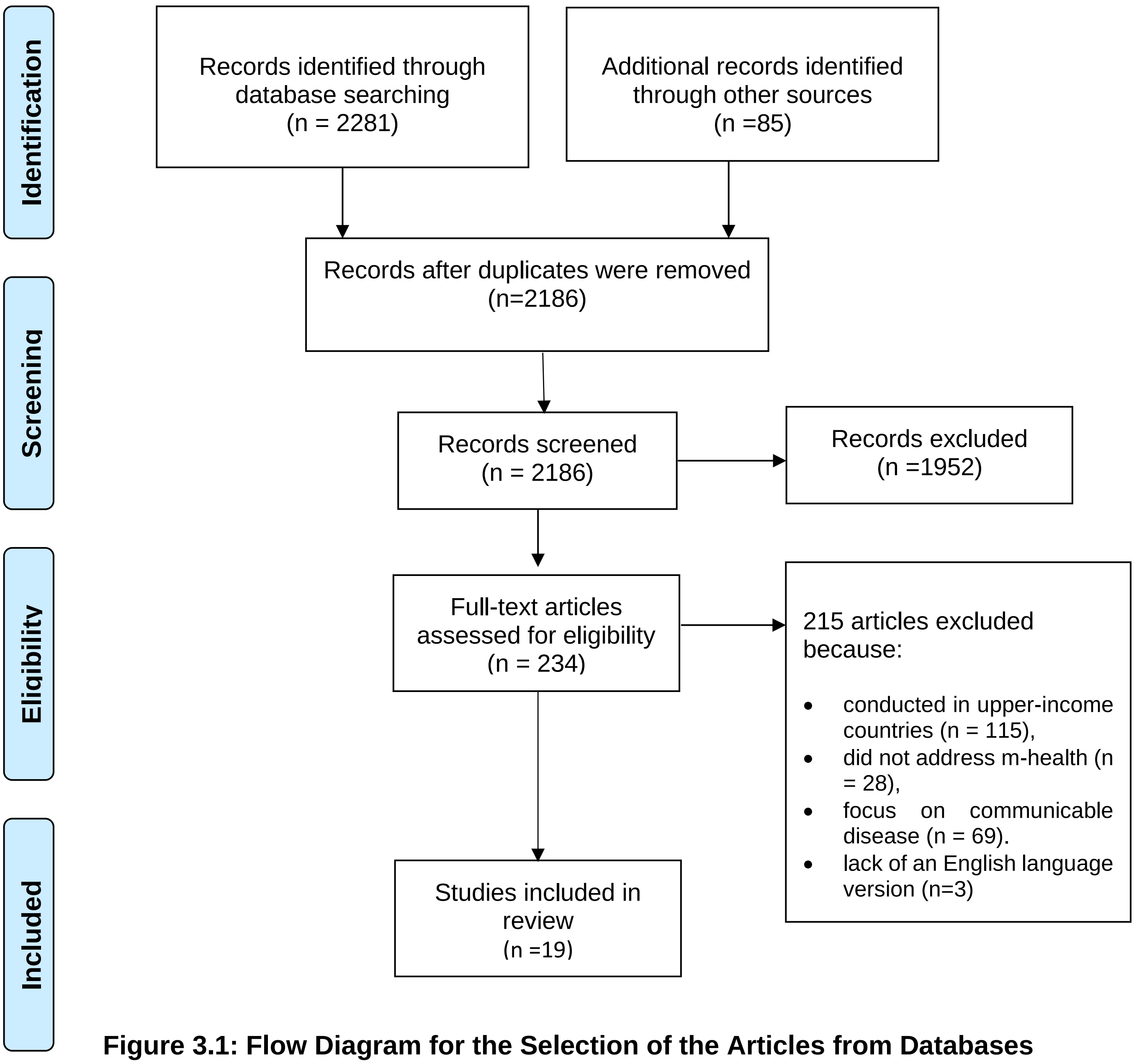

Figure 3.1: Flow Diagram for the Selection of the Articles from Databases

3.2.2 Literature Characteristics

The outcomes analysis included country type, study type, study duration, participants, sample size, mHealth model, name and description of the mobile apps, their modules and function, aim, summary of outcomes and challenges. The included empirical studies were performed in nine countries. Of the included empirical studies, 13 were quantitative, and only one was qualitative. Of the quantitative studies, seven (7) were Randomized Controlled Trials (RCT).

In total, 2476 participants were included in this integrative literature review. The number of subjects in each study ranged from 22 (Rotheram-Borus, Tomlinson, Gwegwe, Comulada, Kaufman & Keim, 2012:3) to 781 (Van Olmen et al., 2017:36) study participants. Only one study included non-diabetic patients, while the other 13 included patients with T2DM. The duration of the intervention (n=12) was less than five months in four studies (Kumar et al., 2015:641; Shahid et al., 2015:167; Takenga et al., 2014:5; Zolfaghari et al., 2012:1924).

Table 3.1 provides a detailed description of the empirical studies included in this review.

Table 3.1: Description of the Included Empirical Studies.

Author, Year	Country	Type of Study/Duration	Participants	Sample Size	mHealth Domain
Shetty et al., 2011	India	RCT/ 1 year	Patients with T2DM	225	Patient communication & Support for DSM, Patient Education
Tamban et al., 2013	Philippines	RCT/ 6 months	Patients with T2DM	104	Patient Education
Takenga et al., 2014	Congo	RCT/ 2 months	Patients with T2DM	40	Personal Health Record (PHR), Treatment plan (Decision Support System)
Shahid et al., 2015	Pakistan	RCT/ 4 months	Patients with T2DM	440	Patient communication. Support for DSM
Kumar et al., 2015	India	Facility-based parallel RCT/ 3 days	Non-Diabetic Individuals	268	Screening
Shariful et al., 2015	Bangladesh	RCT/ 6 months	Patients with T2DM	236	Patient Education
Van Olmen et al., 2017	Congo, Cambodia & Philippines	RCT/ 2 years	Patients with T2DM	781	Patient Education
Jha et al., 2016	India	Prospective Intervention Study/ 20 Months	Patients with T2DM	109	Patient communication & Support for DSM, Patient Education
Zolfaghari et al., 2011	Iran	A quasi-experimental, two-group, pretest, and post-test design/ 3 months	Patients with T2DM	77	Patient communication & Support for DSM, Patient Education
Watkins et al., 2018	South Africa	Qualitative	Patients with NCDs	63	Patients Patient communication & Support for DSM
Le et al., 2011	South Africa	System Development Research	Patients with T2DM	60 for User Requirement 5 for System Evaluation	Data Collection (Personal Health Record) and treatment plan (Decision Support System)
Pastakia et al., 2011	Kenya	Not reported/ 6 months	Patients with T2DM	43	Data Collection and Disease Management

Author, Year	Country	Type of Study/Duration	Participants	Sample Size	mHealth Domain
Rotheram-Borus et al., 2012	South Africa	Not Provided/ 6 months	Patients with T2DM	22	Patient communication & Support for DSM (Psychoeducational)
Haddad et al., 2014	Iraq	Not Provided/ 29 weeks	Patients with T2DM	42	Patient Education

The Joanna Briggs Institute Critical Appraisal Tools were used to assess the risk of bias in the 13 studies included. Out of seven RCT articles, five presented a low risk of bias (Kumar et al., 2015:640-644; Shahid et al., 2015:166-171; Shetty et al., 2011:711-714; Takenga et al., 2014; Tamban et al., 2013:143-149) and two articles presented moderate (Shariful Islam, 2015:1-29) and high risks of biases (Van Olmen et al., 2017:33-41). Among the five interventional ones, two articles presented low risks (Haddad, Istepanian, Philip, Khazaal, Hamdan, Pickles, Amso & Gregory, 2014:454-459; Zolfaghari et al., 2012:1922-1931), two moderate risks (Jha, Dogra, Yadav, Siddiqui, Panda, Srivastava, Raghuvanshi, Kaur, Bhargava & Mathur, 2016:1-6; Rotheram-Borus et al., 2012:1-14), and one high risk (Pastakia, Karwa, Kahn & Nyabundi, 2011:721-726). The qualitative study presented moderate risks (Watkins et al., 2018:139-147) (see Annexure B for detailed risk of bias analysis results).

In addition to the empirical studies, three review articles (Ajay & Prabhakaran, 2011:778-783; Ariani, Koesoema & Soegijoko, 2017:15-69; Simon & Seldon, 2012:125-132) and two policy documents (Kay et al., 2011:1-112; World Health Organization, 2016a:1-92) were included in this integrative literature review. The scope of these papers was different: One article was focused on mHealth and mobile phones application in diabetes management, two articles reviewed the application of mHealth for NCDs, and two articles presented opportunities for mHealth both for communicable disease and NCDs management. Except for one article, the scope of all papers was mHealth applications in developing nations. Table 3.2 provides detailed descriptions of the five nonempirical documents.

Table 3.2: Description of Included Review Articles and Policy Papers

Authors, Year	Types of Articles	Scope	Domain of mHealth
Ajay et al., 2011	Review Article	Cell phones opportunity in Diabetes Management in Developing Countries (mHealth for Diabetes)	Application of mHealth in three Domains: • Health System, • Patients, and • Healthcare professionals
Ariani et al., 2017	Review Article	mHealth for Communicable and NCD in developing countries	Application of mHealth in: • Disease Management, • Patient communication Education, • Data collection • E-prescription and therapy plan
Simon & Seldon, 2012	Review Article	Mobile biosensors and Smartphones for Developing Countries: focusing on NCDs.	• Data Collection (Personal Health Records), and • Therapy plan (Decision Support System)
Kay et al., 2011	Policy Paper (WHO)	mHealth for Communicable and NCD in developing countries	Application of mHealth in: • Emergency toll-free telephone services • Patient communication and Education, • Data collection and Surveillance, and • Mobile telemedicine
World Health Organisation, 2016	Policy Paper	mHealth for diabetes in both developing and developed counties	Application of mHealth in three domains: • Prevention • Enforcement • Treatment

3.2.3 The Domain of mHealth Initiatives

There is no common consensus on categorisation for the domain of mHealth initiatives for Non-communicable Diseases (NCDs), including diabetes management. The sub-objective of this integrative literature review was to examine the models of mHealth initiatives for diabetes management in developing nations. The models of mHealth were juxtaposed against the types of outcomes and codes generated (see Annexure I data reductions and analysis example).

Patient education was one of the emerging mHealth domains for diabetes management. Seven of 14 empirical studies focused on providing patient education to bring behavioural changes. The use of mHealth for patient education was also supported among review articles and policy papers included in this review. Ajay and Prabhakaran (2011:780) outlined that mHealth tools are useful for providing educational interventions and can bring positive changes in diabetes management.

Maintaining the Personal Health Record (PHR) of diabetic patients is another mHealth Domain identified in this review. Two empirical studies discussed mHealth PHR for collecting, storing, transmitting, and monitoring patients' data. Among review articles, Simon and Seldon (Simon & Seldon, 2012:126) outlined how the data collected by mobile biosensors could be converted to information and transmitted to the central database. Another review article found that using mHealth to collect and transmit data could be less expensive for developing countries than using Electronic Health Records (EHR) (Ariani et al., 2017:43). The article also argued that using mHealth to collect and transmit data improves patient data tracking, monitoring of diabetes management trends, quality of care and surveillance data quality (Ariani et al., 2017:43). Two policy papers emphasized the use of mHealth for patient **data collection and monitoring** (Kay et al., 2011:41; World Health Organization, 2016a:37).

The result of this review identified the mHealth domain focused on using the **Clinical Decision Support System (CDSS)** for a treatment plan and diabetes management. Two empirical studies found that CDSS was effective in assisting HCPs in developing an evidence-based treatment plan and, as a result, in improving diabetes management (Le, van der Merwe & Abrahams, 2011:2-3; Takenga et al., 2014:2). The review article highlighted that developing countries with a high shortage of specialists and clinicians could benefit from mHealth-based CDSS (Ariani et al., 2017:43). The CDSS has the potential to help primary healthcare workers in developing countries manage patients with uncomplicated diabetes. The policy papers supported this, mHealth-based CDSS improves information access for HCP to design treatment at the point of care. The support system for HCP also includes the provision of online resources like treatment guidelines and teleconsultation with senior professionals/experts (Kay et al., 2011:38; World Health Organization, 2016a:46).

Patient Communication and support for DSM was another mHealth domain identified for diabetes management. Four empirical studies used mHealth to communicate and support patients in improving their DSM (Jha et al., 2016:3; Pastakia et al., 2011:724; Shahid et al., 2015:167; Shetty et al., 2011:711-712). Patient communication and support include patient monitoring with timely feedback, reminder calls for treatment and follow-up visits, treatment plan communications based on the collected patient data and creating a peer-support group led by HCPs. This opportunity of mHealth was also reported in nonempirical articles; mHealth used for patient communication and support of DSM is expected to improve adherence to DSM and treatment compliance (Ariani et al., 2017:44; Kay et al., 2011:51).

Screening is another mHealth domain frequently mentioned in review articles and policy papers. Ajay and Prabhakaran (2011:781) discussed how an mHealth based checklist and a risk-scoring system could assist HCPs in identifying individuals at higher risk of developing diabetes and conducting targeted screening tests. One empirical study discussed using mHealth to improve screening rates in healthcare settings (Kumar et al., 2015:641).

3.2.4 Findings on Diabetes mHealth Applications in Low and Middle-income Countries

Data were extracted from 13 quantitative studies, one qualitative study, and two review articles to identify available mHealth applications for diabetes management in low and middle-income countries (LMICs). Eight empirical studies applied Short Message Service (SMS) interventions for T2DM management. Out of these, four studies measured the effectiveness of diabetes management supplemented with SMS intervention compared to the control group assigned for standard care. Two studies used only one group to test Diabetes SMS interventions. Three studies tested telephone call intervention for diabetes management; only one used a control group. One study combined SMSes and telephone calls and compared the effect with standard care. The difference between voice calls and SMS-based interventions was tested in one study. Two diabetes data collection and communication applications were identified in this review: Integrated mobile and web-based applications for diabetes in the Congo (Mobil Diab) and the Mobile Diary application. However, only the Mobil Diab application was tested with standard care, and no evidence was provided on the effectiveness of the mobile diary application for diabetes management.

3.2.4.1 SMS Interventions

The SMS was used as an mHealth intervention for diabetes management in eight studies. The frequency of SMSes ranges from one SMS per day (Shariful Islam, 2015:6) to one per week (Haddad et al., 2014:455-456). The duration of SMS intervention varied from three months (Zolfaghari et al., 2012:1924) to one year (Van Olmen et al., 2017:34). The total SMSes sent to participants ranged between 31 SMSes/patient (Haddad et al., 2014:455-456) to 408 SMSes per patient (Van Olmen et al., 2017:34).

Out of five SMS applications, four applications used Application-to-Person (A2P) trafficking, and one study used Person-to-Person (P2P) trafficking. All four A2P SMS applications were web-based and required web tools and API (application programming interface). The information architecture applied for transmitting SMSes includes Frontline SMS cloud version (Van Olmen et al., 2017:35), BulkSMS: Web to SMS (Haddad et al., 2014:456), Telenor-based Grameenphone Bangladesh: Web-based (Shariful Islam, 2015:6), and U.P. Manila National Telehealth Center (Tamban et al., 2013:145). Only Frontline SMS is open-source software. Grameenphone and BulkSMS are business software, and an educational institute owns U.P. Manila National Telehealth Centre.

The SMS interventions were mainly focused on patient education mHealth domain. Seven of eight empirical studies used SMS interventions to educate patients and bring behavioural changes in diabetes management. The review articles also highlighted the potential of SMSes for patient education. Telecom vendors and operators commonly provide SMSes in the local language, making it cost-effective to disseminate patient education via SMSes.

Two studies used a theoretical framework to guide the intervention and provide tailored messages. Van Olemn et al. (2017:35) developed an SMS based on the theory of planned behaviour, focusing on behavioural, normative and control beliefs.

Another SMS intervention by Shariful et al. (2015:6) was based on behavioural learning theory and the transtheoretical model (TTM) of behavioural change. Tamban et al. (2013:144) used the International Diabetes Federation (IDF) guideline to develop tailored messages, though the guideline link with behavioural change theory was not discussed.

The content addressed through SMSes includes behaviour change communication using behavioural theories, education/counselling related to diet, physical exercise, medication adherence, DSM, disease complication, the consequence of non-compliance to the therapy plan, psychosocial components, and principles and tips on diabetes management. Despite the detailed process not being outlined by included studies, most of the SMS contents were developed by experts and based on the recommendation outlined in diabetes management guidelines.

Patient communication and support for DSM was another domain of SMS interventions. Two empirical studies used SMSes for reminders of follow-up visits and treatment adherence (Jha et al., 2016:2; Shetty et al., 2011:711). One empirical study used SMSes to create peer support for improving DSM (Rotheram-Borus et al., 2012:3-4). Table 3.3 summarises SMS applications for T2DM management in low and middle-income countries.

Table 3.3: SMS Interventions for T2DM Management in Low and Middle-Income Countries.

Author, Year	Purpose of the SMS	SMS Content	Theoretical framework	Frequency & duration of SMS	Information Architecture	Interoperability
Jha et al., 2016	Patient communication and support for DSM, patient education	Daily Tips on managing their disease	Not reported	Not reported	-	-
Van Olmen et al., 2017	Patient education	Message addressing behavioural, normative, and control beliefs	Theory of Planned Behaviour	Averagely 4 times/week (408 SMSes/patient)	Frontline cloud internet version. Requires web tool and API(A2P)	Open Software
Haddad et al., 2014	Patient education	Diet, treatment, complication, blood glucose monitoring, clinical attendance	Not reported	1 SMS/week for 7 months (31 SMSes/patient)	BulkSMS: Web to SMS (A2P) (developed by Celerity Systems (Pty) Ltd.)	Business Software
Rotheram-Borus et al., 2012	Peer support	SMS exchange between peer groups on psychoeducational sessions	-	Exchanged an average of 123 SMSes weekly	-	-
Shariful et al., 2015	Patient education	Tips on healthy diet and exercise, diabetes self-management, alert on treatment and follow-up visits, disease complication	Behavioural learning theory and trans-theoretical model of behavioural change	1 daily SMS for 6 months (90 SMSes/patient)	Telenor-based Grameenphone Bangladesh. Web-based (A2P)	Business Software
Shetty et al., 2011	Patient communication & Support for DSM, patient education	Reminders on drug prescription, physical exercise, and Instruction on therapy plans and healthy lifestyle	Not reported	1 SMS every 3 days (122 SMSes/patient)	-	-
Tamban et al., 2013	Patient Education	Education on diet, exercise, and the consequence of non-adherence to D.M. treatment	No theoretical framework, but follow IDF guidelines	3 SMSes/week for 6 months (75 SMSes/ patient)	U.P. Manila National Telehealth Center (A2P)	Institutional website
Zolfaghari et al., 2011	Patient education	Recommendations on diet adherence, medication adherence, and exercise adherence	Not reported	6 SMSes/week for 3 months (72 SMSes/patient)	P2P using a GSM network	Open

Key concepts from Table 3.3

- mHealth is used to disseminate education for patients with T2DM.

- mHealth is used for patient communication as a reminder for follow-up visits and treatment adherence.
- mHealth used to create a support group for DSM.
- Interoperability is not well covered, and it can be a major challenge when mHealth is not integrated into the national health information system.

3.2.4.2 Telephone Call Interventions

A telephone call was used as an mHealth intervention for diabetes management in five studies. The frequency of voice calls varies from one call per subject (Kumar et al., 2015:641) to 24 calls per subject (Pastakia et al., 2011:724). All calls used the GSM network platform. The telephone calls were made by principal investigators (Kumar et al., 2015:641; Shahid et al., 2015:167; Zolfaghari et al., 2012:1924-1925), community health workers (Pastakia et al., 2011:724), and physicians/diabetes educators (Jha et al., 2016:3).

The telephone interventions mainly focused on patient communication and support for the DSM domain. The purpose of the telephone call was to provide tailored feedback remotely based on patient data. The purpose comprises remote patient monitoring with timely feedback (Jha et al., 2016:3; Shahid et al., 2015:167) and remote data collection for tailored feedback (Pastakia et al., 2011:724).

The telephone call was used to monitor patients' blood glucose levels remotely and to provide appropriate feedback based on blood glucose readings. Similarly, studies conducted in Kenya used telephone calls to collect data related to blood glucose and insulin by community health workers from patients; the data were then used centrally to design a treatment plan and then transmitted by community health workers to the patients through phone calls (Pastakia et al., 2011:724).

One study used a Telephone call reminder for screening (Kumar et al., 2015:641), and the expected outcome was to improve the screening rate. Only one study compared the effectiveness of telephone calls with SMSes for patient education (Zolfaghari et al., 2012:1924). Table 3.4 provides descriptions of telephone call intervention for T2DM management in low and middle-income countries.

Table 3.4: Telephone Call Interventions for T2DM Management in Low and Middle-income Countries

Author, Year	Purpose of the Application	Content	Frequency Voice calls	Caller Identity	Network Platform
Jha et al., 2016	Remote patient monitoring and feedback	Assess patient glycemic control and provide timely feedback to correct problems.	Weekly telephone calls for 5 months (20 calls/ subjects)	Physicians/ diabetes educators	GSM
Kumar et al., 2015	Reminder calls for screening.	Provide a reminder call on the same evening of the first test to come for a definitive test.	One call	Principal investigator	GSM
Shahid et al., 2015	Remote patient monitoring and feedback	Collect patient blood glucose levels remotely and provide timely feedback based on the data via call.	One call every 15 days for 4 months (8 calls/ subject)	Principal investigator	GSM
Pastakia et al., 2011	Remote Data Collection and on-treatment plan communication	Health data collected (blood glucose level and treatment) from patients via call and transmit treatment plan based on the data to patients via call.	Weekly telephone calls for 6 months (24 calls/ subject)	Community Health Workers	GSM
Zolfaghari et al., 2011	Patient education	Risk factors of disease, the importance of maintaining blood glucose levels reminders on adherence to diet, exercise, medication taking, and blood glucose measurement.	16 calls/subject	Principal investigator	GSM

Key concepts from Table 3.4

- mHealth is used for patient communication as a reminder for follow-up visits and treatment adherence.
- mHealth is used for screening.
- mHealth is used to disseminate education for patients with T2DM.

3.2.4.3 mHealth Application-based Interventions

In this review, three diabetes mHealth applications were identified for maintaining Personal Health Record (PHR) (data collection, storage, transmission, and monitoring) and Clinical Decision Support System (CDSS): Mobil Diab (Takenga et al., 2014:3), Mobile Diary (Le et al., 2011:3), and mobile biosensor application (Simon & Seldon, 2012:127). The use of mHealth for maintaining PHR and CDSS was also highlighted by review articles included in this study (Ajay & Prabhakaran, 2011:780; Ariani et al., 2017:55).

The three applications allow patients to register biomarkers, including blood glucose, using their mobile phones linked to blood glucose meters via Bluetooth. Mobil Diab and Mobile Diary applications also permit data entry through the web (Le et al., 2011:3; Takenga et al., 2014:3-4). The Mobil Diab applications allowed web-based data collection entry of clinical patient data and automatically captured data from a glucometer supporting the Institute of Electrical and Electronics Engineers (IEEE) 11073 Personal Health Data Standard (PHD). Smith and Seldon (2012:126) alluded to the IEEE 11073 PHD Standard as the most appropriate for mHealth-based biosensors. The Mobile Diary application system implementation also included a Bluetooth-enabled blood glucose meter to capture glucose data (Le et al., 2011:2).

The patient can store recorded data via the web at the central database. The Mobil Diab application created a central platform for secure storage and additional information processing. The Mobile Diary application also has a central database to store data. Only Mobil Diab allows restricted access to the central database for multiple users: patients, healthcare professionals (HCPs), hospitals and administrators, and transmitted through a secured interface to the hospital information system. HCP had restricted access to a central database to design treatment plans (Takenga et al., 2014:3-5).

Another feature of PHR identified from the review is data transmission. The Mobile Diary application converts data to eXtensible Markup Language (XML) format to transmit data to different components of the system using a web server, which is connected to the central system to store and retrieve information (Le et al., 2011:3). In the Mobil Diab, the HTTP protocol and the GSM network is used to transmit data between different parts of the system. Especially for patients without a smartphone, data transmissions like therapy plans or feedback from HCP are done by SMSes using a GSM network (Takenga et al., 2014:3).

The mHealth PHR application also has a system to support patient data monitoring. The Mobil Diab system provides a graphical representation of trends and statistics to monitor patients' data (Takenga et al., 2014:4). The Mobile Diary application also has a monitor to analyse patient information (Le et al., 2011). This was highlighted in review articles; the mHealth application can serve as a real-time information system, providing quality data for monitoring patients with diabetes (Ajay & Prabhakaran, 2011:781; Ariani et al., 2017:56). The system can send an alarm message to HCPs if the patient data is critical. HCPs also communicated the treatment plan via SMS or the Web.

Besides maintaining PHR, the mHealth application supports the treatment/therapy plan using CDSS. The Mobil Diab system further processes the acquired data at the central database to provide high-quality information through diagrams and statistics for HCPs. This information supported the HCP in making accurate decisions in designing a treatment plan (Takenga et al., 2014:4). The CDSS system aided in treatment plan decisions by providing organized data and shortening clinical logbook review time for analysing patient data trends (Ajay & Prabhakaran, 2011:781). The Mobil Diab system can alert HCP if the patient data is critical. HCP also communicated the treatment plan via SMS or the Web. As a supplement to the CDSS, the Mobil Diab system allows HCP to get consultations from specialists (Takenga et al., 2014:5).

The Mobil Diab mobile application supports the Android system, and the web platform is interoperable with HL7, CDA, WSDL, and XML (Takenga et al., 2014:5). The Mobile Diary Application was originally designed for the Nokia series using the J2ME platform. However, it also supports Android, Window systems, and XML (Le et al., 2011:2). Mobile biosensor supports X73PHD, XML, HL7, IHE, CDA, Continuity of Care Record, IEEE 11073 PHD Standard, and XDR (Simon & Seldon, 2012:126).

Regarding security and privacy, the Mobil Diab employed different features in the four-layered platform architecture. Authentication and authorisation of different users were employed to ensure security. The system used cryptographic mechanisms to ensure the confidentiality of patient data. The Advanced Encryption Standard (AES) was employed to encrypt all data captured and transmitted through the system. The system also ensured privacy, creating authorisation for access of different patient data (Takenga et al., 2014:4). The Mobile Diary Application only discussed the presence of a login system using a username and password for secure entry of information (Le et al., 2011:3). Table 3.5 describes mHealth application-based interventions for T2DM management in low and middle-income countries.

Table 3.5: Diabetes mHealth for Data Collection and Communication

Author, Year	Purpose of the Application	Content	Information Architecture	Interoperability
Takenga et al., 2014	Mobil Diab. maintains personal health records, storage of health records, monitoring of patient data, decision support system, and treatment.	For patients: collects and stores personal health records, accesses recorded data, and decision support on diabetes management based on the data. They access treatment plans from HCP via the Web or SMS. For HCP: accesses patient personal health records, alarm messages via SMS if the patient data is critical, a decision support system to design a treatment plan, and transmit the treatment plan to patients via web or SMS. For Health System: tracks patterns and trends in the diabetes management process, presents statistics that cover everything doctors and patients need, accesses control of different user categories, and secures interface to hospital information systems.	Four Layer Architecture. Encrypted using the symmetric encryption method AES.	Mobile Application (Android, iPhone, and iPads) Web Based: HL7, CDA, WSDL, and XML.
Le et al., 2011	Mobile Diary Application	Data collection: allows users to register health	Three layers, designed using	Nokia Symbian, Windows, Android

	(Maintain Personal Health record)	records, including blood glucose (linked to blood glucose meter via Bluetooth). Allows data entry through the website. Data display system. Data storage at the central database (Web-based). Data communication: allows communication of recorded data from the central database to social networks.	Java 2 Platform, Micro Edition (J2ME)	
Simon & Seldon, 2012	Maintains personal health records using mobile biosensors	Data from mobile biosensors are collected, converted to useful information using international classification for primary care, and stored on a smartphone. Phone-based recorded information is communicated to a more central database via a "Telehealth Service Centre" (TSC) using a broadband network or through SMS (GSM network). Biosensors are connected to mobile by Bluetooth.	Three layers: Medical device (M.D., Agent), Concentrator Device (CD, manager), and Host System (H.S.)/ Third-Party Host Systems (TPHS, Aggregator)	MD-CD or MD-SP interface for MD; X73PHD; HL7; and IHE Cross-Enterprise

Key concepts from Table 3.5.

- mHealth is used for maintaining PHR, including data collection, storage, transmission, and monitoring.
- mHealth Biosensor connected with Bluetooth was used to capture clinical data.
- mHealth is used to monitor patient data using graphics of data trends and statistics.
- mHealth supports treatment design using CDSS and consultation with senior experts/specialists.
- Different structural interoperability standards were employed for the mHealth application.
- Semantic interoperability was not well addressed.

- Authentication, authorisation, cryptographic mechanisms, and AES were used to ensure security, confidentiality, and privacy.

3.2.5 Outcomes of mHealth Interventions in Low and Middle-income Countries

An overview of major outcomes on mHealth initiatives for diabetes management in low and middle-income countries based on the findings reported by each of the included studies analysed in this integrative literature review is categorised into six topics and presented under this subsection.

3.2.5.1 Clinical and Health Outcomes

Glycemic control was measured in ten studies using HbA1c (Haddad et al., 2014:456; Jha et al., 2016:3; Pastakia et al., 2011:724; Shahid et al., 2015:167; Shariful Islam, 2015:6; Shetty et al., 2011:712; Takenga et al., 2014:6; Tamban et al., 2013:145; Van Olmen et al., 2017:35; Zolfaghari et al., 2012:1925), and fasting blood glucose (Jha et al., 2016:3; Shetty et al., 2011:712).

According to Haddad et al. (2014:457), the mean baseline HbA1c was 79 mmol/mol and decreased to 70 mmol/mol 6 months after the SMS intervention. Similarly, a study conducted in Bangladesh revealed a significant HbA1c mean square difference between the control and SMS intervention groups. Among the trial participants, the least squares mean difference of HbA1c from baseline to after six months was -0.85 in the SMS group and -0.18 in the control group (Shariful Islam, 2015:10). According to Tamban et al. (2013:146), a significant difference was observed in mean HbA1c (SMS = 6.99 + 0.86, control = 7.34 + 0.90). However, two studies on SMS interventions reported that no significant changes in HbA1c were observed between control and SMS groups (Shetty et al., 2011:712; Van Olmen et al., 2017:36). According to Shetty et al. (2011:712), despite the significant changes on Fasting Blood Glucose between the SMS and control group, the changes on HbA1c was not significant.

Three telephone call interventions also reported higher HbA1c changes (Jha et al., 2016:3; Pastakia et al., 2011:724; Shahid et al., 2015:168). The Jha et al. (2016:3) results show a statistically significant reduction in HbA1c (8.8 ± 1.2 to 7.4 ± 1.3, $p=0.001$). The Mobil Diab multi-purpose application also demonstrated the amelioration of the HbA1c (from 8.67% to 6.89%) and the mean amplitude of glycemic excursions, characterised by both the mean blood glucose and its standard deviation (Takenga et al., 2014:9).

Improvement in the occurrence of diabetic foot ulcers was another clinical outcome measured in one SMS intervention study (Van Olmen et al., 2017:35). The frequency of diabetic patients with foot wounds decreased significantly more in the SMS intervention group than in the control group according to this study (Van Olmen et al., 2017:37).

Another SMS intervention study found that the intervention groups had significantly lower LDL-C levels and a higher proportion of patients with hypertriglyceridemia. (Shetty et al., 2011:713).

3.2.5.2 Diabetes Self-management Knowledge

Two articles evaluated the effect of diabetes mHealth intervention on DSM knowledge and practice. According to Jha et al. (2016:3), the diabetes knowledge scores marked a statistically significant improvement in the intervention group (voice calls and SMSes). Similarly, Haddad et al. (2014:457) reported an increment in mean knowledge scores among SMS intervention groups, and the mean knowledge score was significantly correlated before and after the SMS intervention was correlated.

3.2.5.3 Diet, Physical Exercise, and Medication Adherence

Four articles evaluated the effect of mHealth on dietary and medication adherence. In a qualitative synthesis by Watkins et al. (2018:144), patients reported using mHealth to adhere to their diabetic medication.

According to the RCT by Shahid et al. (2015:168), patients who had received voice call interventions significantly improved their adherence to the dietary plan after four months of intervention. However, medication adherence significantly declined as compared to the control group. Another RCT by Tamaban et al. (2013:146) revealed a significant change in the mean number of meals/day after six months of SMS intervention. Similarly, Zolfaghari et al. (2012:1926) compared the effect of SMS and telephone call interventions on diet and medication adherence. The diet and medication adherence improved during the post-test, and there was no significant difference between SMS and telephone call groups in diet and medication intake.

Two studies also reported improvement in physical exercise (Shahid et al., 2015:168; Tamban et al., 2013:146). Tamban et al. (2013:146) revealed that the mean number/minutes of exercise was significantly higher among the intervention group than the control group after the SMS-based patient education.

3.2.5.4 Screening and Follow-up

Kumar et al. (2015:642) tested the effect of mobile phone reminders on eligible outpatient attendants to follow up for definitive tests by facility-based RCT. Most outpatients who received phone call reminders returned for definitive tests compared to in control group. It also improved the screening yield of diabetes.

3.2.5.5 mHealth Usability and Users' Acceptance

Only four empirical studies measured and reported user acceptance of the mHealth intervention. Haddad et al. (2014:457) used a survey questionnaire to measure users' satisfaction with the SMS interventions and reported that all users were satisfied with the interventions and wished to continue the SMS services. Takenga et al. (2014:9) also evaluated the mHealth PHR application by patients and HCPs and reported a positive evaluation of the mHealth application in terms of three metrics: usability and design, therapy satisfaction, and acceptance. The Mobile Diary application by Le et al. (2011:5) was also positively evaluated by the users. Shetty et al. (2011:713) reported that patients preferred to receive an SMS on all aspects of T2DM treatment. All four studies do not report the evaluation tool used to measure user acceptance.

3.2.5.6 Diabetes mHealth Cost-effectiveness

All studies did not conduct a systematic economic evaluation to determine the cost-effectiveness of the mHealth intervention. Only Kumar et al. (2015:643) discussed cost-effectiveness but not based on economic evaluation. Table 3.6 describes the outcomes of mHealth interventions for diabetes management in low and middle-income countries.

Table 3.6: Outcomes of Diabetes mHealth Interventions in Low and Middle-income Countries

Author, Year	Country	Methods	Major Findings
Jha et al., 2016	Iraq	Diabetes Care 24x7®: Voice call and SMS intervention. The intervention group (n=39) received weekly telephonic follow-ups by diabetes educators to assess their glycemic control and provide feedback, and additionally, they received daily tips on managing diabetes via SMS. The control group (n=70) received standard diabetes education.	• A statistically significant reduction was observed in HbA1c (8.8 ± 1.2 to 7.4 ± 1.3, p=0.001). A significant increment in: • Diabetes knowledge scores (19.9 ± 2.5 vs. 17.9 ± 3.98, p = 0.005) and • Quality of life indices (88.5 ± 7.8 vs. 83.5 ±10.7, p=0.015)
Van Olmen et al., 2017	Congo, Cambodia, and the Philippines	DSMS: SMS intervention. The intervention group (n= 401) was assigned to DSMS care and received education via SMS. The control group (n=380) was assigned to DSME.	After 2 years: • The proportion with controlled HbA1c was higher intervention group (33.9%) than in the control group (31.1%), but the difference was not statistically significant
Watkins et al., 2018	South Africa	A qualitative investigation on the use of mobile phones by patients and HCP for healthcare purposes.	• Patients used their mobile phones as alerts for medication adherence or clinic visits. • Patients valued receiving voice call reminders. • Physicians used their phones to gather evidence for a therapy plan.
Haddad et al., 2014	Iraq	SMS intervention for 6 months on five education-related themes relating to diet, treatment, complication awareness, blood glucose monitoring, and enhancement of clinic attendance.	• The mean knowledge score increased from 8.6 (SD 1.5) at baseline to 9.9 (SD 1.4) 6 months after receipt of SMSes (P= 0.002). • The mean HbAc1 value decreased from 79 mmol/mol to 70 mmol/mol (P= 0.001)

Author, Year	**Country**	**Methods**	**Major Findings**
Kumar et al., 2015	India	Voice calls for screening. The investigator called the same evening after the first test requesting them to come for definitive tests.	• 85.7% of outpatients in the intervention group returned for the definitive test as compared to 53.3% in the control group. • Screening yield was higher in the intervention group (18.6%) than in the control group (10.2%)
Rotheram-Borus et al., 2012	South Africa	Diabetes Buddies: SMS intervention psychoeducational group sessions. The intervention groups were provided mobile phones and encouraged to call or text a buddy to support each other's behaviour change.	• Within 3 months, women increased their sleep and reported higher positive action and social support coping. • Within 6 months, spiritual hope decreased.
Shahid et al., 2015	Pakistan	Voice call intervention. Users in the intervention group (n=220) received regular (15 days) feedback based on their blood glucose over the past readings of 15 days on the phone for 4 months. The control group (n=220) was examined initially and after 4 months of phone contact.	• Reduction in mean HbA1c levels was highly marked in the intervention group (-1.46) compared to the control (-0.48). • Patients in the intervention group showed improvement ($p < 0.001$) in following the diet plan from 17.3% at baseline to 43.6% at 4 months.
Shariful et al., 2015	Bangladesh	SMS intervention. The intervention users (n=106) received education on diabetes self-management using SMSes, versus the control group (n=94) received standard patient care.	• The least squares mean difference of HbA1c from baseline to after 6 months was -0.85 (-1.05, -0.64) in the SMS group and -0.18 (-0.41, 0.04) in the control group.
Shetty et al., 2011	India	SMS intervention. The intervention group (n=110) received SMSes every 3 days for 1 year on principles of diabetes management versus the control group (n=105) who received standard care.	• Most patients in the SMS group preferred receiving messages on all aspects of treatment. • At the end of one year, the mean FPG (185+57 mg/dl to 166+54, p<0.002) and 2h P.G. (263 + 84 mg/dl to 220 + 67, p <0.002) levels decreased significantly in the SMS group.

Author, Year	Country	Methods	Major Findings
			• There was no significant difference in the mean HbA1C values in both groups. However, the percentage with A1c<8% decreased significantly in the SMS group.
Shetty et al., 2012	Kenya	Voice call intervention for 6 months. Data, including blood glucose, were collected from 43 patients by community health workers via cell phones. The data were transmitted to the central server and used for the therapy plan. Community health workers communicated with patients regarding the therapy plan via phone calls.	• Within 6 months, A1C decreased from 13.18% (95% CI 12.83 to 13.53) to 10.5% (95% CI 9.86 to 11.13; p < 0.001).
Takenga et al., 2014	Congo	Mobil Diab: Integrated mobile apps and web-based applications. The intervention group (n=20) assigned in Mobil Diab care enabled the users to collect blood data and access therapy plans based on the recorded data on their mobile via web and SMS. The control group (n=20) received standard care. The system also enabled healthcare personnel to extract patients' data and transmit therapy plans.	• Significant improvement in the mean HbA1c values for the intervention group (from 8.67% to 6.89%) • Constructive evaluations of the system from patients and medical staff have been presented based on three metrics: usability, efficiency and therapy satisfaction, and system acceptance.
Tamban et al., 2013	Philippines	SMS intervention. The control group (n=52) was assigned to standard care. The intervention group (n=52) standard care plus education vis SMSes 3 times per week for 6 months on diet and exercise.	• After 3 months, a significant difference was observed in mean HbA1c (SMS=6.99 + 0.86, control= 7.34 + 0.90, p= 0.0452). • At 6 months, a significant difference was seen in the mean number of meals/day, significantly higher than in the

Author, Year	Country	Methods	Major Findings
			intervention group, 2.61 versus 2.29. • The mean number of minutes/exercises was significantly higher in (the SMS group, which is 37.40, than control, 31.44 (p= 0.021)
Zolfaghari et al., 2011	Iran	SMS versus voice call intervention. The SMS group (n=38) received 6 messages on diabetes self-management every week for 3 months. The telephone call group (n=39) received voice calls for 3 months regarding diabetes self-management.	• No significant changes were reported in HbA1c between the two groups. • Both groups had significant mean changes. • At 3 months, patients had a mean increase in physical exercise, diabetic medication taking, and diet adherence compared with the pretest, with no statistically significant difference in the two groups.
Le et al., 2011	South Africa	Mobile Diary Application: it is a Diabetes application. The application allows users (patients) to record data, including blood glucose, display data recorded, and share and communicate data recorded.	• System usability evaluation results show that it took users an average of 6.1 minutes per day to record all data.

3.2.6 Key Themes of Success Reported in the Literature

Glucose Control

- mHealth intervention had a positive impact on improving glucose control among diabetic patients. Out of 10 empirical studies, only two articles reported non-significant differences between the intervention and control group in HbA1c value. Despite this, one study reported a substantial increment in the mean Fast Blood Glucose and 2h PG, and the percentage with A1c<8% decreased significantly in the mHealth intervention group.

- There is still a gap in the long-term effect of mHealth intervention on glycemic control. Only one study measured the long-term effect of the mHealth intervention on glycemic control. However, the reported effect is mixed.
- SMSes and voice calls were the key mHealth intervention types that demonstrated glucose control success. One study compared SMSes with telephone calls, and both interventions resulted in a comparable positive effect on glycemic control.
- Most interventions were not tailored to the individual or supported by theoretical frameworks.
- DSM and knowledge were not adequately covered, which could have impacted glycemic control practice.

Users' Satisfaction with mHealth Intervention

- Three empirical studies reported patient satisfaction and positive evaluation of the mHealth interventions.
- The tool/characteristics used to measure user satisfaction, acceptance and usability are not reported.

Higher Adherence and Less Loss to Follow Up

- SMS and voice call interventions resulted in improvements in medication and diet adherence.
- Voice call interventions reduced loss to follow-up or "no-show" rates.

Increased coping and self-management

- SMS and voice call interventions improved coping and DSM.
- SMS group support interventions also reduced depression and sleeping problems.

3.2.7 Challenges of mHealth Initiatives for Diabetes Management in Low and Middle-income Countries

Challenges of mHealth initiatives for diabetes management in low and middle-income countries identified from this integrated literature review are presented next by classifying and grouping them under six categories: research and evidence-related, government-related, infrastructural, economic, users-related and system application- and interface-related challenges.

3.2.7.1 Research- and Evidence-related Challenges

The existence of a limited number and quality of research studies in general, a lack of data on cost-effectiveness and a lack of knowledge/evidence on mHealth benefits and public health outcomes are discussed hereunder as challenges of mHealth initiatives categorised by the reviewer as research- and evidence-related challenges.

3.2.7.1.1 Limited Research Studies

Although some studies have recently addressed the effectiveness of interventions delivered via telephones and the internet, the number of these studies, the themes they covered as well as the study areas they focused on so far suggest a lot more remains to be done regarding the use of mHealth in diabetes management initiatives. According to a policy report, many of the top six barriers to mHealth implementation are related to the need for further knowledge and information (Kay et al., 2011:63). Focusing on the drawbacks of cell phone solutions, Ajay and Prabhakaran (2011:779) similarly emphasized that the major obstacle in scaling up of mHealth infra-structure includes the lack of a well-designed RCT, the small size of studies, and the quasi-experimental and pre-post design. Another report implied that the existence of limited research might be due to a lack of funding (Rotheram-Borus et al., 2012:9).

3.2.7.1.2 Lack of Data on Cost-effectiveness

There is little published evidence on the effectiveness of mHealth interventions or their cost-effectiveness, particularly in low-income settings. That is why this integrated literature review pointed to a lack of data on cost-effectiveness or inadequate power to evaluate effectiveness and cost-effectiveness as the major mHealth initiative challenge pertaining to lack of evidence (Ajay & Prabhakaran, 2011:779; Jha et al., 2016:5; World Health Organization, 2011:69). According to Kay et al. (2011:67), this challenge was the fourth-highest barrier cited by the WHO Member States. Kay et al. (2011:71) added that evaluation, the first step in providing these data, is not being undertaken for most mHealth programs (only 12% of Member States have evaluated mHealth programmes). In other words, although the level of mHealth activity is growing in countries, evaluation of those activities by the WHO member states is deficient. This is not entirely unexpected, as mHealth is still relatively new and unexplored, but this practice needs to change.

3.2.7.1.3 Lack of knowledge/evidence on mHealth benefits and public health outcomes

Besides the unknown cost-effectiveness of mHealth initiatives discussed above, the lack of knowledge concerning the possible applications of mHealth and public health outcomes is another challenge related to the lack of evidence in mHealth initiatives. Among others, this challenge of lack of clear evidence of its benefits was particularly stressed in the works of Ajay and Prabhakaran (2011:782) and Kay et al.(2011:76).

3.2.7.2 Government-related Challenges

Most mHealth applications, initiatives, and strategies have suffered from the absence of support from relevant government legislations, policies, and procedures (Ajay & Prabhakaran, 2011:779; Ariani et al., 2017:22; Rotheram-Borus et al., 2012:9; Watkins et al., 2018:145). These government-related mHealth initiative challenges in diabetes management are discussed below in terms of six subheadings: lack of governmental policies, competing for health system priorities, lack of strategic implementation, lack of governmental support, lack of governmental regulations and data privacy and security risks.

3.2.7.2.1 Lack of Governmental Policies

Most m-health initiatives are negatively affected by a lack of governmental policies (Ariani et al., 2017:22). It is apparent that without data on cost-effectiveness and evidence of its benefits and public health outcomes, mHealth will not quickly become a part of government policy or be protected by legal guidelines on privacy (the third- and fifth-highest barrier cited, respectively), nor will policymakers be aware of its possible applications. According to Kay and his colleagues (Kay et al., 2011:76), the latter was the second most-cited mHealth barrier by WHO member countries.

3.2.7.2.2 Competing Health System Priorities

A key barrier related to the lack of government policies included conflicting health system priorities. Conflicting priorities generally indicate that funding is allocated to other initiatives ahead of mHealth (Kay et al., 2011:75). It is difficult to get policymakers to understand the importance of prioritising scaling up mHealth activities over other public health intervention projects when there is little evidence on the financial feasibility of mHealth interventions, such as cost-effectiveness and operating costs (Ariani et al., 2017:25). Indeed, if these barriers were resolved, the case for expenditure on mHealth would most likely be bolstered, putting it into perspective among the competing costs that every health system must face, which was the number one cited barrier by WHO member countries to implementation (Kay et al., 2011:67).

3.2.7.2.3 Lack of strategic implementation

Perhaps due to a lack of general interest or understanding of the field on the side of the government, lack of strategic implementation is another government-related challenge in mHealth initiatives. According to Kay et al. (2011:71), rather than strategic implementation, the emergence of mHealth is occurring in many WHO member states through experimentation with technologies in many health settings.

3.2.7.2.4 Lack of governmental support

According to Rotheram-Borus et al. (2012:9), the challenge with pilot programmes is finding opportunities to sustain investments for new programmes over time, especially amid economic recessions. Researchers are unlikely to be able to mobilize the resources to network with the policymakers who could provide funding lines for this work. Kay and his colleagues (2011:21) similarly mentioned the lack of supporting policies as a challenge for mHealth initiatives in T2DM management.

3.2.7.2.5 Lack of governmental regulations

Another key barrier to mHealth initiatives included legal issues (Ajay & Prabhakaran, 2011:782; Ariani et al., 2017:22; Kay et al., 2011:77; Watkins et al., 2018:145). In this regard, lack of government regulation is another government-related challenge identified by this integrative literature review. According to Ajay and Prabhakaran

(2011:782), governmental regulation is required to enforce compliance by the industry to various standards (e.g., context-specific practice guidelines and data standards for interoperability).

3.2.7.2.6 Data privacy and security risks

The lack of a regulatory framework inevitably leads to challenges to privacy, security, and interoperability (Ariani et al., 2017:24; Kay et al., 2011:76; Watkins et al., 2018:145). Data security and citizen privacy require legal and policy attention to ensure that mHealth users' data are properly protected (Kay et al., 2011:76). Data security is a particularly important issue to address within the policy area. There are legitimate concerns about the security of citizen information by programmes using mHealth technologies. In particular, message transmission and data storage security can put citizen information at risk if the necessary precautions are not taken (Kay et al., 2011:76).

3.2.7.3 Infrastructural Challenges

Infrastructural challenges, and a lack of accessible digital infrastructure, is identified as a major barrier to mHealth initiatives for diabetes management in low and middle-income countries (Ariani et al., 2017:19; Jha et al., 2016:5; Kay et al., 2011:63; Van Olmen et al., 2017:40; Watkins et al., 2018:145).

According to Ariani et al. (2017:20), poor infrastructure is one of the main hurdles to be overcome when implementing m-health programs. This is because poor telecommunication infrastructure may prohibit optimal use of (broadband) internet services and applications from handheld portable devices to access and update electronic medical records.

In South Africa, the bottom-up use of mobile phones has been evolving to fill the gaps to augment primary care services. However, barriers to access, such as poor digital infrastructure, remain (Watkins et al., 2018:145). As a way out, Watkins and colleagues (2018:145) noted that doctors had developed their own informal mHealth solutions in response to their work needs and lack of resources due to their rurality.

Referring to the challenge posed by poor digital infrastructure as logistical difficulties, Jha et al. (2016:5) also touched upon this barrier to mHealth initiatives. Reporting that the implementation of their mHealth intervention was more problematic than foreseen, Van Olmen and his colleagues (2017:40) pointed to technological barriers that limited their abilities to reach all the participants as one responsible factor. Ariani et al. (2017:20) explained that the challenge to m-health systems to improve healthcare quality might be due to a lack of investment in infrastructure.

3.2.7.4 Economic Challenges

Poorer populations have indeed been shown to have reduced access to the health information on the web than those with more wealth (Clarke et al., 2016; as cited in Watkins et al., 2018) (Watkins et al., 2018:40). Challenges to mHealth systems to improve the quality of healthcare also included the absence of long-term financial viability (Ariani et al., 2017:19). To this, Kay and his colleagues (2011:76) added operating costs as a challenge to mHealth initiatives for diabetes management in low and middle-income countries.

Results from the study by Takenga and colleagues (2014:9) confirmed that some disadvantages, such as costs for an internet connection, were the preoccupation of both categories of users that participated in the research. Similarly, websites and social media were intermittent due to a lack of financial ability to afford airtime for these patients and health workers (Watkins et al., 2018:145).

3.2.7.5 User-related Challenges

The time users need to get used to mHealth digital applications, and their poor physical health status, low digital literacy, and failure to pay attention are discussed next as user-related challenges in mHealth initiatives for diabetes management in low and middle-income countries.

3.2.7.5.1 The Time Needed by Users to Get Used to the Application

According to Takenga and his colleagues (2014:9), some disadvantages, such as the time needed to get used to the application, were the preoccupation of both categories of the users tested in their study.

3.2.7.5.2 Users' Poor Physical Health Status

Physical factors such as poor eyesight influence the usability of mobile phones for healthcare, shaping communication patterns (Watkins et al., 2018:144). For instance, a participant in the research conducted by Watkins and colleagues (2018:144), a female patient found in the age group between 70 and 79 years, responded, "*My eyes are very poor, I cannot see clearly. I can see that there is something written on the phone screen, but I do not see anything."*

3.2.7.5.3 Users' Low Digital Literacy

Studies have reported that low digital literacy has produced unfavourable outcomes regarding the success of mHealth initiatives for diabetes management in low and middle-income countries (Ariani et al., 2017:25; Le et al., 2011:1; Watkins et al., 2018:143). Less educated populations have been shown to have reduced access to the health information on the web compared to those with a higher educational level (Watkins et al., 2018:143). This challenge is discussed below regarding participants who participated in the mHealth communication process—patients and HCPs.

Low digital literacy among patients: Patients' lack of online search skills reduced access to mHealth information on diabetes. For example, the patients in the study undertaken by Watkins and colleagues (2018:13) were reported to be disadvantaged and lacked web searching strategies. This is because patients who use their phones to find health information on the web require self-taught web literacy (Watkins et al., 2018:143). Inexperience with reading website content can lead to the retrieval of inaccurate or irrelevant information (Le et al., 2011:1; Watkins et al., 2018:144). This is because, as Watkins and colleagues (2018) reported, patients had insufficient opportunities or experience with websites.

Low digital literacy among health professionals: Not only was the problem of digital literacy observed among patients/users but also HCPs. Considering this fact, Watkins and colleagues (2018:144) revealed that some health workers accessed websites and used social media to gather health information but lacked web search strategies; many did not know what to search for and where to search.

Regarding challenges to mHealth systems to improve the quality of healthcare and diabetes management due to low digital literacy among patients and some health professionals in low and middle-income countries, Ariani et al. (2017:25) generally reasoned that inadequate training in technological advances is a contributing factor.

3.2.7.5.4 User's Failure to Pay Attention

According to Zolfaghari and his colleagues (2012:1927), patients may not have paid attention to their received messages. Moreover, the commercialisation of the SMS market resulted in subjects becoming overwhelmed with messages, which led to a degree of lethargy in reading them. According to Van Olmen and his colleagues (2017:145), the organisational capacity required to develop and send messages regularly varied across the programs these researchers evaluated. This variation led to differences in message frequency and coverage efficacy across the three programmes. The coverage was best only in one of the programmes, where more than half of the patients remembered receiving most messages (Van Olmen et al., 2017:145).

3.2.7.6 System Application- and Interface-related Challenges

This section presents the lack of mHealth information available in local languages and problems with mobile applications and interfaces as the two main issues involved in system application- and interface-related challenges of mHealth initiatives of diabetes management in low and middle-income countries.

3.2.7.6.1 Lack of mHealth Information Available in Local Languages

On top of low digital literacy among users, the challenges of mHealth initiatives for diabetes management in low and middle-income countries were made even worse, based on the report by Watkins and colleagues (2018:145), by the lack of health information available in local languages. That is, even if users are literate and knowledgeable enough to use the mHealth technological apparatuses and applications developed to meet this end, if, for instance, the messages are transmitted only in English and users are not proficient in this language, it would become a barrier to acquire required information on diabetes.

Problems with mobile applications and interfaces: Some studies and reports concerned with mHealth initiatives for diabetes management in low and middle-income countries, such as those by Ajay and Prabhakaran (2011:781), Haddad et al. (2014:458) and Van Olmen et al. (2017:40), revealed that mobile application- and interface-related challenges were encountered in delivering services. Such technological barriers generally limit the ability to target specific individuals and tailor text messages to the (different) patients' needs (Van Olmen et al., 2017:40).

Disclosing that they encountered some practical problems in delivering their mHealth intervention, Haddad and his colleagues (2014:457) also stated that interference from the telecommunications provider and loss of some SMS messages when the recipient was located beyond network reach were experienced. As related to mobile interfaces, Ajay and Prabhakaran (2011:782) reported that the small size of the display screen and keypad were impediments to their mHealth initiative.

3.2.7.7 Discrepancies in Outcomes Reported in the Reviewed Literature

Discrepancies in outcomes reported by reviewed literature were encountered in two instances. While the first has to do with economic challenges, the other is on low digital literacy related to user/patient-related challenges of mHealth initiatives for diabetes management in low and middle-income countries.

3.2.7.7.1 Economic Challenges

Although most studies that particularly dealt with economic challenges and reviewed in this integrated literature review reported that economic factors such as the absence of long-term financial viability (Ariani et al., 2017:18), operating costs (Kay et al., 2011:76), costs for internet connection (Takenga et al., 2014:9), and lack of financial ability to afford airtime (Watkins et al., 2018:145) were responsible for negatively influencing mHealth initiatives for diabetes management in low and middle-income countries, two studies (Shetty et al., 2011:713; Tamban et al., 2013:147) with rather different results regarding this economic factor were also encountered.

A study by Tamban and his colleagues (2013:147) asserted that subjects could afford to connect to the internet to combine SMS with the internet. Stating that mobile telephones are being widely used, even in low-income countries, as they are cheap and convenient and SMS has become a popular and cheap mode of easy and widespread communication, Shetty and colleagues (Shetty et al., 2011:713) similarly reported that the results suggested positive responses with frequent motivation using SMSes as a feasible mode of communication which is cheap and practical.

3.2.7.7.2 Low Digital Literacy

Despite studies having reported low digital literacy among users (both that of patients and some health workers) as a barrier to the successful implementation of mHealth initiatives for diabetes management in low and middle-income countries (Ariani et al., 2017:26; Watkins et al., 2018:145), a study by Rotheram-Borus et al. (2012:8) argued that literacy was not required for such interventions and hence was not a challenge.

Ruling out computers as technological devices used in mHealth initiatives and focusing on mobile phones instead, Rotheram-Borus and his colleagues (2012:8) stated that Computer Assisted Programmed Interviews (CAPI) systems had been state-of-the-art in data collection for about the last quarter of a century, typically using laptop computers. The authors also admitted that computer literacy is low and computers are expensive, especially in low and middle-income counties (LMICs). Nevertheless, argued Rotheram-Borus et al.(2012:9), persons who find computers intimidating use mobile phones in their daily lives.

Going along with such an argument, the statement by Rotheram-Borus and his colleagues (2012:9) suggested that the relationship between digital literacy and mobile phone utilisation for mHealth purposes should be approached from the perspective that the use of mobile phones reduces literacy issues that have been a critical barrier for the adoption of previous electronic data collection platforms, and not the other way around. Accordingly, literacy is not required for mobile phone data collection; picture icons are often used (Rotheram-Borus et al., 2012:9).

3.3 DISCUSSION ON FINDINGS OF PHASE I

This integrative literature review identified the use of mHealth for T2DM management in low and middle-income countries. The significant findings of the integrative literature review are discussed below.

3.3.1 Types of mHealth Intervention

This review identified three types of mHealth intervention: SMSes, telephone calls, and application-based interventions. Similarly, Wang et al. (2020:451) categorised the mHealth interventions into three types; the mHealth SMS and application-based intervention categories were similar to this study.

3.3.1.1 SMS Interventions

The most common mHealth intervention types for T2DM management identified in this review was SMS. In the studies included in this review, SMSes were used for patient education alone and with telephone calls. This was also evident in other review papers; most mHealth studies used SMS technology to educate patients with T2DM (Kebede, Liedtke, Möllers & Pischke, 2017; Kitsiou et al., 2017; Muralidharan, Ranjani, Anjana, Allender & Mohan, 2017).

The patient education contents addressed by SMS interventions were healthy diet and exercise, DSM, treatment, complication, blood glucose monitoring, alert on treatment and follow-up, and psychosocial support; the finding was in line with other review studies (Correia, Waqas, Huat, Gariani, Jornayvaz, Golay & Pataky, 2022:5; Haider, Sudini, Chow & Cheung, 2019:33; Hovadick, Reis & Torres, 2019:213; Sahin, Courtney, Naylor & E Rhodes, 2019:8; Whittemore, Siverly, Wischik & Whitehouse, 2020:517). According to Hovadick et al. (2019:217), SMS contents that address different DSM areas are more effective in improving clinical outcomes. One study included in this review also reported that patients prefer to receive messages on all aspects of T2DM management.

The included studies did not adequately document the SMS content development process. Other review articles also mentioned the lack of a detailed report on the development of SMS content (DeKoekkoek, Given, Given, Ridenour, Schueller & Spoelstra, 2015:2729; Haider et al., 2019:34). The lack of rigour in the SMS development process could have a negative impact on the scalability and adoption of successful interventions into clinical practice. However, few interventions mentioned the involvement of experts and the use of national and international guidelines, which is consistent with other similar review article studies (Sahin et al., 2019:7; Sahin, Courtney, Naylor & Rhodes, 2021:60; Whittemore et al., 2020:521). This could be critical in locally improving the validity and usability of the SMS content.

The frequency of SMS messages ranges from one per day to one per week. There is no conclusive evidence of the effect of SMS frequency on the outcomes of patient education interventions. According to Sahin et al. (2019:9), minor SMS frequencies could be more effective for clinical outcomes. On the contrary, another review article recommended moderate to high frequencies of SMSes for effective clinical outcome improvement (Dobson, Whittaker, Pfaeffli Dale & Maddison, 2017:10). Despite these contradictory reports, SMS frequency may be determined by individual preference and the behavioural theory used for message tailoring. The SMS frequency should be determined after careful preference analysis to reduce patient fatigue.

Similar to other review articles (Dobson et al., 2017:9; Haider et al., 2019:33; Heitkemper, Mamykina, Travers & Smaldone, 2017:1033; Sahin et al., 2021:9), the majority of the patient education interventions included in this review lack theoretical grounding. Only two studies used a theoretical framework to guide the intervention. One study used a theory of planned behaviour focusing on behavioural, normative, and control beliefs, and another study based on SMS intervention used a combination of behavioural learning theory and the transtheoretical behavioural change model. The trans-theoretical model has been widely used in interventions to address patients' unique needs and expectations at various stages of behaviour change and was also frequently mentioned in other review articles (Arambepola, Ricci-Cabello, Manikavasagam, Roberts, French & Farmer, 2016:6; Long, Bartlett, Farmer & French, 2019:8; Sahin et al., 2019:9).

According to meta-analysis studies, using behavioural theory for SMS message tailoring could be more advantageous and effective in bringing about positive behavioural changes and clinical outcomes (Correia et al., 2022:13; Haider et al., 2019:33). In contrast, as found in this study, SMS interventions that did not employ messaging tailoring techniques had a positive and significant impact on T2DM management. This could require further studies, but the use of theory-based or non-theory-based tailoring of SMS messages is preferable (Correia et al., 2022:13; Dobson et al., 2017:9; Sahin et al., 2019:9).

All the SMS interventions included in this review used one-way communication. According to evidence, one-way SMS intervention resulted in a similar effect in DSM practice and clinical outcomes compared to two-way messages (Arambepola et al., 2016:7; Farmer, McSharry, Rowbotham, McGowan, Ricci-Cabello & French, 2016:571). Since one-way messages are cheap and only require basic mobile phones, that could make it preferable for low and middle-income countries.

3.3.1.2 Telephone Call Interventions

The second type of intervention identified in this review was telephone call interventions. The number of phone calls ranged from one call to 24 calls per subject. This was higher than another meta-analysis study, and the study reported phone calls ranging from two to 16 calls per subject (Suksomboon, Poolsup & Nge, 2014:5). Even though the effect of call frequency on diabetes management and treatment outcomes has not been documented, a moderate frequency could be adequate to minimise fatigue for HCPs and patients.

Most telephone call interventions focused on communication and support for DSM. Similar to other review studies, the telephone calls used to provide tailored feedback for patients based on remotely collected data (Farias, Dagostini, Bicca, Falavigna & Falavigna, 2020:5; Heitkemper et al., 2017:1029; Huang, Tao, Meng & Jing, 2015:R97; Lee, Greenfield & Pappas, 2018:5; Villalobos, Vela & Hernandez, 2020:5).

The purpose of the phone call was to improve DSM through communication and support, and the majority of calls were made in person by HCPs or principal investigators, which is consistent with other review articles (Huang et al., 2015:R97; Lee et al., 2018:5; Villalobos et al., 2020:5). When compared to an automated phone call, the presence of such regular communication with an HCP maintains active engagement and increases the level of accountability of patients (Faruque, Wiebe, Ehteshami-Afshar, Liu, Dianati-Maleki, Hemmelgarn, Manns & Tonelli, 2017:E352; Heitkemper et al., 2017:1033; Huang et al., 2015:R99; Villalobos et al., 2020:7). Tailored communication based on patient clinical data and the current status is also important for achieving the desired DSM outcome, and it should take patient needs and literacy into account (Heitkemper et al., 2017:1033; Villalobos et al., 2020:9).

One study used telephone call interventions to improve screening and diagnostic rates by reminding patients to return for definitive T2DM diagnostic tests. The opportunity of a mobile phone-based digital screening checklist to identify individuals at high risk of developing T2DM is also identified by this review.

3.3.1.3 mHealth Application-based Interventions

Only two empirical studies and one review article were focused on mHealth application-based interventions for diabetes management. The application-based interventions for diabetes management were also reported by other review articles (Debon, Coleone, Bellei & De Marchi, 2019:2510; Kitsiou et al., 2017:7; Wang et al., 2017:451) despite the interventions being few (Wang et al., 2017:451).

The application-based interventions addressed the mHealth domains of maintaining Personal Health Record (PHR) and supporting treatment/therapy plans, consistent with other review articles. (Debon et al., 2019:2510; Kitsiou et al., 2017:7; Wang et al., 2017:451).

The Wang et al. (2017:455) review also discussed the applicability of mHealth biosensors for capturing patient data. The system enables automatic data capture and transmission via Bluetooth-enabled mHealth devices or other connectivity tools (Kitsiou et al., 2017:8). These data can be remotely stored, further processed, and presented for HCP in the form of usable information (El-Sappagh, Ali, El-Masri, Kim, Ali & Kwak, 2018:21918). Moreover, this could tackle geographical barriers for patients and engage patients in capturing their data. HCPs could also easily involve patients in collecting quality clinical data and designing patient-centric diabetes management (El-Sappagh et al., 2018:21918). This review reported the IEEE 11073 PHD as the most appropriate standard for mHealth-based biosensors. The IEEE 11073 PHD developed standardised the transmission of the measured data from different devices to the mHealth central system (El-Sappagh et al., 2018:21936; Huang, Wang & Wang, 2020:2).

The mHealth PHR application also allows for storing data in the central database. Despite not being reported in this review, a central database could be key to connecting mHealth with the hospital information system. This connection enables end-to-end comprehensive diabetes management and assists in transmitting real-time data between HCPs and patients (El-Sappagh et al., 2018:21923).

The treatment/therapy plan domain was the feature identified in the mHealth application. The applications use Clinical Decision Support System (CDSS) to provide accurate and useful information using graphs and statistics to support the HCPs in designing a tailored treatment plan. CDSS has been used to enhance therapy prescriptions and the quality of clinical care, reduce treatment errors and improve compliance with recommended standard management guidelines (Gupta & Roy, 2017:432; Jia, Zhao, Chen & Zhang, 2019:67; Moreira, Rodrigues, Korotaev, Al-Muhtadi & Kumar, 2019:3537). Using such a mHealth application with CDSS enables HCP to make more accurate and timely decisions (Istepanian & AlAnzi, 2020:718; Istepanian & Woodward, 2016:6; Zaman, De Silva, Goh, Evans, Singh, Singh, Singh, Singh & Thrift, 2022:6). mHealth CDSS could save time spent analysing large sets of paper-based clinical data and searching online information to support treatment decisions by HCPs; it could support them to shift their attention in designing an effective treatment plan. Furthermore, the corrective feedback and suggestions provided by the system could create a learning opportunity for HCPs to improve their skills (Sim, Ban, Tan, Sethi & Loh, 2017:11-12).

CDSS provides various services, including diagnostics, alarm systems, disease management, drug prescription, and control. The CDSS feature of the mHealth PHR application identified in this review supports disease management and includes an alarm system to notify critical data for HCPs (Sutton, Pincock, Baumgart, Sadowski, Fedorak & Kroeker, 2020:1). Though the CDSS feature is not a standalone system in the application, it must be intelligent enough to make the appropriate decision in real-time. This requires correct and complete data from the current state and previous patient history (Agarwal, Glenton, Tamrat, Henschke, Maayan, Følhus, Mehl & Lewin, 2021:4; El-Sappagh et al., 2018:21927). The application included in this review used the mobile biosensor to collect the current real-time state of data and was linked with a hospital information system to get the medical history of patients with diabetes. This enables CDSS to make customised decisions based on recent and historical patient data (El-Sappagh et al., 2018:21927).

The CDSS's ability to make appropriate decisions also depends on the type and suitability of information sources. The CDSS is programmed to follow knowledge inferred from information sources like domain experts and standardised treatment guidelines (El-Sappagh et al., 2018:21928; Sutton et al., 2020:2). This kind of CDSS is categorized as knowledge-based CDSS. Another category is non-knowledge-based CDSS which does not employ programming based on expert knowledge; rather, the CDSS uses machine learning techniques and artificial intelligence to generate decisions (Agarwal et al., 2021:4; El-Sappagh et al., 2018:212927; Sutton et al., 2020:1). The mHealth application also allows HCPs to get consultation and support from senior professionals.

3.3.1.4 Implementation Models

Most of the interventions included in this review are short-term studies and standalone, not supported by the governmental or nongovernmental entities for scaling up after the pilot test. This is the reality in most of the mHealth interventions conducted in low and middle-income countries (LMICs). A review article stated that most evidence for the efficacy and efficiency of mHealth programs comes from small-scale studies with short intervention periods, raising concerns about their sustainability, scalability, and impact. Collaboration among various organizational entities, public-private partnerships, and funding for large-scale implementation could be critical for LMICs (McCool, Dobson, Whittaker & Paton, 2022:528).

3.3.2 Outcomes of mHealth Interventions

3.3.2.1 Glycemic Control

Most mHealth interventions for diabetes management measured glycemic control as the primary outcome using HbA1c and Fasting Blood Glucose. HbA1c is a key indicator of clinical outcome in patients with T2DM because it is related to diabetic complications and indicates average glycemic control over more than a few months (American Diabetes Association, 2018b:S1). In this review, ten empirical studies used HbA1c to measure glycemic control, and two used Fast Blood Glucose. Out of these, eight articles reported a significant difference between the intervention and control group in HbA1c value. This positive effect of mHealth on HbA1c level was also evident in other review articles (Cui, Wu, Mao, Wang & Nie, 2016:8; Haider et al., 2019:33; Johnston, Zemanek, Reeve & Grills, 2018:3-4; Kitsiou et al., 2017:8; Robson & Hosseinzadeh, 2021:886; Yoshida, Boren, Soares, Popescu, Nielson & Simoes, 2018:5; Zhang, Cheng, Zhu, Huang & Shen, 2021:610).

Among SMS-based interventions, studies in Iraq, Bangladesh and the Philippines found that HbA1c levels improved significantly after the SMS interventions. SMS interventions have been shown to be effective in achieving desired changes in glycemic control (Sahin et al., 2019:9; Wang et al., 2020:8; Whittemore et al., 2020:524). The result of this review was consistent with other systematic reviews; among all types mHealth interventions included, the review identified SMS-based behavioural interventions as particularly effective in improving glycemic control (Heitkemper et al., 2017:1033; Yoshida et al., 2018:8). On the other hand, two SMS interventions reported insignificant changes in HbA1c. One of these studies found significant changes in Fasting Blood Glucose value.

Due to the nature of the integrative literature review, this study did not determine the pooled effect of SMS-based patient education in glycemic control. Though, the positive effect of SMS patient education in glycemic control was well-established by other review and meta-analysis studies. A meta-analysis of 13 trials found that SMS-based interventions had a statistically significant pooled effect on glycemic control (Arambepola et al., 2016:6). Another meta-analysis of 17 trials found a small but statistically significant pool effect in glycemic control (Wu, Kee, Threapleton, Ma, Lam, Lee, Wong & Chung, 2018:9). The SMS effect is primarily due to the availability of convenient, frequent and powerful interaction between HCPs and patients to influence diabetes management (Heitkemper et al., 2017:1033; Kitsiou et al., 2017:12).

This review shows that three telephone call interventions also reported significant improvement in glycemic control among intervention groups. This was consistent with other review and meta-analyses articles (Heitkemper et al., 2017:1032; Hu, Wen, Wang, Yang, Liu, Li & Xu, 2019:407; Huang et al., 2015:R97; Riazi, Larijani, Langarizadeh & Shahmoradi, 2015:4; Robson & Hosseinzadeh, 2021:8; Zhang et al., 2021:610). According to a meta-analysis of 18 articles, the telephone call interventions significantly reduced the HbA1c level (Huang et al., 2015:R96).

All telephone calls that reported positive changes in glycemic control were human call-based interventions, and HCPs or the principal investigator made the calls. The frequent human interaction between HCPs and patients could increase accountability and commitment to DSM practice among patients, which could explain the positive clinical outcomes. According to the meta-regression analysis by Huang et al. (2015), human call-based intervention is more effective in improving glycemic control than automated calls. The participation of HCPs in interventions is effective for telephone calls and other mHealth interventions. According to two review articles, the direct involvement of HCPs significantly improves the clinical outcomes of mHealth interventions (Hou et al., 2018:2011; Mao, Lin, Wen & Chen, 2020:9).

Most of the telephone call interventions in this review supported the patients by collecting data remotely and providing feedback based on the collected data. The provision of telephone call support based on the current patient data could also enable HCPs to provide tailored feedback for patients to improve glycemic control. Suksomboon et al. (2014:6), based on the review, recommended that telephone call providers conduct an extensive patient assessment before providing telephone support. The provision of telephone call support based on the assessment of current patient data could enable HCPs to provide tailored feedback for patients to improve glycemic control.

The Mobil Diab, mHealth PHR application intervention, reported significant improvement in glycemic control among the intervention group. The application features include data collection using biosensors, data monitoring, and CDSS. The data collection and storage basically support the data monitoring and process of information for CDSS to enhance diabetes management.

In this review, one study reported that the CDSS effectively improved glycemic control. The CDSS effect in improving glycemic control was consistent with other review studies (Riazi et al., 2015:7; Sakurai & Ohe, 2017). Evidence shows a direct association between the amount of mHealth PHR data processed in a central database and a significant decrease in HbA1c levels (Sakurai & Ohe, 2017:1371). The CDSS effects on glycemic control and other outcomes are mainly due to the tailored approach for diabetes management, in which the care plan was formulated according to each patient's clinical characteristics (Riazi et al., 2015:7; Sakurai & Ohe, 2017:1372).

As noted in this review, less sophisticated techniques could support mHealth CDSS in assisting HCPs with clinical decisions. These techniques include making standard management guidelines and references electronically accessible on mobile phones and offering teleconsultations with senior experts (Deldar, Bahaadinbeigy & Tara, 2016:280).

Most of the studies included in this review measured short-term outcomes. Only one study measured the long-term effect of SMS interventions on glycemic control, which reported insignificant changes in HbA1c. The result of this study shows that there is still a gap in the long-term effect of mHealth intervention on diabetes management. This aligns with other studies highlighting that more evidence is required for long-term follow-up (Dobson et al., 2017:10; Huang, Yan & Huang, 2019:568; Thakkar, Kurup, Laba, Santo, Thiagalingam, Rodgers, Woodward, Redfern & Chow, 2016:348).

3.3.2.2 Knowledge of Diabetes

Two SMS interventions reported significant improvement in diabetes-related knowledge of patients in mHealth intervention groups. The effect of SMSes in improving knowledge is also reported in review articles (Dobson et al., 2017:9; Haider et al., 2019:33; Huang et al., 2019:569). This review shows that diabetes-related knowledge outcomes were not measured by most mHealth interventions, which could have impacted glycemic control practice. Especially, mHealth interventions focused on patient education should address whether there is a knowledge change due to the interventions.

3.3.2.3 Adherence to Diet, Medication, and Physical Exercise

The review reported that mHealth interventions improved patients' adherence to recommended dietary practices, medication, and physical exercises. This was consistent with other review studies (Fatehi, Gray & Russell, 2017:1; Nkhoma, Soko, Banda, Greenfield, Li & Iqbal, 2021:7; Riazi et al., 2015:5; Thakkar et al., 2016:343; Wang et al., 2020:6). Improving medication and diet adherence is difficult and complex. Different approaches were used targeting diet and medication adherence, including patient education (using SMSes and telephone calls), reminders (SMSes, telephone calls, beepers, pagers, mobile applications, DSM support), and monitoring systems (digital pill counters). In this review, the SMSes (patient education) and telephone call interventions (DSM support) resulted in positive outcomes in improving adherence to medication and diet. A meta-analysis of 16 RCTs also reported the effect of SMSes on medication adherence, and SMS interventions almost doubled the likelihood of medication adherence among patients with chronic disease (Thakkar et al., 2016:343).

SMS-based patient education and telephone call-based support could be simple and easy interventions for HCPs to improve medication and diet adherence. SMS- or telephone call-based DSM support could even provide a similar effect on medication and diet adherence. Telephone call support tailored and based on remotely collected patient clinical data could be an effective intervention to establish adherence and be used in conjunction with the mHealth PHR application (Alonso-Domínguez, García-Ortiz, Patino-Alonso, Sánchez-Aguadero, Gómez-Marcos & Recio-Rodríguez, 2019:12; Nkhoma et al., 2021:7).

In this review, one article reported that the mean number of minutes of exercise significantly increased after the SMS interventions. This result was consistent with the article by Cui et al. (2016:10), stating that mHealth interventions effectively encourage lifestyle changes such as physical exercise.

3.3.2.4 User Acceptance and Cost-effectiveness

In this review, only four studies evaluated user acceptance and reported positive outcomes regarding user satisfaction, acceptance, usability, and design, consistent with other review articles (Cui et al., 2016:12; Haider et al., 2019:35; Robson & Hosseinzadeh, 2021:12).

All empirical studies included in this review did not provide an economic evaluation of the cost-effectiveness of mHealth interventions. However, according to the economic evaluation study, in addition to the effectiveness in improving glycemic control, mHealth intervention is also cost-effective compared to routine clinical care (Li, Sun, Hou & Chen, 2021:6). Other systematic review articles also reported that mHealth interventions for T2DM management reported are cost-effective (Iribarren, Cato, Falzon & Stone, 2017:15; Rinaldi, Hijazi & Haghparast-Bidgoli, 2020:12). Though, the lack of economic evaluation among mHealth interventions in LMICs was highlighted (Rinaldi et al., 2020:12). Lack of adequate economic evaluation would make it difficult for low and middle-income countries for scaling-up mHealth interventions considering the budget constraints and competing health priorities. This was one major challenge identified by this review.

3.3.3 Challenges for mHealth Implementation

Limited evidence of effectiveness and efficiency was identified as a major challenge for implementing diabetes-related mHealth in low and middle-income countries (LMICs). This was confirmed by Marcolino et al. (2018:7), while another article (Wu, Gong, Wang, Gu, Ding, Zhang, Chen, Yan, Oldenburg & Xu, 2019:11) stated that quality mHealth studies are few and limited in low-resource settings. The lack of well-designed RCTs, small study sizes, and inadequate funding are related to the presence of limited evidence. According to the review of Hoque et al. (2020:2804), most mHealth studies were not reported according to the recommended quality standards and methodological criteria. Detailed and acceptable outcome measures are not common in mHealth studies, affecting the quality of evidence.

This review identified a lack of cost-effectiveness data or insufficient power to evaluate effectiveness and cost-effectiveness. Most of the empirical evidence did not provide data on a cost-benefit analysis, and the outcome measures were only directed to clinical aspects. The lack of evidence makes it difficult to realise and anticipate benefits and savings on a large scale (Majumdar, Kar, Palanivel & Misra, 2015:8). This is understandable given that mHealth is still in its early stages and thus underutilised, but this practice must change. Developing countries should expand funding for researchers and higher education institutes to produce quality evidence for mHealth implementations.

The lack of government policies and systems for cascading mHealth interventions based on the available evidence is another challenge that negatively affected the mHealth interventions. Other review articles emphasise that a lack of standardisation and regulatory frameworks in LMICs is creating a challenge for the scalability of mHealth Interventions. (Bali, 2018:4; Folaranmi, 2014:15; Kruse, Betancourt, Ortiz, Luna, Bamrah & Segovia, 2019:9; Nsor-Anabiah, Udunwa & Malathi, 2019:2899). That is why Nsor-Anabiah et al. (2019:2900) suggested the integration of mHealth interventions in the national health policy and strategies as a priority action for LMICs (Nsor-Anabiah et al., 2019:2900). This integration of mHealth in the national policy should go beyond the general use and it should identify the type of mHealth to be implemented for a specific disease like T2DM (Nsor-Anabiah et al., 2019:2899). The involvement of different stakeholders is also crucial during integrating mHealth into government policies.

The competing health system priorities in LMICs are another challenge and reason for the lack of policies and poor funding for mHealth initiatives. This challenge is worsened by inadequate quality published evidence on the cost-effectiveness of mHealth interventions to be considered as priority agenda by policymakers. Other review papers also identify these conflicting health system priorities as the main challenge for cascading mHealth interventions in LMICs (Folaranmi, 2014:15). Nsor-Anabiah and his colleagues (2019:2900) stressed the alignment of mHealth interventions with the most relevant national priorities.

The fragmented mHealth interventions not supported by a strategic implementation are another challenge affecting the scalability of the interventions. Most mHealth interventions are tested on a small scale, and no clear framework exists for scaling effective and efficient mHealth interventions. This is supported by evidence that fragmentation or lack of integration into routine healthcare could be the reason for the failure of mHealth interventions (Aranda-Jan, Mohutsiwa-Dibe & Loukanova, 2014:11; Bali, 2018:6; Latif et al., 2017:11547).

One reason for the poor integration of mHealth is the lack of government support, another challenge identified in this review. Lack of government support makes it difficult for researchers and project implementers to break through the healthcare system and mobilise resources for large-scale implementation. Most mHealth interventions are financially supported by government and non-government organizations during the initial test, and the alternative business model is not established for large-scale implementations (Bali, 2018:5). Countries oversee the private sector and investors’ roles, and most projects depend on public funds. Especially in LMICs, mHealth intervention failures are attributed to a lack of government guidance, policies, and financial support for large-scale implementation (Aranda-Jan et al., 2014:11).

Another challenge this review identified was the lack of government regulations on mHealth interventions. This review emphasized that government regulations could be required to enforce an agreement to various data and interoperability standards. Especially LMICs should use acceptable standards and interoperable mHealth technologies using an open-source architecture to reduce costs for implementation (Eze, Gleasure & Heavin, 2020:182). In line with the standardisation of hardware and software, the standardization of national guidelines is also crucial (Bali, 2018:3).

The lack of government regulations also creates further risks to the security and privacy of patient data. The security and privacy regulations are important to reduce security risks and enforce the mHealth implementation based on acceptable security and privacy standards. LMICs have not established a regulatory framework to ensure the secure capture, storage, and retrieval of sensitive clinical data (Nsor-Anabiah et al., 2019:2899; Vayena, Dzenowagis, Brownstein & Sheikh, 2018:66). As a result, LMICs should prioritize the establishment of a strong regulatory framework by assessing current privacy and security standards and considering their applicability to local contexts (Iwaya, Ahmad & Babar, 2020:150101). Multi-layer security and privacy architecture should be in place to effectively implement mHealth (Ndlovu, Scott & Mars, 2021c:9).

This review also showed that inadequate infrastructure is a major barrier to the effective implementation of mHealth interventions. This was echoed by Kruse and his colleagues (Kruse et al., 2019:8), stating that the three major barriers to effective implementation mHealth in low and middle-income countries were inadequate infrastructure, low availability of equipment, and the technology gap. The main reasons for inadequate infrastructures identified by studies are a lack of investment and poor coordination with ICT sectors (Bali, 2018:3; Kruse et al., 2019:8; Nsor-Anabiah et al., 2019:2899). Especially in low and middle-income countries, the lack of infrastructure is due to telecom vendors’ lack of coverage and quality (Bessin, Ouédraogo & Guinko, 2020:208). LMICs should invest in their digital infrastructure and collaborate with telecom vendors to address infrastructure gaps. Policymakers should also consider a tax break for telecom vendors to provide mHealth services (Kruse et al., 2019:9; Nsor-Anabiah et al., 2019:2900).

The cost of mobile phones, especially smartphones, is a barrier to implementing mHealth. Even if the mobile phone cost is reduced, airtime and internet costs create another burden (Latif et al., 2017:11547). In this review, the lack of financial ability to afford airtime and internet by patients and HCP is a major challenge for mHealth interventions. Despite the presence of various mHealth intervention types, finding a cost-effective way to benefit from these interventions is a priority for developing countries. That is why countries should emphasise more cost-effective mHealth interventions for diabetes care aligned with the economic challenges (Istepanian, Casiglia & Gregory, 2017:8). As identified in this review, some studies argued that telephone call and SMS interventions are widely accessible, affordable, and cost-effective methods for LMICs. These countries need to identify more cost-effective mHealth interventions for diabetes care. Istepanian, Kulhandjian, and Chaltikyan (2020:726) recommended shifting the focus from a smartphone-centric model to low-cost interventions like mobile teleconsultation systems.

Low digital literacy by HCPs is another barrier to overcome for the successful implementation of mHealth. Other review papers confirm this (Asemahagn, 2015:6; Bali, 2018:3; Latif et al., 2017:11547; Nsor-Anabiah et al., 2019:2899; O'Connor, O'Donoghue, Gallagher & Kawonga, 2014:1). The main reason for low digital literacy is a lack of education and training in digital technologies, leading to technology confusion and resistance to its adoption (Nsor-Anabiah et al., 2019:2899). mHealth interventions require strong support by providing rigorous and continuous training for HCPs to improve awareness and literacy of digital technologies (Fleming, Petrie, Bergenstal, Holl, Peters & Heinemann, 2020:257; Nsor-Anabiah et al., 2019:2900). Amdie and Woo (2020:36) recommended competency-based curricula integration in pre-service education to improve digital literacy.

Another challenge identified by this review is Interface related challenges. This includes a lack of mHealth interventions in a local language, poor screen design, complex interfaces, non-tailored interventions, and interference from telecommunications vendors. User-centric and iterative development based on continuous end-user evaluation is recommended for improving as interface-related problems (Farao, Malila, Conrad, Mutsvangwa, Rangaka & Douglas, 2020:3; Schnall, Rojas, Bakken, Brown, Carballo-Dieguez, Carry, Gelaude, Mosley & Travers, 2016:246; Wilson, Bell, Wilson & Witteman, 2018:3).

3.4 SUMMARY

This chapter provided the results and a discussion of the integrative literature review. The general characteristics of the selected articles, as well as the risk of bias assessment results, were described. The mHealth domain was thematised and described. The mHealth intervention types and their purpose were described, and the domain was highlighted. Key themes of the outcomes of the mHealth interventions investigated were presented and discussed. The challenges that hinder the effective implementation of mHealth were identified and discussed.

Chapter 4 presents the Phase II study findings and discussion.

CHAPTER 4

ANALYSIS, PRESENTATION, AND DISCUSSION OF FINDINGS OF PHASE II

4.1 INTRODUCTION

This chapter presents an analysis and description and a discussion of results from the cross-sectional survey study (Phase II). In Phase II, data were collected on socio-demographic characteristics, mobile phone experiences, perception regarding the use of mHealth, perceived usefulness, critical features of the mHealth applications, perceived complexity or ease of use and the intention to use in the future.

Quantitative analysis was conducted: descriptive and inferential. Descriptive statistics are presented in a table and narrated using frequency, percentage, mean, and standard deviations. A component factor analysis was conducted for three sub-scales: perceived usefulness, perceived complexity/ease of use and intention to use. The eligibility assessment and Principal Component Analysis (PCA) results are presented in tables. A Structural Equation Model (SEM) was used to assess the relationship between dependent and independent variables in the theoretical framework. A p-value >0.05 was used to determine statistically significant values. The discussion on Phase II findings is also presented in this chapter.

4.2 FINDINGS OF PHASE II

4.2.1 Demographic Data

In this study, 272 Healthcare Professionals (HCPs) participated, and 65.1% (n=177) HCPs were female. 61.4% (n=167) were in the 21-30 age group, and 32.7% (n=89) were in the 31-40 age group. Most of the HCPs (66.2%; n=180), were bachelor’s degree holders, and only 9.9% (n=27) were master’s degree holders. Regarding their position in a health centre, 59.6% (n=162), 35% (n=95), and 5.5% (n=15) were nurses, health officers and general practitioners, respectively.

All Healthcare Professionals (n=272) owned a cell (mobile) phone; out of these, 88.6% (n=241) owned a smartphone that could install and use applications. Most of the HCPs

(47.4%; n=129), have used cell phones for 6 to 10 years, and 36% (n=98) have used cell phones for more than ten years. Most (66.9%; n=182) HCPs had no access to the internet at the health centre. 74.6% (n=203) did not attend a course, and 88.2% (n=240) had not attended in-service training related to eHealth/mHealth. Detailed data are presented in Table 4.1.

Table 4.1: General Characteristics and Mobile Phone Experience (n=272)

Characteristics	Response	Frequency	Percentage
Gender	Male Female	95 177	34.9 65.1
Age	21-30 years 31-40 years Above 50 years	167 89 16	61.4 32.7 5.9
Highest level of education	Master's degree Bachelor's degree Diploma (Level IV)	27 180 65	9.9 66.2 23.9
Working position in the health centre	General Practitioner Nurse Health Officer	15 162 95	5.5 59.6 35.0
Own a cell phone	Yes No	272 0	100 0
Type of mobile phone	Smartphone (install and use applications) Basic (only used for voice and text messages)	241 31	88.6 11.4
Cell phone use in years	1-5 years 6-10 years Above 10 years	45 129 98	16.5 47.4 36.0
Do you have access to the internet at the health centre?	Yes No	90 182	33.1% 66.9%
Did you study any course related to eHealth/mHealth during your undergraduate or postgraduate study?	Yes No	69 203	25.4% 74.6%
Did you attend any training related to eHealth or mHealth?	Yes No	32 240	11.8% 88.2%

Healthcare Professionals (HCPs) were asked about their cell phone use frequency for different activities. 72.4% (n=197) used to make phone calls all the time. 39.3% (n=107) and 47.1% (n=128) regularly used their cell phone's text messaging and data storage features, respectively. Only 36.8% (n=100) browsed the internet on their cell phones all the time, and 48.2% (131) participants regularly read books and reading material using their cell phones. 44.1% (n=120) regularly used their cell phones to capture data, memos, or events.

Table 4.2: Activities Using Mobile Phones (n=272).

How often do you use your cell phone for the following activities?	**All the time**	**Regularly**	**Occasionally**	**Rarely**	**Never**
	1 **F (%)**	**2** **F (%)**	**3** **F (%)**	**4** **F (%)**	**5** **F (%)**
For making phone calls	197 (72.4)	65 (23.9)	8 (2.9)	2 (0.7)	0
For text messaging	85 (31.3)	107 (39.3)	66 (24.3)	14 (5.1)	0
For checking data stored on your cell	64 (23.5)	128 (47.1)	47 (17.3)	20 (7.4)	13 (4.8)
For checking e-mail	23 (8.5)	93 (34.2)	64 (23.5)	39 (14.3)	53 (19.5)
For browsing internet	100 (36.8)	93 (34.2)	26 (9.6)	18 (6.6)	35 (12.9)
For reading books, articles, or any reading materials	42 (15.4)	131 (48.2)	58 (21.3)	18 (6.6)	23 (8.5)
For capturing data, memos, or events	47 (17.3)	120 (44.1)	55 (20.2)	23 (8.5)	27 (9.9)

4.2.2 Perception Regarding the Use of mHealth

On the perception of diabetes-related mHealth use, all items scored more than 4 points from 5 points on the Likert scale. The highest mean (4.39) was recorded for the item "mHealth application will make it easier for the patient tracking system," The smallest mean (4.12) was recorded for the item "using mHealth will increase healthcare reach to patients with diabetes."

Around 84.2% (n=229) agree that mHealth will allow Healthcare Professionals (HCPs) to disseminate prevention strategies. HCPs who strongly agreed and agreed on the mHealth application use for early diagnosis of fluctuations in blood glucose were 41.2% (n=122) and 41.2% (n=112), respectively. 41.5% (n=113) and 47.8% (n=130) agreed and strongly agreed on the mHealth capability to capture and share data by health professionals. Most HCPs (50.7%; n=138), perceived that mHealth would empower diabetes patients to improve their glycaemic control. 52.2% (n=142) and 47.1% (n=128) HCPs strongly agreed that mHealth would allow health professionals to communicate with diabetic patients in real-time and disseminate health education easily, respectively.

Around 84.2% (n=229) agree that the patient tracking system will be easy through the mHealth application. Most of the HCPs (53.7%; n=146), strongly agreed that the mHealth application would make the decision support system helpful. Detailed data are presented in Table 4.3.

Table 4.3: Perception of Use of Diabetes-related mHealth (Attitude) (n=272).

Items	1 F(%)	2 F(%)	3 F(%)	4 F(%)	5 F(%)	Mean
Using the mHealth application will allow health professionals to disseminate prevention strategies	6 (2.2)	9 (3.3)	28 (10.3)	127 (46.7)	102 (37.5)	4.14
Using the mHealth application will make it easier for early diagnosis of fluctuations in blood glucose	10 (3.7)	10 (3.7)	28 (10.3)	112 (41.2)	112 (41.2)	4.13
Using mHealth will increase healthcare reach to patients with diabetes	10 (3.7)	9 (3.3)	28 (10.3)	116 (42.6)	109 (40.1)	4.12
Using mHealth will allow a health professional to capture and share data	7 (2.6)	7 (2.6)	15 (5.5)	113 (41.5)	130 (47.8)	4.29
mHealth application will make it easier to monitor diabetes patients	10 (3.7)	7 (2.6)	16 (5.9)	107 (39.3)	132 (48.5)	4.26
mHealth will empower diabetes patients to self-manage their condition	6 (2.2)	5 (1.8)	27 (9.9)	114 (41.9)	120 (44.1)	4.24
mHealth will empower diabetes patients to improve their glycaemic control	3 (1.1)	8 (2.9)	31 (11.4)	92 (33.8)	138 (50.7)	4.30
Using mHealth will enable health professionals to communicate with diabetic patients in real time	7 (2.6)	9 (3.3)	24 (8.8)	90 (33.1)	142 (52.2)	4.29
mHealth will allow health professionals to disseminate health education easily	9 (3.3)	4 (1.5)	17 (6.3)	114 (41.9)	128 (47.1)	4.28
Using the mHealth application will make it easier to prevent complications	9 (3.3)	8 (2.9)	21 (7.7)	96 (35.3)	138 (50.7)	4.27
mHealth application will make it easier for the patient-tracking system	8 (2.9)	11 (4.0)	24 (8.8)	99 (36.4)	130 (47.8)	4.22
mHealth application will make the decision support system helpful	5 (1.8)	2 (0.7)	20 (7.4)	99 (36.4)	146 (53.7)	4.39

1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly agree

4.2.3 Perceived Usefulness of the Diabetes mHealth Application

From the theoretical framework, the perception of usefulness was measured using six items with a 5-point Likert scale. The scale has strong internal consistency with 0.87 Cronbach's Alpha. The highest mean (4.4) was recorded for the item: "Using mobile phone would support my performance in increasing patient Self-Management practice." The smallest mean (4.26) was recorded for the item: "Using mobile would improve patient satisfaction on the provided healthcare."

Most (39.3%; n=107) Healthcare Professionals (HCPs) agreed, and 48.5% (n=132) strongly agreed that mHealth would improve their communication with diabetic patients. Around 40.1% (n=109) agreed, and 49.6% (n=135) strongly agreed that mobile phones would improve their performance in maintaining patients' health records. Regarding the mHealth support of health professionals in patient Self-Management practice and maintaining patient adherence to the treatment regimen (medication and diet), 52.6% (n=143) agreed, and 48.9% (n=133) strongly agreed, respectively. 88.3% (n=241) agreed that managing diabetes using mHealth would be cost-effective. HCPs strongly agreed (49.6%; n=135) that mHealth would improve patient satisfaction. Detailed data are presented in Table 4.4.

Table 4.4: Perceived Usefulness of Diabetes mHealth Application (n=272).

	1 F(%)	**2 F(%)**	**3 F(%)**	**4 F(%)**	**5 F(%)**	**Mean**
Using a mobile phone would improve my performance in communicating with diabetic patients.	5 (1.8)	7 (2.6)	21 (7.7)	107 (39.3)	132 (48.5)	4.30
Using a mobile phone would improve my performance in maintaining patients' health records (collecting, storing, monitoring, and transmitting data for diabetes patients).	5 (1.8)	5 (1.8)	18 (6.6)	109 (40.1)	135 (49.6)	4.34
Using a mobile phone would support my performance in increasing patient Self-Management practice.	3 (1.1)	6 (2.2)	14 (5.1)	106 (39.0)	143 (52.6)	4.40
Using a mobile phone would improve my performance in maintaining patient adherence to the treatment regimen (medication and diet).	3 (1.1)	7 (2.6)	21 (7.7)	108 (39.7)	133 (48.9)	4.33
Using mobile phones would be cost-effective in diabetes management.	2 (0.7)	11 (4.0)	18 (6.6)	95 (34.9)	146 (53.7)	4.37
Using mobile would improve patient satisfaction with the provided healthcare.	5 (1.8)	9 (3.3)	32 (11.8)	91 (33.5)	135 (49.6)	4.26

1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly agree

4.2.4 Perception of the Critical Features of the Diabetes mHealth Application

Healthcare Professionals (HCPs) were asked about their perceptions of the criticality of 12 features for diabetes-related mHealth. The highest mean (4.37) was reported for the mobile diary application feature, and the smallest (4.12) was reported for the remote patient monitoring system.

Out of a total, 86.1% (n=234) of HCPs agreed that SMS is a critical feature for diabetes-related mHealth. Around 47.1% (n=128) agreed, and 45.6% (n=124) strongly agreed that voice call features are critical for diabetes-related mHealth. Regarding mobile biosensors for collecting biomarkers, 38.6% (n=105) agreed, and 47.1% (n=128) strongly agreed on its criticality for diabetes-related mHealth features. 90.5% (n=246) reflected their agreement that Personal Health Record (PHR) features are critical for diabetes-related mHealth. 45.6% (n=124) of HCPs also strongly agreed that a Bluetooth that links mobile phones to the blood glucose meter is a critical feature for diabetes-related mHealth.

43.0% (n=117) agreed, and 46% (n=125) strongly agreed that connecting diabetes-related mHealth to the central database is critical. Around 92% (n=250) and 82.3% (n=224) agreed regarding the criticality of alarm features and remote patient monitoring systems for diabetes-related mHealth, respectively. Regarding the decision support system for health professionals, 87.5% (n=238) agreed on its importance for diabetes-related mHealth. Most HCPs agreed (38.2%; n=104) and strongly agreed (45.2%; n=123) that security features with restricted access systems are critical. Most (86.8%; n=236) HCPs considered interoperable systems critical for mHealth. Detailed data are presented in Table 4.5.

Table 4.5: Perception of Critical Features of a Diabetes mHealth Application (n=272).

Items	1 F(%)	2 F(%)	3 F(%)	4 F(%)	5 F(%)	Mean
SMS features	14 (5.1)	11 (4.0)	13 (4.8)	105 (38.6)	129 (47.4)	4.19
Voice call features	6 (2.2)	6 (2.2)	8 (2.9)	128 (47.1)	124 (45.6)	4.32
Mobile Biosensor for collecting Biomarkers (for example, blood glucose levels)	4 (1.5)	10 (3.7)	25 (9.2)	105 (38.6)	128 (47.1)	4.26
Personal Health Record features (for data collection, storage, and communication)	5 (1.8)	6 (2.2)	15 (5.5)	118 (43.4)	128 (47.1)	4.32
Bluetooth that links mobile phones to a blood glucose meter	4 (1.5)	14 (5.1)	33 (12.1)	97 (35.7)	124 (45.6)	4.19
Mobile connected to a central database (like a hospital information system or HMIS, or Electronic Health Record)	4 (1.5)	9 (3.3)	17 (6.3)	117 (43.0)	125 (46.0)	4.29
Mobile diary application	3 (1.1)	7 (2.6)	17 (6.3)	104 (38.2)	141 (51.8)	4.37
Alarm features to indicate critical features	5 (1.8)	6 (2.2)	11 (4.0)	122 (44.9)	128 (47.1)	4.33
Remote patient monitoring system	8 (2.9)	19 (7.0)	21 (7.7)	109 (40.1)	115 (42.3)	4.12
A decision support system to design appropriate interventions for diabetic patients	4 (1.5)	6 (2.2)	24 (8.8)	101 (37.1)	137 (50.4)	4.33
Security features with restricted access system	4 (1.5)	13 (3.7)	28 (10.3)	104 (38.2)	123 (45.2)	4.21
An interoperable system that easily interacts with other software	4 (1.5)	10 (3.7)	22 (8.1)	99 (36.4)	137 (50.4)	4.31

1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly agree

4.2.5 Perceived Complexity/ease of use of Diabetes mHealth Application

The perceived complexity/ease of use scale was assessed on a 10-point Likert scale using seven items. The mean score for all items was above 6.5. The highest mean (7.21) was reported on the statement, “It would be easy for me to become skilful at using the diabetes mHealth application.” The lowest mean (6.87) was reported on the statement, “I know how to use a mobile phone to collect and store data and communicate intervention plans (to maintain PHR).” A mean value of 7.12 was reported for the perceived ease of use of mHealth applications to support and the perception that mHealth applications would be satisfying. Detailed data are presented in Table 4.6.

Table 4.6: Perceived Complexity/ease of Use of Diabetes mHealth Application (n=272).

Items	Mean	SD
I would find it easy to use a mobile phone to communicate and counsel diabetic patients.	6.89	2.8
I would find it easy to use a mobile phone to collect and store data and communicate intervention plans (to maintain PHR).	6.87	2.7
Using mobile phones to manage diabetic patients would be easy for me.	6.97	2.6
I would find it easy to get a diabetes mobile health application to support my tasks.	7.12	2.5
My interaction with the diabetes mobile health application would be satisfying.	7.12	2.6
I would find the diabetes mobile health application to be flexible to interact with.	6.93	2.5
It would be easy for me to become skilful at using a diabetes mobile health application.	7.21	2.5

4.2.6 Intention to Use the Diabetes mHealth Application

The intention to use a diabetes-related mHealth application was assessed using a 5-point Likert scale of 10 items. The mean score for all items was above 4. The highest mean (4.46) was reported for two items: "Using for decision support system" and "I intend to use the functions and content of diabetes mHealth application as often as possible." The lowest mean (4.34) was reported for "Tracking diabetic patients."

Most (91.9%; n=250) HCPs reflected their intention to use diabetes-related mHealth applications for early diagnosis and treatment of diabetes. 41.2% (n=112) agreed, and 53.7% (n=146) strongly agreed that they intended to use mHealth to provide health education for patients. 51.8% (n=141) showed strong agreement about using a diabetes-related mHealth application to capture, store, share and monitor patient data. 38.2% (n=104) agreed, and 54.4% (n=148) strongly agreed that they would use diabetes-related mHealth for communicating in real-time with patients. 90.1% (n=245) reflected their future intentions to use mHealth for empowering patients on self-management of diabetes. Detailed data are presented in Table 4.7.

Table 4.7: Intention to Use Diabetes mHealth Application (n=272).

Items	1 F(%)	2 F(%)	3 F(%)	4 F(%)	5 F(%)	Mean
Early diagnosis and treatment of diabetes	2 (0.7)	7 (2.6)	13 (4.8)	116 (42.6)	134 (49.3)	4.37
Provision of health education	4 (1.5)	2 (0.7)	8 (2.9)	112 (41.2)	146 (53.7)	4.45
Maintaining PHR (capturing, storing, and sharing patient data)	1 (0.4)	8 (2.9)	14 (5.1)	108 (39.7)	141 (51.8)	4.40
Monitoring diabetic patient data	1 (0.4)	3 (1.1)	16 (5.9)	111 (40.8)	141 (51.8)	4.43
Communicating in real-time with diabetic patients	3 (1.1)	4 (1.5)	13 (4.8)	104 (38.2)	148 (54.4)	4.43
Empowering patients on self-management of diabetes	2 (0.7)	4 (1.5)	21 (7.7)	108 (39.7)	137 (50.4)	4.38
Tracking diabetic patients	4 (1.5)	5 (1.8)	24 (8.8)	101 (37.1)	138 (50.7)	4.34
Using the decision support system	4 (1.5)	1 (0.4)	14 (5.1)	101 (37.1)	152 (55.9)	4.46
I would use the mobile health application to manage diabetic patients in the future.	2 (0.7)	4 (1.5)	11 (4.0)	112 (41.2)	143 (52.6)	4.43
I intend to use the functions and content of the diabetes mHealth application as often as possible.	1 (0.4)	4 (1.5)	16 (5.9)	99 (36.4)	152 (55.9)	4.46

1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly agree

4.2.7 Principal Component Analysis

A reliability analysis was conducted, and two items from the perceived usefulness and one from the perceived complexity/ease of use were removed due to low factor loading. The perceived usefulness (4 items), perceived complexity/ease of use (6 items), and the intention to use (10 items) were subjected to Principal component analysis (PCA). Before performing PCA, the suitability of data for factor analysis was assessed using correlation coefficients and the Kaiser-Meyer-Olkin measure of sampling adequacy (KMO). The presence of many correlation coefficients above 0.3 and KMO values above 0.6 with statistical significance results for Bartlett's Test of Sphericity ($p<0.05$); are the eligibility criteria for further analysis in the PCA. The PCA result for each scale is presented here.

4.2.7.1 PCA for Perceived Usefulness

Inspection of the correlation matrix shows coefficients above 0.3 for all items. As presented in Table 4.8, the KMO value was 0.827. Bartlett's Test of Sphericity reached statistical significance, supporting the factorability of the correlation matrix.

Table 4.8: KMO and Bartlett's Test for Perceived Usefulness

Eligibility Test for PCA	Value
Kaiser-Meyer-Olkin measure of sampling adequacy	0.827
Bartlett's Test of Sphericity Approx. Chi-Square df Sig.	 609.7 6 .000

The number of factors depends on eigenvalues; we are interested only in components with an eigenvalue of 1 or more using Kaiser's criterion. As presented in Table 4.9, the PCA revealed the presence of one component with an eigenvalue above 1, which is 3.167, explaining the variability of 79.17% of all variables. That means the four items used for assessment are appropriate to explain one factor: the perceived usefulness scale.

Table 4.9: Total Variance Explained by Perceived Usefulness Scale

Component	Initial Eigenvalues		
	Total	**% of variance**	**Cumulative %**
1	3.167	79.17	79.17
2	0.446	11.15	90.32
3	0.243	6.07	96.39
4	0.144	3.61	100.00

Regarding the loading of items, factor loading >0.5 is very significant. As presented in Table 4.10, All six items/variables have a strong loading factor greater than 0.8.

Table 4.10: Component Matrix of Perceived Usefulness Scale

Items	Component 1
PU1. Using a mobile phone would improve my performance in communicating with diabetic patients.	0.83
PU2. Using a mobile phone would improve my performance in maintaining patients' health records (collecting, storing, monitoring, and transmitting data of diabetes patients).	0.92
PU3. Using a mobile phone would support my performance in increasing patient Self-Management practice.	0.93
PU4. Using a mobile phone would improve my performance in maintaining patient adherence to the treatment regimen (medication and diet).	0.87

4.2.7.2 PCA for Perceived Complexity/ease of Use

In the correlation matrix analysis, all items/variables have coefficients above 0.3. As presented in Table 4.11, the KMO value was 0.905, with a statistically significant value for Bartlett's Test (p=0.000), supporting the factorability of the correlation matrix.

Table 4.11: KMO and Bartlett's Test for Perceived Complexity/Ease of Use

Eligibility Test for PCA	Value
Kaiser-Meyer-Olkin measure of sampling adequacy	0.905
Bartlett's Test of Sphericity	
Approx. Chi-Square	1982.051
df	15
Sig.	.000

As presented in Table 4.12, the PCA revealed the presence of one component with an eigenvalue above 1, which is 5.396, explaining the variability of 89.93% of all variables. That means the seven items used for assessment are appropriate to explain one factor: the perceived complexity/ease of use scale.

Table 4.12: Total Variance Explained by Perceived Complexity/ease of Use Scale

Component	Initial eigenvalues		
	Total	% of variance	Cumulative %
1	5.396	89.931	89.931
2	.269	4.488	94.419
3	.124	2.068	96.488
4	.090	1.502	97.989
5	.076	1.263	99.252
6	.045	.748	100.000

Regarding the loading of items, all six items/variables have a strong loading factor greater than 0.9. The data is presented in Table 4.13.

Table 4.13: Component Matrix of Perceived Complexity/Ease of Use

Item/variable	Component 1
PEOU1. I would find it easy to use a mobile phone to communicate and counsel diabetic patients.	0.94
PEOU2. I would find it easy to use a mobile phone to collect and store data and communicate intervention plans (to maintain PHR).	0.95
PEOU3. Using mobile phones to manage diabetic patients would be easy for me.	0.96
PEOU4. I would find it easy to get a diabetes mobile health application to support my tasks.	0.96
PEOU5. My interaction with the diabetes mobile health application would be satisfying.	0.94
PEOU7. It would be easy for me to become skilful at using a diabetes mobile health application.	0.92

4.2.7.3 PCA for Intention to Use

Inspection of the correlation matrix shows coefficients above 0.3 for many items. As presented in Table 4.14, the KMO value was 0.941. Bartlett's Test of Sphericity reached statistical significance (p=0.000), supporting the factorability of the correlation matrix.

Table 4.14: KMO and Bartlett's Test for Intention to Use

Eligibility Test for PCA	Value
Kaiser-Meyer-Olkin measure of sampling adequacy	0.941
Bartlett's Test of Sphericity	
Approx. Chi-Square	2500.95
Df	45
Sig.	.000

As presented in Table 4.15, the PCA revealed the presence of one component with an eigenvalue above 1, which is 7.911, explaining the variability of 79.106% of all variables. That means the ten items used for assessment are appropriate to explain one factor: the intention to use scale.

Table 4.15: Total Variance Explained of Intention to Use Scale

Component	Initial eigenvalues		
	Total	% of variance	Cumulative %
1	7.911	79.106	79.106
2	.477	4.771	83.877
3	.374	3.736	87.612
4	.308	3.081	90.693
5	.242	2.422	93.115
6	.206	2.060	95.175
7	.175	1.750	96.925
8	.123	1.230	98.155
9	.104	1.038	99.193
10	.081	.807	100.000

Regarding the loading of items, factor loading >0.5 is very significant. As presented in Table 4.16, all six items/variables have a strong loading factor greater than 0.8.

Table 4.16: Component Matrix of Intention to Use Scale

Item/variable	Component 1
BI1. Early diagnosis and treatment of diabetes	0.91
BI2. Provision of health education	0.93
BI3. Maintaining PHR (Capturing, storing, and sharing patient data)	0.91
BI4. Monitoring diabetic patient data	0.94
BI5. Communicating in real-time with diabetic patients	0.88
BI6. Empowering patients on self-management of diabetes	0.87
BI7. Tracking diabetic patients	0.89
BI8. Using a decision support system	0.87
BI9. I would use the mobile health application to manage diabetic patients in the future.	0.86
BI10. I intend to use the functions and content of the diabetes mHealth application as often as possible.	0.92

4.2.7.4 Construct Reliability and Validity

The content validity of the measurement was maintained since the measurement was developed based on the integrative literature review in Phase I of this research project. As shown in Table 4.17, loading factors, composite reliability, and average variance extracted are analysed to check the convergent validity of the measurement. The loading factors for all items range from 0.83-0.96. The Cronbach's Alpha for perceived usefulness, perceived complexity/ease of use, and intention to use was 0.91, 0.98, and 0.97, respectively. The composite reliability of the measurement ranges from 0.94-

0.97. The average variance extracted was 0.79 for perceived usefulness, 0.89 for perceived complexity/ease of use, and 0.81 for intention to use.

Table 4.17: Measurement Model

Construct	No of Items	Loadings	Composite Reliability	Average Variance Extracted	Cronbach's Alpha
Perceived usefulness	4	0.83-0.93	0.94	0.79	0.91
Perceived complexity/ease of use	6	0.92-0.96	0.98	0.89	0.98
Intention to use	10	0.86-0.94	0.97	0.81	0.97

Additionally, discriminate validity is tested by comparing the correlation matrix with the calculated square root of the average variance extracted. As shown in Table 4.18, the square root of the average variance extracted was higher than the corresponding correlation.

Table 4.18: Correlation Matrix and the Square Root of the AVE

	PU	PEOU	BI
PU	**0.889**		
PEOU	0.125	**0.943**	
BI	0.673	0.203	**0.90**

Note: PU= Perceived Usefulness; PEOU=Perceived Ease of Use; BI= Behavioural Intention to use

4.2.8 Structural Equation Modelling (SEM)

4.2.8.1 Measurement Model

Goodness-of-fit statistics were analysed to check model fitness, and as shown in Table 4.19, the fit indices were as follows: goodness-of-fit index (GFI)=0.91, adjusted goodness-of-fit index=0.87, comparative fit index (CFI)=0.96, normal fit index (NFI)=0.92, incremental fit index (IFI)=0.96, and root mean square error of approximation (RMSEA)=0.06. Most of the indices of the measurement models reached the recommended acceptable model fitness values.

Table 4.19: A Goodness-of-fit Statistics of the Model

Fit Index	X^2/df	GFI	AGFI	CFI	NFI	IFI	RMSEA
Acceptable Value	<3	>0.90	>0.85	>0.95	>0.90	>0.90	<0.08
Actual Value	2.1	0.91	0.87	0.96	0.92	0.96	0.06

4.2.8.2 Measurement Model

Perceived usefulness significantly affected health professionals' behavioural intention to use diabetes-related mHealth (β=0.6, t=10.39, p<0.001). Perceived complexity/ease of use significantly affected health professionals' behavioural intention to use diabetes-related mHealth (β=0.05, t=1.99, p<0.05). Perceived complexity/ease of use also significantly affected health professionals' perceived usefulness of diabetes-related mHealth (β=0.1, t=2.43, p<0.05). The structure model result is presented in Table 4.20.

Table 4.20: The Hypothesis of the Structure Model

Hypothesis	Relationship	B	t-value	p-value	Decision
H1	PU→ BI	0.6	10.39	<0.001	Supported
H2	PEOU→ BI	0.05	1.99	0.04	Supported
H3	PEOU→PU	0.1	2.43	0.02	Supported

4.2.9 Other Predictors of Intention to Use mHealth

A linear regression analysis was conducted to identify other predictors (not included in the theoretical framework) for intention to use by following the basic assumptions described in Chapter 2.

All the assumptions described in Chapter 2 are met. The overall regression model was statistically significant (R^2= 0.59, F (17, 254) = 21.9, p ≤0.000). In the model, cell phone use in years (β=-0.13, p<0.01), studying eHealth/mHealth related course (β=0.449, p≤0.000), regular phone use for reading (β=-0.137, p<0.05), and the score of attitudes towards mHealth (β=0.44, p≤0.000) were the predictors for behavioural intention to use mHealth by HCPs. Table 4.21 provides the detailed result of the regression analysis.

Table 4.21: Predictors of Behavioural Intention to Use mHealth: Multiple Linear Regression Analysis

Variables	Estimates	t-value	p-value	VIF
Constant		13.2	0.000	
Gender: male	0.037	0.89	0.376	1.1
Age	-0.012	-0.27	0.791	1.2
Education level: Master	0.059	1.42	0.162	1.1
Education level: Diploma	-0.053	-1.24	0.216	1.1
Own smartphone	-0.031	-0.63	0.529	1.5
Cell phone use in years	-0.13	-2.90	0.004*	1.3
Studied mHealth/eHealth course	0.449	7.9	0.000*	2.0
Attend mHealth/eHealth training	0.03	0.54	0.588	1.9
Regular phone use for call	0.005	0.10	0.919	1.3
Regular phone use for text	0.004	0.074	0.941	1.6
Regular phone use for checking stored data	-0.031	-0.55	0.584	1.9
Regular phone use for email	0.042	0.81	0.418	1.7
Regular phone use for the internet	-0.027	-0.47	0.643	2.2
Regular phone use for reading	-0.137	-2.24	0.016*	2.0
Regular phone use for capturing memo	-0.041	-0.71	0.478	2.0
Attitude towards mHealth (score)	0.44	10.2	0.000*	1.2
R^2= 0.59 **p-value ≤0.000**				

**Statistically significant predictors (p-value<0.01)*

4.3 DISCUSSION OF PHASE II FINDINGS

Phase II of this study reported the Healthcare Professionals' perception/attitude, perceived usefulness, perceived ease of use/complexity, and behavioural intention to use mHealth for T2DM management. The study also validated the TAM model for adopting diabetes mHealth by HCPs and identified factors that predict the future use of mHealth by HCPs. The discussion of major findings is provided below.

4.3.1 Mobile Phone Use by Healthcare Professionals

All Healthcare Professionals (HCPs) participating in Phase II owned a cell phone, and most (88.6%) smartphones that could install applications. This was comparable with another study conducted in Northern Ethiopia, where 87.1% of HCPs owned a smartphone (n=341) (Tegegne, Endehabtu, Guadie & Yilma, 2022:4). Another study conducted in Northwest Ethiopia reported that 95.1% of physicians and 73.5% of nurses working in two teaching hospitals owned smartphones (n=406) (Seboka, Yilma & Birhanu, 2021b:4).

Similarly, another study conducted in Iran and Saudi Arabia also reported that 84% and 96.4% of HCPs owned a smartphone, respectively (Abolfotouh, BaniMustafa, Salam, Al-Assiri, Aldebasi & Bushnak, 2019:4; Koehler, Vujovic & McMenamin, 2013:5). The reasons could be the increased penetration of mobile phones with affordable prices. At the end of 2020, 490 million people (46%) in Sub-Saharan Africa had subscribed to mobile services, around 20 million increments from 2019 (GSMA Intelligence, 2021:3). In 2020, 44% of the Ethiopian population owned a smartphone, and this was expected to reach 58% by 2025 (GSMA Intelligence, 2021:13). This increased access of smartphones by Healthcare Professionals (HCPs) is an opportunity to implement complex mHealth applications like mHealth PHR which require smartphones for installation. Though, in developing countries like Ethiopia, this should be analysed carefully if the mHealth interventions also require smartphone access by patients. For example, one study conducted in Southwest Ethiopia reported that only 46.7% (n=233) of the patients with diabetes owned smartphones (Bogale, Habte, Haile, Guteta, Mohammed & Gebremichael, 2022:1504).

Most of the Healthcare Professionals (HCPs) used their cell phones all the time to make calls and text messages. Only one-third of the HCPs always browsed the internet, and 12.9% did not use it. The use of mobile phones for reading materials and capturing memos was also low among HCPs. This was consistent with the study conducted in Northwest Ethiopia, where only 34.3% of nurses browsed the internet. The Northwest Ethiopia study also reported that 54.4% of the physicians browsed the internet, but it is difficult to compare it with the current study since the physicians in this study are few (5%) (Seboka et al., 2021b:5). Correspondingly, most of the HCPs (33.1%) in this study had no access to the internet which is lower than the Northern-Ethiopia study, which reported that 60.4% of HCPs has access to the internet (Tegegne et al., 2022). The difference could be explained by the study subjects used; in the Northern-Ethiopia study, participants were HCPs with any social media account, which might overrepresent HCPs with internet access to social media.

The high percentage of mobile device ownership and usage is significant for this study because it increases accessibility and the viability of using mHealth for diabetes management. It may also address the low acceptance caused by a lack of mobile phones by HCPs.

4.3.2 mHealth Related Education and Training

Most Healthcare Professionals (HCPs) did not get education or training related to eHealth/mHealth. In the regression analysis, studying a course related to eHealth/mHealth was a positive predictor for behavioural intention to use HCPs. According to Ross et al. (2016:9), competence influences HCP acceptance and implementation of digital health.

Northwest Ethiopia reported that around 63% attended computer training. However, this may not be adequate, and it recommended including health informatics courses in their curricula to improve the health-related digital literacy of HCPs (Jimenez, Spinazze, Matchar, Huat, van der Kleij, Chavannes & Car, 2020:5; Moss, Süle & Kohl, 2019:58). The provision of adequate and continuous in-service training is also crucial to improve digital awareness and literacy (Feroz, Jabeen & Saleem, 2020). As revealed in this study, attending courses related to mHealth positively affects the intention to use mHealth by HCPs. This could imply that integrating courses on digital health into the curriculum is crucial to improve digital literacy and acceptance of mHealth by HCPs.

4.3.3 Perception on Use and Criticality of mHealth

Overall, Health Care Professionals (HCPs) reflected positive perceptions (positive attitudes) on using mHealth to disseminate prevention strategies, early diagnosis of fluctuations in blood glucose, data sharing, patient monitoring, patient support and communication, patient education and CDSS. The positive perception of HCPs of mHealth has also been reported by some studies (Ayanlade, Oyebisi & Kolawole, 2019:7; Ayatollahi et al., 2018:94). A study conducted in Northwest Ethiopia reported a positive perception of HCPs on using information technology to monitor diabetic patients (Seboka et al., 2021b:4).

A positive attitude by Health Care Professionals (HCPs) could influence whether they would use mHealth technologies in future. This study's result showed that a person's attitude positively affects future intention to use mHealth. The regression analysis shows that one standard deviation in attitudinal scores increases the behavioural intention score by 44%. This was consistent with the study conducted in Northwest

Ethiopia, though that study was focused on using any information technology for patient monitoring (Seboka et al., 2021b:7).

The use of voice calls, SMSes, biosensors, Personal Health Record (PHR), a central database, an alert system, CDSS, security, and interoperability were considered critical by HCPs who participated in Phase II. Although the HCPs did not rate the criticality of the features, HCPs who participated in the Northwest Ethiopia study showed their willingness to use SMSes and voice calls to monitor patients with diabetes (Seboka et al., 2021b:6). This presence of a positive attitude by HCPs is important to implement SMSes and voice calls for diabetes management since these features are easily accessible and inexpensive.

4.3.4 Technology Acceptance

Technology acceptance or intention to use is mandatory for scaling mHealth in clinical care. The intention to use is an important factor for the actual usage of mHealth. Studies argued that behavioural intention directly predicts actual usage (Gagnon et al., 2016b:217; Nadal, Sas & Doherty, 2020:10; Shemesh & Barnoy, 2020:1148). In other words, If HCPs reflected positive feelings about mHealth, they would use them in the real working environment (Nadal et al., 2020:10). In the same way, Sekhon, Cartwright & Francis (2017:11) emphasised that if mHealth were perceived negatively and regarded as unacceptable by HCPs, even the state-of-the-art mHealth interventions would be unlikely to provide a positive outcome. In this study, most HCPs reflected their intention to use mHealth for diabetes management (Mean=4.4 out of 5). This was comparable to the study conducted in Iran, where physicians (Mean=4.22) and nurses (Mean=4.07) showed their intention to use telemedicine for diabetes management. The scope of the Iran study, however, was limited to telemedicine, a single component of mHealth.

This study revealed that Health Care Professionals (HCPs) intend to use mHealth to monitor diabetic patient data. The remotely monitored data through mHealth devices could be effective for HCPs to provide tailored intervention and feedback for diabetic patients based on the current state of clinical data. This was similar to the finding from Burundi: mHealth use for patient monitoring was highly adopted by HCPs (Ndayizigamiye & Maharaj, 2017:180). On the contrary, a study conducted in

Northwest Ethiopia reported low readiness (65.5%) among physicians and nurses for using telemonitoring in diabetes management (Seboka, Yilma & Birhanu, 2021a:4). Yet, it is difficult to compare the Northwest Ethiopia study with the current study since there is a difference in measurement, scope of the mHealth solution, and setting. The presence of intention by HCPs to use mHealth for monitoring patients with T2DM is also reported by studies conducted in Iran (Ayatollahi et al., 2018:96), and Australia (Muigg, Kastner, Duftschmid, Modre-Osprian & Haluza, 2019:4).

mHealth has an opportunity for decision support from complex algorithms and knowledge-based support to simple teleconsultation with senior experts (Agarwal et al., 2021:4). According to this study's result, most HCPs intend to use mHealth for decision support. Similarly, the Burundi study reported that more than two-thirds of HCPs accepted using mHealth for diagnostic and treatment support (Ndayizigamiye & Maharaj, 2017:180). The CDSS system, based on detailed analysis of previous and current patient data, is considered effective for designing tailored interventions by HCPs. The support via teleconsultation could be crucial for developing countries considering the infrastructure gap (Ayatollahi et al., 2018:96). Most HCPs reflected their intentions to use mHealth for early diagnosis and maintaining PHR. Similarly, a study conducted in Burundi showed that 83.5% of HCPs reflected an intention to use mHealth to collect clinical data (Ndayizigamiye & Maharaj, 2017:180).

The presence of mHealth enhances communication with patients, especially for patients located in remote areas. This study's results showed that HCPs intend to use mHealth to communicate in real-time with diabetic patients. This finding was in line with the findings of other studies that HCPs had the intention to use mHealth to enhance communication with patients (Chérrez-Ojeda, Felix, Mata, Vanegas, Simancas-Racines, Aguilar, Gavilanes, Chedraui & Vera, 2020:14; Hampshire, Porter, Mariwah, Munthali, Robson, Owusu, Abane & Milner, 2017:35; Odendaal, Watkins, Leon, Goudge, Griffiths, Tomlinson & Daniels, 2020:3). The use of mHealth not only enhances the communication, but it also creates collaboration between HCPs and patients and improves the quality of clinical care (de Jong, Donelle & Kerr, 2020:11; Qudah & Luetsch, 2019:1083; White, Thomas, Ezeanochie & Bull, 2016:208).

According to this study, most Health Care Professionals (HCPs) showed their intention to use mHealth for patient education. The acceptance and applicability of mHealth for patient education are widely discussed in the literature. HCPs believe mHealth is helpful and convenient for patient education (Jain, Sui, Ng, Chen, Goh & Shorey, 2020:11; Ndayizigamiye & Maharaj, 2017:180). mHealth is also regarded as a cost-effective intervention for health promotion and education (Gagnon et al., 2016b:217; Rinaldi et al., 2020:12).

4.3.5 Perceived Usefulness and Technology Acceptance

Health Care professionals (HCPs) perceived mHealth as useful for supporting their performance in T2DM management. The mean score of PU items among HCPs was above 4 out of 5. Studies support this finding; PU is a significant facilitator for HCP adoption and frequent use of mHealth for daily clinical activities (Gagnon et al., 2016b:218; Nezamdoust, Abdekhoda & Rahmani, 2022:7; Villalba-Mora, Casas, Lupiañez-Villanueva & Maghiros, 2015:483). Similarly, the positive perception by HCPs of the usefulness of mHealth for T2DM management is reported by several studies (Ayatollahi et al., 2018:95; Liu & Cheng, 2015:9; Nezamdoust et al., 2022:7). HCPs are highly likely to use mHealth when they perceive its benefits in their daily clinical care activities; they hesitate to use mHealth if they are unaware of the benefits or are unconvinced about its value for clinical practice (Duhm, Fleischmann, Schmidt, Hupperts & Brandt, 2016:7).

Structural Equation Model (SEM) analysis revealed that Perceived Usefulness (PU) directly and significantly impacts HCPs intention to use mHealth for T2DM management. The effect of PU in HCP adoption of mHealth was alluded to by other similar studies and review articles (Agbenyo, 2019:14; Dash, Shadangi, Kar & Prusty, 2019:1287; Gagnon et al., 2016b:218; Garavand et al., 2017:406; Kalayou, Endehabtu & Tilahun, 2020:1832; Liu & Cheng, 2015:9; Nezamdoust et al., 2022:7). According to a systematic review, perceived usefulness is regarded as critical and a direct factor for HCP adoption of mHealth (Gagnon et al., 2016b:218). Another review also emphasized the importance of PU for HCPs' adoption of mHealth and urged policymakers and implementers to consider PU in the design and development of mHealth (Garavand et al., 2017:407).

4.3.6 Perceived Complexity/Ease of Use and Technology Acceptance

The phase result shows that Health Care Professionals (HCPs) perceived mHealth as less complex and easy for T2DM management in their local setting. This is in line with a similar study where physicians and nurses considered the telemedicine system easy to use for diabetes management (Ayatollahi et al., 2018:95). The PEOU was frequently stated as an important factor and direct predictor for positive perception and acceptance of the mHealth system by HCPs (Ayatollahi et al., 2018:95; Liu & Cheng, 2015:9; Nezamdoust et al., 2022:7). mHealth's ease of use and uncomplexity are significant factors for learning and using mHealth systems among HCPs (Brewster, Mountain, Wessels, Kelly & Hawley, 2014). The ease of use is often linked with the usability and interfaces of mHealth systems. Studies alluded to its user-centric and intuitive design, simple layout, and interface customisation as influencing factors for ease of use (Lord, Moore, Ramsey, Dinauer & Johnson, 2016:10; Schnall et al., 2016:247; Zhou, DeAlmeida & Parmanto, 2019b:13). Though usability alone is not enough for ease of use, training for example, could also be an important factor; HCPs supported by training would find mHealth systems easy to use (Odendaal et al., 2020:31).

The Structural Equation Model (SEM) analysis also determined that Perceived ease of use (PEOU) or complexity directly and significantly affects HCPs intentions to use mHealth for T2DM management. This finding is in line with results reported from other studies (Ayatollahi et al., 2018:96; Dash et al., 2019:1287; Kalayou et al., 2020:1832; Liu & Cheng, 2015:9; Nezamdoust et al., 2022:5)

The Phase II Structural Equation Model (SEM) analysis shows that Perceived ease of use (PEOU) or complexity predicted HCPs' PU of mHealth for T2DM management. This finding is in line with results reported from other studies (Ayatollahi et al., 2018:96; Dash et al., 2019:1287; Kalayou et al., 2020:1832; Liu & Cheng, 2015:9; Nezamdoust et al., 2022:5).

4.4 SUMMARY

This chapter presented the analysis of perceived usefulness, perceived ease of use/complexity, and behavioural intention to use mHealth for T2DM management.

After factor analysis, an SEM was conducted to test the theoretical model. Regression analysis was also conducted to identify factors affecting behavioural intention to use mHealth for T2DM management by HCPs.

Chapter 5 presents the integration of Phase I and Phase II findings.

CHAPTER 5

INTEGRATION, INTERPRETATION, AND DISCUSSION OF COMBINED FINDINGS

5.1 INTRODUCTION

This chapter outlines the integration of Phase I and Phase II findings. Phase I involved the integrative literature review on the use of mHealth technologies for diabetes management, with special emphasis on how mHealth was implemented and the implementation challenges. Phase II was a survey to examine potential barriers and facilitators for diabetes mHealth intervention in Ethiopia. The theoretical concepts of perceived usefulness, ease of use and behavioural intention to use were used to measure acceptance of mHealth by healthcare professionals. The findings from both phases were presented separately in Chapters 3 (qualitative) and 4 (quantitative). The quantitative phase was informed by the results obtained from the integrative literature review. The theoretical framework guided the integration and interpretation of combined findings.

5.2 THE INTEGRATION PROCESS

> *"All too often I hear new researchers (and a surprising number of experienced ones as well) tell me that they are conducting mixed methods research, but on closer inspection, I find that they are simply collecting and analysing quantitative and qualitative data. Such collection and analysis certainly represent the basic starting point for a mixed methods study, but the true value, I believe in mixed methods, lies in the integration of the two data sets" by John Creswell (Fetters & Molina-Azorin, 2017:427)*

As clearly outlined by literature, the major aspect of the mixed method approach is the integration of qualitative and quantitative data, and scientists increasingly emphasise integration as the core for mixed methods (Fetters & Molina-Azorin, 2017:427; Guetterman et al., 2015:554; Oliveira, 2020:1). Meaningful integration enables studies to obtain the true benefits of mixed methods by creating a whole that is greater than the sum of the individual qualitative and quantitative parts (Guetterman et al., 2015:555). The integration of qualitative and quantitative results of this study took place at the interpretation level (see Figure 5.1).

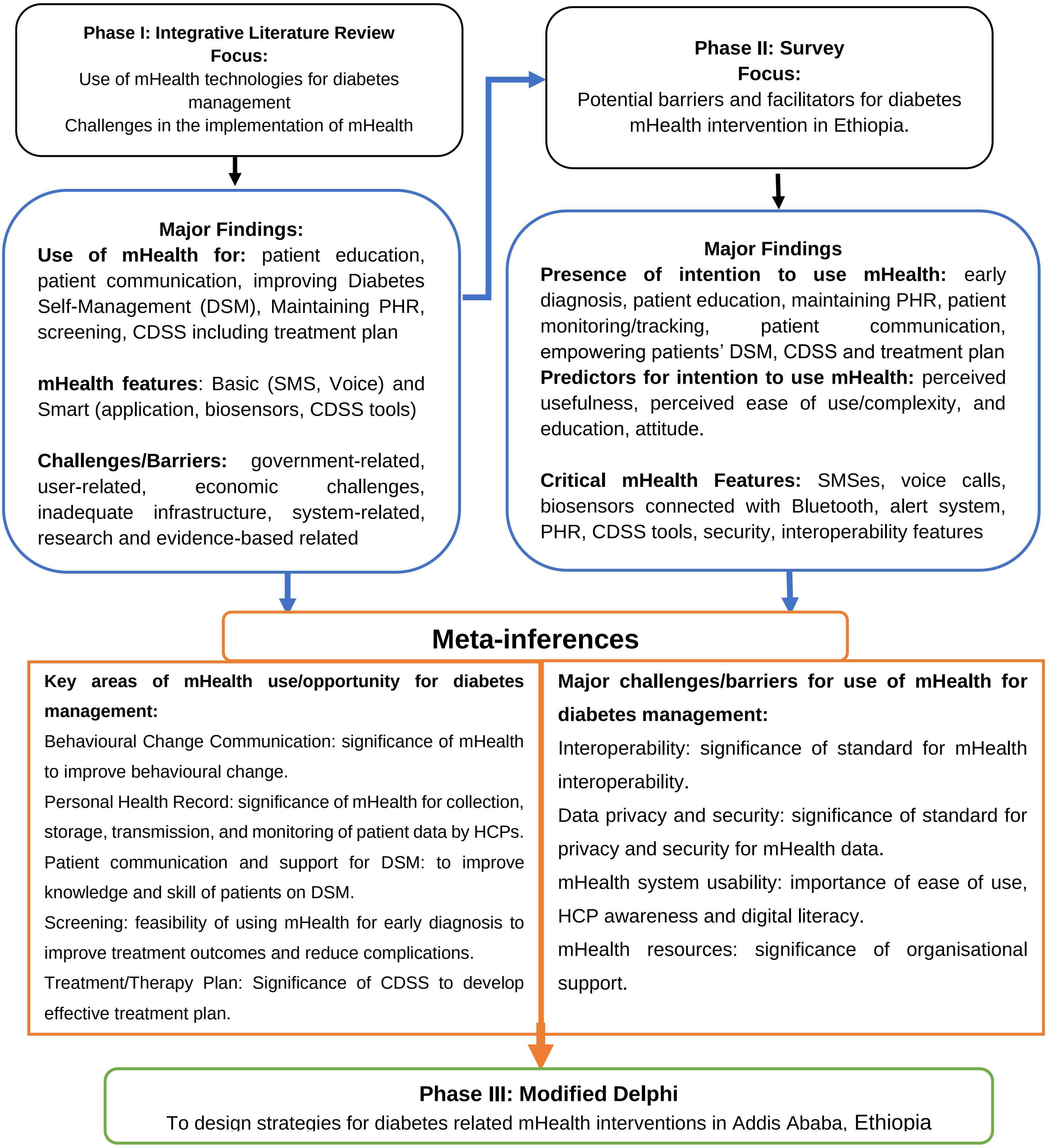

Fig 5.1: Integration of Phase I and Phase II Findings

As illustrated in Figure 5.2, in Phase I, an integrative literature review was conducted to get an understanding of mobile health applications for diabetes management in low and middle-income countries. This included identifying what worked and what didn't. The Phase I findings informed the subsequent quantitative data collection in Phase II. Then the integration of Phase I and Phase II findings enabled the formulation of meta-inferences and the interpretation thereof.

The integration allowed the identification of complementarity between Phase I and Phase II findings (Fetters, Curry & Creswell, 2013:2143; Guetterman et al., 2015:555). The aim was to highlight the opportunities for mHealth interventions for diabetes management and proceed to phase II to relate those opportunities to healthcare professionals' (HCPs) perceived usefulness and intention to use mHealth. This would, in turn, reveal potential facilitators and barriers to mHealth implementation in Ethiopia.

Data integration has primarily been accomplished in two ways: (1) by writing about the data in a discussion in which the separate results of quantitative and qualitative analyses are discussed, and (2) by a joint display of qualitative and quantitative data in the form of a table (Creswell & Plano Clark, 2017:26; Guetterman et al., 2015:556).

This study used a joint display to present the connection between the findings of the qualitative and quantitative results. Both findings were displayed side-by-side to support the meta-inferences. These meta-inferences guided the development of proposed strategies for diabetes-related mHealth in primary healthcare in Addis Ababa, Ethiopia. Table 5.1 summarises quantitative and qualitative findings and the meta-inference that emerged from the integration.

Table 5.1: Joint Display of Qualitative and Quantitative Results

mHealth use for diabetes management and challenges	Phase I result (Integrative Literature Review)	Phase II result (Survey)	Meta-Inferences
Patient education	Out of 14 empirical pieces of evidence included in the review, 7 were designed for patient education. The patient education contents are focused on the following: - diet, physical exercise, treatment, - diabetes self-management, - blood glucose monitoring - disease complication, - psychosocial components. Two studies used the behavioural learning model/theory for developing patient education messages. All review articles and policy papers discussed the potential of mHealth for patient education.	Perception of opportunities of mHealth for Behavioural change communication (BCC): 84.2% of Healthcare Professionals (HCPs) agreed that mHealth would allow professionals to disseminate prevention strategies. 89% of HCPs perceived that mHealth would allow professionals to disseminate health education easily.	Behavioural change communication: opportunity of SMSes for improving patients' behaviour on diabetes management. Positive attitude of HCPs toward mHealth
		Perceived usefulness: 91.6% of HCPs perceived that they would find mHealth useful to support their efforts to improve patients' self-management. The item/statement has a strong loading factor in the perceived	Strong indicators of intention to use

mHealth use for diabetes management and challenges	Phase I result (Integrative Literature Review)	Phase II result (Survey)	Meta-Inferences
		usefulness scale (>.0.9).	
		Intention to use: 84.9% of HCPs reflect their intention to use mHealth for patient education. The item/statement has a strong loading factor in the behavioural intention scale (>0.9).	
	All patient education /BCC intervention studies used the SMS tool for transmitting BCC messages. The frequency of SMSes ranges from one SMS per day to one SMS per week. Out of 5 studies, 4 used A2P messaging, and 1 used P2P messaging.	Around 86% of HCPs agreed on the criticality of the SMS feature for diabetes-related mHealth. The HCPs regularly use their mobile phones for text messaging.	
Patient communication and diabetes self-management (DSM)	In the review of empirical evidence, 4 mHealth interventions were used for patient communication. The patient communication focused on a reminder for treatment and follow-up visits and a reminder of the consequence of non-	Perception of opportunities of mHealth for patient communication and reminders: 85.3% of HCPs perceived that mHealth has an opportunity for professionals to	Patient communication and support for DSM: to improve the knowledge and skill of patients on DSM.

mHealth use for diabetes management and challenges	Phase I result (Integrative Literature Review)	Phase II result (Survey)	Meta-Inferences
	compliance to the therapy plan. Most of the review articles and policy papers highlighted the potential of mHealth for patient communication.	communicate with patients in real-time. 82.7% of HCPs reflected positively that mHealth would increase healthcare reach to patients with T2DM.	Possibility of enhanced communication through mHealth
		Perceived Usefulness: 87.8% of HCPs would find mHealth useful to improve their communication skills with patients with T2DM. Most HCPs (88.6%) considered mHealth useful to improve their performance in maintaining patients' adherence to medication and diet. Both items have a strong loading factor in the Perceived Usefulness scale (>0.08).	
		Perceived complexity/ease of use: Most HCPs would find mHealth easy to	

mHealth use for diabetes management and challenges	Phase I result (Integrative Literature Review)	Phase II result (Survey)	Meta-Inferences
		use to communicate with patients. The statement loading factor was strong on the Perceived ease of use scale.	
		Intention to use: Most of the HCPs showed their intention to use mHealth for communicating with patients with T2DM. The item/statement loading factor was strong on the behavioural intention scale (>0.8).	
	Out of 14 studies, 4 used telephone calls as an intervention for patient communication. The purpose of voice calls was: - patient monitoring with timely feedback, - reminder calls for treatment and follow-up visit, - treatment plan communication. Healthcare professionals make all the calls. One call per week is frequently used to	Most respondents considered voice calls a critical feature for diabetes-related mHealth intervention. Frequent use of voice calls by HCPs is an opportunity to enhance patient communication and education utilisation.	

mHealth use for diabetes management and challenges	Phase I result (Integrative Literature Review)	Phase II result (Survey)	Meta-Inferences
	communicate with the patient.		
Diabetes Self-Management (DSM)	mHealth-based support for DSM was the mHealth domain in 4 studies. The purpose was to improve patients' DSM knowledge and skills and provide decision support that fosters DSM.	Perception of opportunities of mHealth: Most of the HCPs (82.4%) agreed that mHealth would make it easier for early diagnosis of fluctuations in blood glucose. 86% and 84.5% of HCPs agreed that mHealth could be used to empower patients on DSM and improve their glycemic control, respectively. Most of the HCPs (86%) perceived that mHealth would make it easier to prevent complications.	
		Mobile diary features are considered critical features to empower patients on DSM by 90% of HCPs.	
		Intention to use: 90.1% of HCPs reflected their future	

mHealth use for diabetes management and challenges	Phase I result (Integrative Literature Review)	Phase II result (Survey)	Meta-Inferences
		intentions to use mHealth for empowering patients in DSM. The statement has a strong loading factor in the scale.	
Personal Health Records (data collection, storage, monitoring and transmitting)	Personal Health Record (PHR) (data collection, storage, monitoring, and communication) was the mHealth domain in 2 empirical studies. The significant impact of mHealth in maintaining PHR was also discussed in all the review articles and policy papers. The purpose of the mHealth initiatives was: - Capture data using Biosensor, - Maintaining PHR (data collection, storage, and communication). Patient Monitoring.	90.5% of HCPs agreed that Personal Health Record features (for data collection, storage, and communication) are critical for diabetes-related mHealth. Perceived usefulness: 89.7% of HCPs considered mHealth useful to improve their performance of maintaining the personal health record of patients with T2DM. The loading factor of the statement was strong in the perceived usefulness scale. Perceived complexity/ease of use: Most HCPs would find mHealth easy to	mHealth has a significant opportunity for Maintaining PHR.

mHealth use for diabetes management and challenges	Phase I result (Integrative Literature Review)	Phase II result (Survey)	Meta-Inferences
		use to maintain PHR. The statement loading factor was strong on the perceived ease of use scale.	
		Intention to use: Most of the HCPs reflected their future intention to use mHealth for data collection, storage, and sharing of patient data. The statement loading factor was strong (>0.9).	
PHR: data collection	A biosensor was used to collect data and Biomarkers from patients with diabetes. The data collected were converted to useful information using international classification for primary care and stored on a smartphone. Bluetooth was used to connect mobile phones and Biosensor.	Perception of opportunities of mHealth: 89.3% of HCPs perceived that mHealth could be used for patient data collection.	mHealth is feasible for data collection and could improve data accuracy and completeness.
		Around 85% of health professionals agree that mobile sensors connected to mobile phones are critical for data collection. 81.3% of participants considered	

mHealth use for diabetes management and challenges	Phase I result (Integrative Literature Review)	Phase II result (Survey)	Meta-Inferences
		Bluetooth as a critical feature for connecting mobile phones and biosensors.	
PHR: Data storage	Two studies discussed the feasibility of relational and non-relational databases for recording to store patients' data.	Perception of opportunities of mHealth: 89.3% of HCPs agreed that mHealth would allow professionals to store patient data.	mHealth is feasible for data storage and could improve data access by HCPs.
		Most HCPs (89%) considered mHealth connected to central databases as critical features for storing patient data.	
PHR: patient monitoring	Two studies effectively used the mHealth PHR system to monitor patient progress remotely. The graphical display system and statistical data were provided for HCP to monitor the patient. Three studies used voice calls to collect biomarkers remotely and used the collected data to monitor the patients.	Perception of opportunities of mHealth: 89.3% of HCPs agreed that mHealth would make it easier for professionals to monitor patients with T2DM. Most of HCPs (84.2%) agreed that mHealth would make the patient tracking system easier.	mHealth PHR is crucial for patient monitoring by HCPs.
		The remote patient monitoring system	

mHealth use for diabetes management and challenges	**Phase I result (Integrative Literature Review)**	**Phase II result (Survey)**	**Meta-Inferences**
		was considered a critical mHealth feature by 82.4% of HCPs.	
		Intention to use: Most of the HCPs (92.6%) showed their future intention to use mHealth for monitoring patients' data and 87.8% of HCPs reflected their intention to use mHealth for tracking diabetic patients. Both statements have a strong loading factor in the Behavioural Intention scale.	
PHR: Data transmission	Two studies used mHealth PHR to transmit data through the web, SMS, and social networks.	Perception of opportunities of mHealth: 89.3% of HCPs agreed that mHealth would allow professionals to share/transmit patient data.	mHealth eases the transmission of patient data.
Screening	One study used the diabetes mHealth initiative for screening and reported improving the screening rate.	Intention to use: 87.8% of HCPs have the intention to use mHealth for tracking diabetic patients.	Screening: feasibility of mHealth for early diagnosis to improve treatment outcomes and reduce complications.

mHealth use for diabetes management and challenges	Phase I result (Integrative Literature Review)	Phase II result (Survey)	Meta-Inferences
		The statement has a strong loading factor in the scale.	
Clinical decision support system (CDSS) for treatment/therapy plan	A treatment plan, including a CDSS, was the scope of four studies. The interventions were successful in diabetes management. The nonempirical articles also indicated the opportunity for teleconsultation from senior experts to support treatment plans by HCP in a primary healthcare setting.	Perception of opportunities of mHealth: 89.3% of HCPs agreed that mHealth would make the CDSS system helpful.	Treatment/Therapy plan: Significance of CDSS to develop an effective treatment plan.
		CDSS was considered a critical mHealth feature for designing treatment plans by 87.5% of HCPs. 92% of HCPs agreed that a system that alerts critical data is an important mHealth feature.	
		Perceived complexity/ease of use: Most of the HCPs perceived that they would find it easy to use mHealth to support their tasks.	
		Intention to use: 91.9% of the HCPs reflected their intention to use mHealth for CDSS.	

mHealth use for diabetes management and challenges	Phase I result (Integrative Literature Review)	Phase II result (Survey)	Meta-Inferences
		The statement has a strong loading factor in the scale.	
Challenges/barriers			
Government-related: Lack of standard for interoperability	Governmental regulation is required to enforce compliance by the industry to various standards. Different messaging standards, Personal Health Devices (PHD) standards, and data transmission standards were employed in mHealth initiatives reviewed in Phase I.	Most survey participants agreed that an interoperable mHealth application is crucial for diabetes management.	Interoperability: significance of standards for mHealth interoperability.
Government-related: Data privacy and security risks	Lack of regulation on data security and patient privacy. Data security privacy is an area that requires legal and policy attention to ensure that mHealth users' data are properly protected.	83.4% of participants considered security and privacy features as critical and useful.	Data privacy and security: significance of standards for privacy and security for mHealth data.
Usability: System-related	Complex and poor usability among mHealth systems.	Perceived ease predictor for future intention to use diabetes-related mHealth.	mHealth system usability: the importance of ease of use, HCP awareness and digital literacy.
User-related: Digital Literacy	The low digital literacy of HCPs was the major barrier to implementing diabetes-related mHealth.	Perceived ease of use among the healthcare professional was a predictor for future intention to use.	

mHealth use for diabetes management and challenges	Phase I result (Integrative Literature Review)	Phase II result (Survey)	Meta-Inferences
		Diabetes-related mHealth.	
		Most of the HCPs did not receive courses related to mHealth during their undergraduate or postgraduate studies.	
		Most HCPs did not receive any training related to eHealth and mHealth.	
User related: Lack of awareness on mHealth	HCPs lack awareness of the opportunities and usefulness of mHealth for diabetes management.	Perceived usefulness among healthcare professionals was a predictor for future intention to use diabetes-related mHealth.	
mHealth resources	Lack of digital infrastructure was one of the major challenges for implementing mHealth intervention in low and middle-income countries.	Most HCPs did not use their mobile phones to browse the internet.	mHealth resources: significance of organisational support.
		Most HCPs did not have access to the internet at the health institutions.	
	Lack of incentives for airtime and internet services.	There is no system to provide incentives for airtime and internet at health centres.	

5.3 INTERPRETATION AND DISCUSSION OF INTEGRATED FINDINGS

As discussed in previous chapters, the feasibility of mHealth for diabetes management is evident in low and middle-income countries (LMICs). The mHealth has different opportunities, including possibilities for patient communication and education (Amdie & Woo, 2020:35; Johnston et al., 2018:10; McCool et al., 2022:527), remote data collection (PHR) (McCool et al., 2022:527), screening (Geldsetzer, Flores, Wang, Flores, Rogers, Bunker, Chang & Tisdale, 2022:99; Osei & Mashamba-Thompson, 2021:3), a treatment/therapy plan (Amdie & Woo, 2020:35; Geldsetzer et al., 2022:99; Osei & Mashamba-Thompson, 2021:5), and diabetes self-management (DSM) (Amdie & Woo, 2020:35). Especially the increase in the penetration of mobile phones and network connectivity could increase the implementation of mHealth in LMIC (GSMA, 2016:3). Qudah and Luetsch concluded that because of improved access and faster response time, mHealth transformed and improved health-professional relationships and treatment outcomes (Qudah & Luetsch, 2019:7).

The opportunities of mHealth for diabetes management identified from the integrated findings of Phase I and Phase II are Behavioural Change Communication (BCC), Personal Health Record (PHR), patient communication and support for DSM, screening, and treatment/therapy plans. The meta-inference from integrated findings also identified challenges/barriers to mHealth use for diabetes management. The themes that emerged from the integrated findings are discussed below in detail.

5.3.1 Various Uses of mHealth

Management of chronic conditions such as diabetes requires effective communication strategies to improve patients' quality of life and reduce mortality. Enhanced communication between health professionals and patients is crucial in improving self-management and treatment outcomes. Evidence shows that there are various dimensions of behaviour change communication (BCC), and if used appropriately, may result in better self-management behaviours, better adherence to diabetes care, greater well-being, greater perceived personal control and self-efficacy, and less diabetes distress (Greenwood, Gee, Fatkin & Peeples, 2017:1016; Jain et al., 2020:3; Qudah & Luetsch, 2019:5; Sibounheuang, Olson & Kittiboonyakun, 2020:7). With the current advancement in health technologies, mHealth has numerous opportunities to enhance patient education and communication. Seven of 14 empirical pieces of evidence were designed for BCC. This opportunity was well-perceived by HCPs. 82% agreed that mHealth would allow professionals to disseminate prevention strategies for patients with T2DM. Around 89% of HCPs also believed that mHealth is an easy platform to disseminate patient education.

In addition, 96% indicated that mHealth would be useful to support their effort to improve patients' self-management. However, the area and contents of the intervention should be focused and relevant to bring the desired behavioural changes. The content for behavioural change needs to include recommendations on a diet, physical exercises, treatment/medication, diabetes self-management (DSM), blood glucose monitoring, diabetic complications, and psychosocial issues. Chester, Stanely, and Geetha (2018:644) outlined that blood glucose monitoring, nutrition, and physical exercise are the essential contents that each patient should be knowledgeable about for managing their conditions.

In low and middle-income countries (LMICs), mHealth initiatives successfully supported behavioural engagement in diabetes management and have resulted in improved glycemic control and clinical outcomes (Hangaard, Laursen, Andersen, Kronborg, Vestergaard, Hejlesen & Udsen, 2021:1935; Johnston et al., 2018:4; Verma, Bahurupi, Kant, Singh, Aggarwal & Saxena, 2021:488; Wang et al., 2020:4; Wu, Guo & Zhang, 2019:8), reduced diabetes complication, improved diabetes self-management (DSM) knowledge and practice (El-Gayar, Ofori & Nawar, 2021:8; Johnston et al., 2018:5; Liu, Xie & Or, 2020:14; Mao et al., 2020:3), and adherence to treatment and follow-up (Liu et al., 2020:16; Wang et al., 2020:4). Thus, improving access to BCC through enhanced technology, is a feasible intervention for developing countries like Ethiopia. This study revealed that mHealth initiatives have higher sustainability prospects when users believe that the technology will support healthcare delivery. Therefore, mHealth could be used as a tool to strengthen primary health care (PHC). The level of acceptance demonstrated by the healthcare professionals lays a fertile ground for mHealth, 84.9% intended to use mHealth for patient education. According to two studies conducted in Northwest and Southwest Ethiopia, a majority of the patients with diabetes showed their willingness to receive education through SMS messages from HCPs (Bogale et al., 2022:1505; Jemere, Yeneneh, Tilahun, Fritz, Alemu & Kebede, 2019:6). This willingness could be a good precursor for the adoption of mHealth for diabetes management in Addis Ababa.

The significant potential for mHealth lies in their use of SMSes, making them ideal for LMICs since they are simple, inexpensive, and require basic mobile devices. Based on the growing body of evidence presented in chapter 3, the SMS is a highly accessible communication mode, relatively inexpensive, and an underused adjunct to T2DM care (Whittemore et al., 2020:521). Findings indicated that SMSes effectively improved clinical outcomes, although not all evidence documented positive results. This could also be an opportunity for diabetes management primary healthcare services in the study area since 86% of health professionals agreed on the criticality of SMS features for diabetes-related mHealth, and 70% used their mobile phones regularly for text messaging. Since the SMS service is considered critical, some essential attributes and strategies must be considered to utilise SMSes effectively. These features and strategies are discussed below.

According to studies, the frequency of SMSes could have a significant impact on the effectiveness of patient education and communication. As discussed in Chapter 3, the frequency of SMSes ranged from one per day to one per week. Multiple SMSes per day could improve behavioural interventions (Orr & King, 2015:411).

The study assumes that efforts to establish well-structured communication channels using mHealth technology need to include strong capabilities for local problem analysis and innovation. There are, however, several concerns that need to be considered, such as the needs of patients, the length of the message as well as the frequency of messaging.

The Centre for Disease Control (CDC) guideline also recommends a short and concise SMS message with less than 160 characters, including spaces, punctuation, and any branding or links to additional information. If necessary, messages could be split into two text messages to accommodate additional content (Abroms, Whittaker, Free, Van Alstyne & Schindler-Ruwisch, 2015:4).

Tailored patient education and communication recognise patient groups' diversity and strive to create individual-focused information that addresses the patient's specific needs and concerns (Liu, 2018:15). The patient's needs and the preferable day and time to receive the message and topic of interest, could be crucial for the effectiveness of the intervention (Sahin et al., 2019:18). The patient's sociodemographic characteristics, DSM knowledge and practice and current health status should be considered for non-theory-based tailoring of SMS contents (Liu, 2018:16; Sahin et al., 2019:16; Whittemore et al., 2020:511).

In addition, the involvement of different stakeholders, including patients and standardised guidelines, is also crucial in developing and customising SMS content. The development of SMSes should also consider language barriers (Whittemore et al., 2020:505) and should include a language switch option to provide the translated version based on the local language preference.

The development of SMSes must consider the audience's literacy level and an eighth-grade reading level is recommended for the adult population (Centers for Disease Control, 2012:5; Schilling, Bennett, Bull, Kempe, Wretling & Staton, 2013:14). Due to the limit on the character number of SMSes, abbreviations could be used sparingly when the abbreviations are well known and do not affect the meaning of the SMS (Centers for Disease Control, 2012:6).

Voice calls are also used to remind patients about treatment and follow-up visits; most HCPs considered voice calls critical for diabetes-related mHealth intervention. The direct interaction with patients, the provision of timely feedback, and reminder calls using voice calls strongly impact monitoring patient data and improving compliance with treatment and follow-up visits (Wang et al., 2020:7; Zhang et al., 2021:613). Telephone calls can be used to collect data from patients, which could be easily entered by health professionals and transferred to the central system using the mobile application. In face-to-face interactions, the health professionals could enter data directly or the patient can insert remotely using their mobile, and the healthcare providers can access, edit, and integrate it with the Hospital Electronic Medical Record (EMR).

Simon and Seldon (2012:126) discussed a remote biosensor that could be used to create a Personal Health Record (PHR); such systems allow patients/HCPs to collect biomarkers and provide decision support on a patient therapy plan. HCPs who embrace the use of technology in healthcare can also capture biomarkers and patient data remotely using mobile phones and biosensors (Arumugam, Colburn & Sia, 2020:2; El-Rashidy, El-Sappagh, Islam, El-Bakry & Abdelrazek, 2021:5). Biosensors were used to collect data and biomarkers from diabetic patients, including tracking body chemistry, diet, physical exercise, and glucose monitoring. mHealth can connect with standalone biosensors or use on-phone sensors (integrated biosensors) (Arumugam et al., 2020:4).

HCPs demonstrated high acceptance of this functionality, and around 85% agreed that biosensors connected to mobile phones are essential for diabetes management. The availability of such features may increase self-care behaviours among diabetes patients. This will make a significant contribution to the overall management of the condition in Ethiopia. It also gives credence to the proposal to adopt mHealth for diabetes management.

There is a high burden of undiagnosed diabetes in LMICs like Ethiopia, primarily due to poor screening practices. According to a systematic meta-analysis study in Ethiopia, the prevalence of undiagnosed diabetes was 5.7%, highlighting the need for interventions to improve the screening service (Yitbarek, Ayehu, Asnakew, Chanie, Bayih, Feleke, Amare, Teshome, Teshome & Arage, 2021:3). Screening supported by mHealth has the potential to improve screening service and rate of diagnosis.

A study that used mHealth for screening and diagnosis, coupled with a voice call reminder for patients to return for definitive tests, reported significant improvements in screening and diabetic diagnosis. In this study, 87.8% of HCPs intended to use mHealth for tracking patients. Around 92% expressed their intention to use mHealth applications for early diabetes diagnosis. It is acknowledged that automated phone reminders reduce patient "no-show" rates (Ali-Ahmed & Halalau, 2016:231). Two studies found that voice call reminders reduced the baseline "no-show" rate and improved return for follow-up tests (Hasvold & Wootton, 2011:359; Opon, Tenambergen & Njoroge, 2020:4). The use of digital screening using mobile phones enhances accessibility, and decision support tools could also be integrated into the form to analyse and provide information on the individual’s risk level and whether a diagnostic test is required (Prabhune, Manoharan & Murugan, 2019:2045).

These mHealth opportunities for diabetes screening, combined with the HCPs' support, create the ideal environment for mHealth implementation in Addis Ababa to reduce the high rate of undiagnosed diabetes and enhance the early identification of disease.

5.3.2 Design and Functionality of mHealth Application

Evidence shows that for any digital health to succeed, several issues need to be considered, including the functionality and design of the application. The most used gates for network trafficking and information architectures are P2P and A2P trafficking. Most SMS interventions used A2P trafficking with a web-based application and API (automated messages). Since bulk messages effectively bring behaviour change among large patient groups, a web-based A2P gateway linked with a decision support system could be crucial to transmit health education and promotion messages from the application to the patient group. A2P SMSes also enhance two-way communication between health professionals and patients. Despite its wide application, system-related barriers, poor digital literacy, and high initial investment could make it difficult to implement A2P in developing countries.

The HCPs’ strong intention to use mHealth for communicating with patients also indicates the potential for mHealth implementation strategies. About 88.6% of healthcare professionals believed mHealth would be useful to improve their performance of supporting patients to adhere to medication and diet.

Compared to the A2P, the P2P (non-automated) messages are inexpensive and comparable in improving glycemic control. P2P enhances individual message tailoring based on clinical data and patient needs and creates personalised communication (Whittemore et al., 2020:510). It is evident that messages tailored to specific patients and communication from HCPs are more likely to be effective (Sahin et al., 2019:15). However, using the P2P platform should be a short-term strategy since it is not cost-effective to communicate general education content and address large patient groups. Managing SMS content and schedule could also create another burden when the number of patients with T2DM increases in the health facility.

Long-term strategies should focus on messaging applications with automated and non-automated messaging features. In the integrative literature review, the features of the messaging application are not discussed in detail. Though, different messaging application features and interactivity are recommended to disseminate information to HCPs. These include: applications based on a smartphone for sending and receiving messages; allowing offline uses; interactive possibilities that allow two-way communication (Hall, Cole-Lewis & Bernhardt, 2015:399; Marko-Holguin, Cordel, Van Voorhees, Fogel, Sykes, Fitzgibbon & Glassgow, 2019:6).

mHealth initiatives for diabetes self-management (DSM) are required at four key points: diagnosis, an annual assessment by a healthcare provider, the emergence of complicating factors, and transitions in care (Powers, Bardsley, Cypress, Duker, Funnell, Hess Fischl, Maryniuk, Siminerio & Vivian, 2015:1378). DSM can improve based on the functionalities and application of mHealth, such as providing distance learning, telemonitoring blood glucose, medication reminders, text messages and voice calls (Riangkam, Sriyuktasuth, Pongthavornkamol, Kusakunniran & Sriwijitkamol, 2021:886).

5.3.2.1 Personal Health Record

mHealth has been used effectively for diabetes management by Healthcare Professionals (HCPs) in primary healthcare settings for maintaining personal health records (PHR), including data collection, storage, transmission and monitoring (Ndlovu, Mars & Scott, 2021b:8; Sousa, Lopes, Guimarães & Santos, 2021:915). The PHR mHealth domain's features were capturing data using a Biosensor, data collection, storage, communication of patient data, and monitoring patients. HCPs also showed a positive view of the use of mHealth for maintaining PHR, as 90.5% agreed that data collection, storage, and communication features are critical for diabetes-related mHealth.

Based on evidence from reviewed studies, mHealth improves data quality, transmission, accessibility, and utilisation for clinical decision-making. It appears that the potential mHealth project will have good support from the users. This bodes well for the effective management of diabetes in Addis Ababa. Around 89% of HCPs considered mHealth useful to improve their performance of maintaining the health information of patients with T2DM. Technology is purported as an effective strategy to ensure the safety of patients and enhance quality by following standards for data management. Therefore, it is possible to initiate a successful mHealth programme in Ethiopia, as 91.5% of HCPs expressed their intention to use mobile phones for capturing, storing, and sharing patient data. The significance of a positive attitude toward technological innovation has been cited as key to the successful implementation of any technology among health professionals.

5.3.2.2 Data Management Processes

As discussed earlier, the contribution of mHealth in data collection and data quality was revealed in this study. Healthcare professionals (HCPs) also viewed this as an opportunity to manage the condition effectively. 89.3% agreed that mHealth could be used for patient data collection. The utilisation of digital forms using the mHealth tool could be significant for LMICs, including Ethiopia, and could improve the quality of patients' data and the use of the information for clinical care.

mHealth could also enhance clinical data storage and create a linkage with electronic health records (Choi, Kim, Kwon, Kim, Kim, Cha, Jeong & Lee, 2020:5-6). Two empirical studies used a relational database for data storage, but there is a need to consider a non-relational database due to its flexibility in storing unstructured data, its ability to manage large data sets and its ease of use (Ndlovu et al., 2021b:8). In the current health system, the personal health record (PHR) mHealth domain is expected to allow data storage in relational and non-relational databases (Sousa et al., 2021:913). The criticality of the data storage feature of mHealth was also well-perceived by HCPs. 89% indicated the importance of using a central database for storing data. Central database storage enhances data access through mHealth for HCPs. This was evident in Ethiopia. Using mHealth for community health data improved the accessibility of data by health extension workers (Mengesha, Steege, Kea, Theobald & Datiko, 2018:ii82; Nigussie, Zemicheal, Tiruneh, Bayou, Teklu, Kibret, Eifler, Hodsdon, Altaye & Rosenblum, 2021:697). This study also shows that there are opportunities for mHealth for data storage by HCPs.

mHealth allows HCPs and patients to transmit easily from and to central databases using mHealth PHR (Choi et al., 2020:5-6). There are two types of transmission channels in mHealth. The first is mobile networks, SMSes based on the GSM network for transferring captured data. The second is TCP/IP networks using HTTP/HTTPS protocol to transfer collected data to the central platform (web-based) (Wang, Miao & Yang, 2018:135). Healthcare professionals had a positive attitude toward using mHealth to enhance data transmission. 89.3% of HCPs agreed that mHealth would allow professionals to share/transmit patient data. The significant contribution of mHealth in enhancing data transmission was also evident in mHealth intervention designed for community health data in Ethiopia (Mengesha et al., 2018:ii83; Nigussie et al., 2021:697). These opportunities and the supportive attitude of HCPs create a positive environment for implementing mHealth technology that includes these data transmission features in Addis Ababa.

One of the functionalities highlighted in Chapter 3 was the monitoring of patient data. The system helps HCPs track patterns and trends by providing a clear graphical representation and statistics of collected patient data (Takenga et al., 2014:2). Simon and Seldon (2012:128) also discussed a data display system for data stored in the central database, allowing HCPs to monitor patients' data. This was well perceived by HCPs. 89.3% agreed that mHealth would make it easier for professionals to monitor patients with T2DM. A data processing display system that generates visual information that is easy to analyse is crucial to monitoring patient data and making evidence-based decisions by HCPs (Sousa et al., 2021:914). The system also allows HCPs to analyse large data volumes, identify critical data and take corrective actions (Azizi, Aboutorabi, Mazloum-Khorasani, Hoseini & Mahmood, 2016:1394; El-Sappagh et al., 2018:21941). These patient monitoring features of mHealth were considered critical by 82.4% of HCPs.

Patient monitoring practice is still poor in LMICs like Ethiopia. According to a study conducted in Ethiopia, patients' critical clinical data were not monitored by HCPs (Desse, Mc Namara, Yifter & Manias, 2022:1). Another study in southern Ethiopia reported poor monitoring of lipid profile and glycemic control by healthcare services (Russo, Sorato, Mesfin, Hailu, Tanga & Bussa, 2022:11). As supported by evidence, this challenge could be improved by mHealth interventions. The presence of an intention to use mHealth for patient monitoring by HCPs is also encouraging. A majority, 92.6%, agreed.

5.3.2.3 Treatment/Therapy Plan

The mobile application also has a Clinical decision support system (CDSS) that assists health professionals in patient monitoring and a therapy plan. The healthcare professional could transmit therapy plans, instructions, and guidance to the patients through SMSes or mobile applications. Around 89% of HCPs also agreed that mHealth would make the CDSS helpful.

One of the strategies of CDSS-integrated mobile applications is to create systems where the information collected from heterogeneous sources such as biosensors, patients, or health professionals could be entered as data and transmitted to the mobile application for health professionals to view. This enables health professionals to track glucose trends and other patient data between visits and contact them via mobile application or SMSes for follow-up or treatment plan communications (Sutton et al., 2020:7). A simple provision of clinical management guidelines in electronic form through mHealth could also improve the clinical decision-making process of HCPs.

The result of this study shows that mHealth CDSS functionalities could improve the quality of treatment plans which was supported by healthcare professionals (HCPs). Basically, CDSS is designed to provide tailored knowledge support for HCPs that guide monitoring and treatment plan decisions. Frequently CDSS are classified as knowledge-based, which provides support based on the algorithms programmed into the mHealth system, and non-knowledge based, which provides support based on the algorithms programmed into the mHealth system and other available data (El-Sappagh, Ali, Hendawi, Jang & Kwak, 2019:5). The knowledge support could be raising critical alerts, follow-up action, and treatment plans. These alerts could pop up on the screens of the mobile device or through SMS. This would allow the creation of collaborative and shared decision-making among patients and HCPs. The use of such knowledge management and technology support for clinical decision-making is not standard in Ethiopia (Belay, Desta, Smithson & Meshesha, 2021:4). Local studies show that the major barrier to good practice in data-informed decision-making is the paper-based medical record system which is not yet enhanced by appropriate technology (Assefa & Shewangizaw, 2021:6; Guadie, Shiferaw & Gashu, 2022:5; Tegenaw, Amenu, Ketema, Verbeke, Cornelis & Jansen, 2021:14). The use of mHealth for CDSS in LMICs like Ethiopia has the potential to strengthen data-driven decision-making practices by providing critical information through enhanced data analysis algorithms and display systems, something which is difficult to achieve through a paper-based system (Agarwal et al., 2021:1; Harada, Miyagami, Kunitomo & Shimizu, 2021:9; Papadopoulos, Soflano, Chaudy, Adejo & Connolly, 2022:724; Sutton et al., 2020:2).

Teleconsultation by senior experts is another opportunity to support decisions and treatment plans by Health care professionals (HCPs). Teleconsultation could enhance the treatment plan by allowing HCPs to get second opinions through expert-level consultation (Deldar et al., 2016:286). The presence of a positive attitude and acceptance by HCPs could facilitate the implementation in Addis Ababa. Using mHealth for consultation and support could improve the subpar clinical care provided due to HCPs' knowledge and clinical decision-making skill deficiencies.

5.3.3 Barriers to Effective Implementation of mHealth

Despite the numerous advantages of using mHealth for diabetes management, there are, however, concerns about the infrastructure for establishing such initiatives in low and middle-income countries (LMICs). Several challenges were cited, such as lack of infrastructure, lack of government regulations, economic challenges, lack of a standard for interoperability, the poor security and privacy of health data, low digital awareness and literacy, and poor usability of the mHealth system (Fatehi et al., 2017:2; Istepanian et al., 2017:8; Kruse et al., 2019:6; Latif et al., 2017:11545-11547; McCool et al., 2022:531). The following subsections address challenges for mHealth implementations identified from the integrated literature review and survey.

5.3.3.1 Interoperability

In this study, the lack of government regulations and standards on interoperability was identified as a major challenge to the effective implementation of mHealth for diabetes management. Most HCPs also agreed that an interoperable mHealth application is crucial for diabetes management. The lack of regulation and standards for Interoperability is also a major challenge in the Ethiopian eHealth system. No enterprise architecture governance body or regulation verifies new eHealth system compliance to other systems (Biru, Birhan, Melkamu, Gebeyehu & Omer, 2022:4-5; Harding, Biks, Adefris, Loehr, Gashaye, Tilahun, Volynski, Garg, Abebaw & Dessie, 2018:5; Wondwosen, Mengistu, Senanu & Victor, 2018:8). Interoperability is a critical aspect of SMS-based patient communication and education. This could be a major challenge if the messaging application does not fit the e-health system. mHealth needs to be part of the Health Information System (HIS) of a health system. There must be convergence between mHealth and other eHealth systems.

In P2P trafficking, interoperability could not be an issue since the GSM network is used locally, but interoperability standards are critical for A2P messaging. The emerging HL7 interoperability standards, including HL7 v.3, mFHAST, MH2F, and Fast Healthcare Interoperability Standards (FHIR), are suggested for low and middle-income countries for messaging applications (Braunstein, 2018:25; Cosío-León, Ojeda-Carreño, Nieto-Hipólito & Ibarra-Hernández, 2018:69; Ndlovu, Mars & Scott, 2021a:8). HL7's FHIR is the most appropriate messaging standard because it fulfils most of the interoperability requirements for the modern healthcare system (De, Huang, Feng, Yue & Yao, 2021:4).

Aligning Bulk SMS applications with national telecom providers is also essential to ensure interoperability and effective utilisation of messaging intervention. In Ethiopia, the Ethio-Telecom uses two options for integrating mHealth service providers: the first option is connecting the SMSC of mobile operators through SMPP or using aggregators via SMPP, and the second option is HTTP based on APIs (Kebede, 2020:23).

Interoperability is also critical, requiring strategies to integrate biosensors with PHR mobile applications. The IEEE 11073 PHD standard allows users to know the nature of the data measured, and the data are not lost when transferred from the sensor to the gateway and then to the central database (Alfian, Syafrudin, Ijaz, Syaekhoni, Fitriyani & Rhee, 2018:20; El-Sappagh et al., 2018:21939; Rani & Narayanan, 2015:1075). The IEEE 11073 PHD standard creates a common framework free from transport-dependent syntax and allows logical connection between biosensors, mobile phones, and computer engines (Alfian et al., 2018:20). The HL7 standards are suitable for the Ethiopia eHealth system (Wondwosen et al., 2018:11). Mobile-based PHR and messaging applications also require standards for semantic interoperability.

5.3.3.2 Security and Privacy

Data security and privacy are central to all health technologies. In this study, 86% of healthcare professionals considered a security system with restricted access a critical feature. Unfortunately, the lack of regulation, security, and privacy standards is a challenge in the Ethiopian eHealth system (Biru et al., 2022:5; Harding et al., 2018:6). However, the existence of government initiatives and digital health strategies may open up the possibility of formulating security and privacy regulations (Precise Consult International, 2021:15) based on the security and privacy gap discovered during the implementation of mHealth for community health workers (Mengesha et al., 2018:ii83; Nigussie et al., 2021:697).

The lack of regulation and standards on mHealth security and privacy was also identified as a challenge for mHealth implementation. Nevertheless, there are measures recommended to overcome these challenges, including encryption, authentication, key exchange, information integrity, authorisation, access control, individual participation and sharing of personal data, and audit and accountability patient education and communication mHealth domain (Iwaya et al., 2020:2; Schwebel & Larimer, 2018:91; Spigel, Wambugu & Villella, 2018). These suggestions could be included in Ethiopia's digital health blueprint and eHealth system regulation to address security and privacy issues.

Another critical feature is Opt-out/Opt-in (subscription) Management features that address patient privacy and security (Iwaya et al., 2020:5). Additionally, national and international security and ethics guidelines and regulations must be maintained to implement SMSes and voice call interventions. Developing a user manual in a local setting could also be crucial for effective implementation (Martinengo, Spinazze & Car, 2020:3).

The security and privacy regulation in low and middle-income countries like Ethiopia should also consider user security measures. User security is a three-step process that includes user identification via password, biometric or two-factor authentication, and authorisation via permissions (what the user can access and do). The authentication can be supported by integrating the Google reCAPTCHA API service (López-Landa, Domínguez-Isidro, Hernández-Velázquez & López-Domínguez, 2018:120; Spigel et al., 2018:3). Validation of services for information access, level of information access and use permissions, software patches and updates, software logs and input validation techniques are all-important in securing mobile applications (Majchrzycka & Poniszewska-Maranda, 2017:281).

5.3.3.3 mHealth System Usability

Lack of mHealth initiatives in local languages, poor user interface, complexity to install and use, poor scalability, and complex troubleshooting and maintenance system are some of the challenges identified in this study. Since HCPs perceived ease of use of mHealth interventions served as a predictor for future intention to use, strategies are required to address the potential system and interface-related challenges. Complex mHealth systems necessitate extensive training to reduce HCPs' workload when attempting to navigate the systems (Liew, Zhang, See & Ong, 2019:2).

Appropriate remedial measures could be user-centric development, keeping the user interface simple, and using the appropriate font type and size (Gurupur & Wan, 2017:1; Katusiime & Pinkwart, 2019:944). The user interface design must be simple and easy to learn and be scalable and allow system integration. It must also be easy to install and maintain to ensure constant updates (Latif et al., 2017:11552; Sousa et al., 2021:913). The associated system design must be scalable and allow system integration (Sousa et al., 2021:913). Extensive assessment by the user and iterative improvement based on feedback are also paramount before implementing the mHealth system (Farao et al., 2020:3; Katusiime & Pinkwart, 2019:945).

Since most of the HCPs who participated in this study had no experience in mHealth, use-centric development would improve the exposure of HCPs to mHealth for effective implementation.

The mHealth initiatives developed in local languages are also crucial to enhance usability. Especially for mHealth applications, the system should be designed to allow multiple interfaces for local languages. This is especially critical for countries like

Ethiopia, with language diversity. The preference for content being in local languages was also revealed in a study by Medhanyie et al. (2015:7) and Nigussie et al. (2021:679).

Low digital literacy among HCPs was one of the major user-related challenges identified in this study. This could have a significant effect on their intention to use as well as their attitude toward health technology. Gagnon et al. (2016b:214) found that perceived ease of use among the HCPs was a predictor of future intention to use mHealth for diabetes management. In this study, most (74.6%) HCPs did not receive formal education on mHealth during their undergraduate or postgraduate studies. Improving the digital literacy of health professionals may result in increased adoption and implementation of digital services and technologies in healthcare settings.

Another user-related challenge revealed by this study is the lack of awareness of mHealth initiatives. Lack of awareness could affect the perception of HCPs and the use of mHealth to support their healthcare delivery (Gagnon et al., 2016b:214). In this study, HCPs' perception of the usefulness of mHealth was a predictor for future intention to use diabetes-related mHealth. The major reasons for low awareness could be a lack of information and experience in the design and implementation of mHealth health service delivery (Gagnon et al., 2016b:218). Most HCPs have no experience regarding mHealth and, as presented earlier, did not receive training on mHealth.

5.3.3.4 mHealth Resources and Infrastructure

It is evident that the effective implementation of any health technology requires adequate infrastructure and resources. Low and middle-income countries experience a myriad of challenges with the implementation of health information systems. There are various and often complex contributory factors. Access to a network and the strength of internet connectivity hamper efforts of successful use (Gurupur & Wan, 2017:2). This study revealed that most (66.9%) HCPs had no internet access, and only 36.8% of HCPs browsed the internet on their cell phones. Despite these challenges, the Ethiopian government is trying to enhance the healthcare system through digital infrastructures.

5.4 OPPORTUNITIES FOR MHEALTH

The penetration of mobile phones and network connectivity creates good ground for the implementation of mHealth in low and middle-income countries (LMICs) (GSMA, 2016:3). mHealth focused on education and behavioural change communication with patients with T2DM shows potential in LMIC settings. These mHealth initiatives successfully support behavioural engagement in diabetes management and have resulted in positive DSM behaviour and clinical outcomes. Significant potential for mHealth in education and behavioural change communication lies in the use of SMSes, making them ideal for LMICs since they are simple and inexpensive.

The importance of mHealth-based behavioural change communication (BCC) is especially significant for Ethiopia due to various challenges in reaching out to the patient to provide education essential for self-management. The study conducted in Ethiopia revealed that most (66.1%) patients with T2DM were unable to maintain good glycemic control (Gebreyohannes, Netere & Belachew, 2019:6). Another meta-analysis reported a lower overall pooled estimate of good diabetes management practice (Dagnew, Debalkie Demissie & Abebaw Angaw, 2021:8). One of the major contributors to poor DSM is the lack of access to health education (Habebo, Pooyan, Mosadeghrad, Babore & Dessu, 2020:8; Mariye, Tasew, Teklay, Gerensea & Daba, 2018:5; Mogessie, Gebeyehu, Kenbaw & Tadesse, 2022:10; Tezera, Sahile, Yilma, Misganaw, Amare & Haidar, 2022:7; Zeleke Negera & Charles Epiphanio, 2020:7).

Despite these gaps, Ethiopia's patient education still solely depends on irregular face-to-face sessions during the monthly clinical follow-up visits. Despite this, little evidence is available regarding mHealth use for patient education and communication in Ethiopia. Most mHealth interventions focus on infectious disease and maternal and child healthcare. For example, Manyazewal et al. (2021:3) found that diabetes is not well represented in digital health technology studies.

Although there are no studies on mHealth for T2DM management in Ethiopia, studies conducted on health extension workers reported the significant role of mHealth in collecting and transmitting community health data (Mengesha et al., 2018:ii82; Nigussie et al., 2021:697). A study in Northern Ethiopia revealed a significant impact of mHealth on the timeliness and completeness of maternity service data in primary healthcare settings (Shiferaw, Workneh, Yirgu, Dinant & Spigt, 2018:9). Mengesha et al. (2018:ii81) found that mHealth improved the completeness and quality of community health data in Southern Ethiopia. Health Extension Workers also reported that mHealth technologies make it easier to transmit and access patients' data (Nigussie et al., 2021:677). This opportunity is also supported by HCPs and reflects positive prospects of adopting mHealth to manage diabetes in primary healthcare settings.

The Ethiopian government has been paving the way for digital health technologies by developing a policy agenda to improve healthcare quality, as evidenced by its health HSTP. One of the four transformation agendas in the HSTP (2020-2025) was the information revolution (Ethiopia Federal Ministry of Health, 2021:11). Furthermore, the country has developed health information systems and digital health-related national documents to lay out a clear path for implementing the information revolution and HIS digitization. This includes Information Revolution Roadmap II (2020-2029), Information Revolution Strategic Plan (2018 -2025), Ethiopia eHealth, ICT Policy, and Digital Health Strategy (2020-24), and Digital Health Blueprint (DHBP). While the sector continues to devise general policies and documents for digital health advancement, the mHealth implementation for NCD management, like diabetes, seems to lag.

This provides excellent opportunities to explore further the feasibility of establishing a malleable platform that can be tailored to individual users to support the management of diabetes. The burden of diabetes in Ethiopian is well known, and supporting HPCs efforts in maintaining patients in therapy through digital health technologies like mHealth could be beneficial. However, the study assumes that such initiatives should be supported by clear strategies, political willingness, financial support, and a guiding framework.

5.5 SUMMARY

This chapter provided a joint display of Phase I and II data and drew a meta-inference. Based on the meta-inference, this chapter also discussed the opportunity of using mHealth for diabetes management, including patient communication and education, remote data collection (PHR), screening, treatment/therapy plans, and DSM. The challenges that hinder the successful implementation of mHealth for diabetes management were also discussed.

The integrated results discussed in this chapter were used to develop the Phase III tool, which focused on strategies and a guiding framework for implementing mHealth for diabetes management. The next chapter presents the results, analysis, and discussion of Phase III of this study.

CHAPTER 6

DEVELOPMENT AND DISCUSSION OF THE STRATEGIES FOR IMPLEMENTING MOBILE HEALTH

6.1 INTRODUCTION

Chapter 5 provided the integration of Phase I and II findings. This chapter describes the development and validation of mHealth strategies for diabetes management in Addis Ababa, Ethiopia. The chapter includes the strategy development process and validation result of the Modified Delphi Round one to three. Detailed descriptions of the validated and acceptable strategies are also covered in this chapter.

6.2 STRATEGY DEVELOPMENT PROCESS

After integrating the findings from Phase I and Phase II and reviewing additional literature, draft strategies were developed by the researcher. In Phase III of this study, three rounds of the Modified Delphi Technique were employed to revise and validate the draft strategies.

As discussed in Chapter 2, the Modified Delphi method is a consensus-building technique that seeks expert judgment on pre-determined contents in an organised fashion and using multiple iterations. The Modified Delphi Technique is the most accepted method for collecting data from expertise (Avella, 2016:306). The major advantage of a Modified Delphi is that it gives a concrete foundation in previously developed evidence and improves the response rate of Round One. The Modified Delphi also allows consensus among experts without meeting face-to-face, which significantly reduces possible bias introduced by group interaction (Strudsholm et al., 2016:9).

The purpose of the Modified Delphi Technique in this study was to reach a consensus on the relevance and applicability of the mHealth strategies for diabetes management in Addis Ababa, Ethiopia. These mHealth strategies were pre-determined based on the integrated finding of Phases I and II of this study.

As depicted in Figure 6.1, the Modified Delphi Technique was employed in three rounds. In the first round, a discussion was held with experts to overview the draft strategies and collect additional suggestions from the panel of experts. The draft strategies were revised by incorporating feedback from the panel of experts and used to develop a data collection tool for the Modified Delphi Round two.

In Round Two, experts rated each strategic activity using a four-point Likert scale. The Round Two findings were used to validate the relevance of strategies and revise the tool by removing disqualified strategies based on a panel expert consensus level (I-CVI ≤ 82%). Ten experts were purposively selected for Rounds One and Two.

In Round Three, another expert group was invited to rate the revised strategic activities using a five-point Likert scale. The Round two findings were used to validate strategies' relevance and acceptability. The final validated and accepted strategies were developed by removing disqualified strategies based on the Round Three expert consensus level (I-CVI ≤ 80%). Figure 6.1 illustrates the flow of the Modified Delphi process.

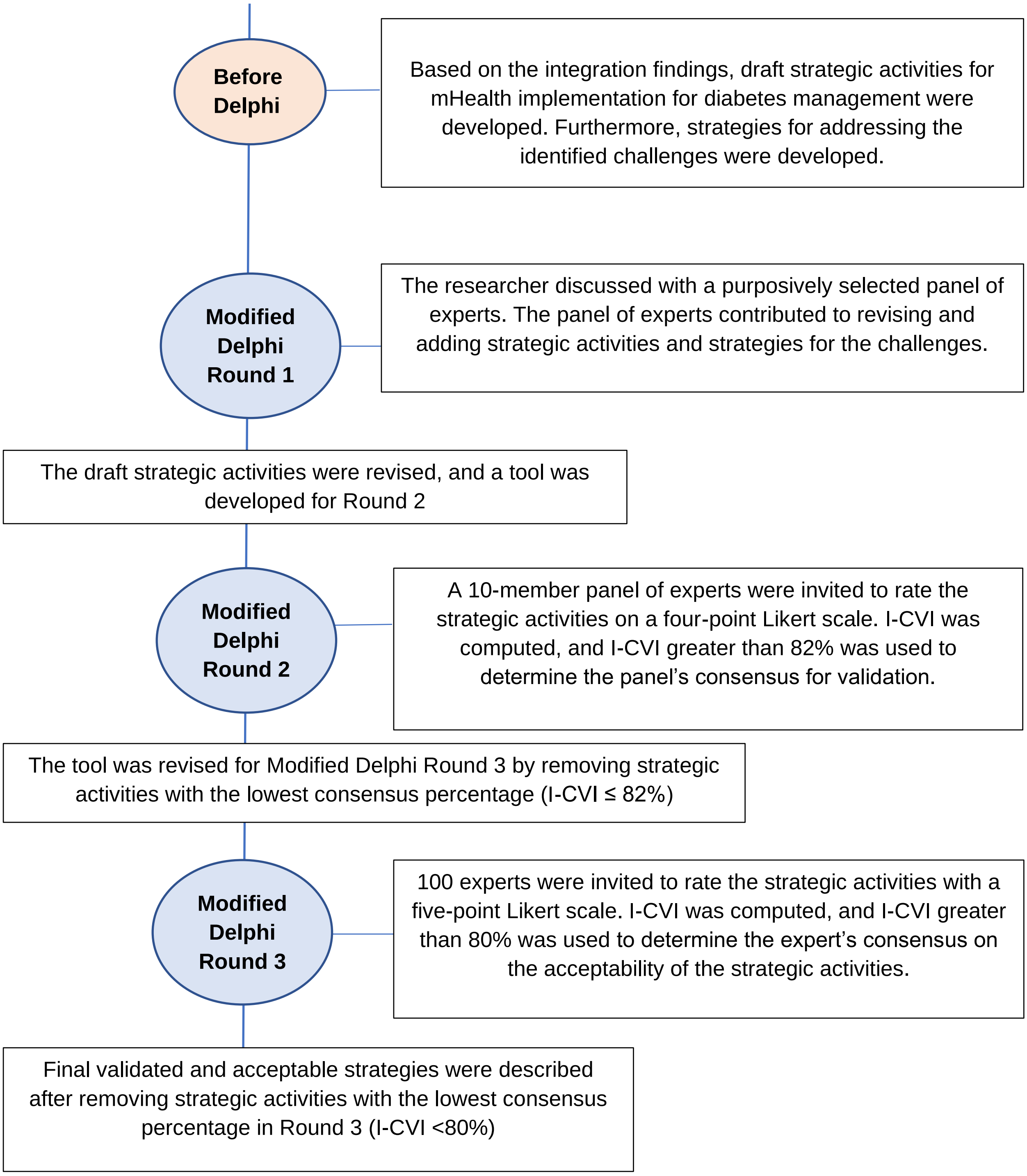

Figure 6.1: Flow Diagram of the Modified Delphi Process

6.2.1 Preliminary Stages

The meta-inference generated by the integrated finding was used to draft strategies. A presentation based on the draft strategies was developed to facilitate discussion with the panel of experts during Round One of Modified Delphi.

6.2.2 Round One

As described in Chapter 2, the expert panel for Round One were purposively selected based on their qualification, professions, setting, and experience in digital health policy design and implementation. The experts were highly experienced in digital health, specifically in mHealth, and were involved in designing and implementing mHealth projects at national and regional levels. The experts also have experience in digital health strategy design and have a close working relationship with the Ministry of Health and regional health bureaus.

After the researcher identified ten members for the panel of experts based on the criteria, the researcher contacted the experts by telephone to explain the research objectives, the Modified Delphi process, and ethical considerations and to obtain their email addresses for further communication. After the verbal agreement was reached, informed consent was sought from the experts through email communication.

Round One was initiated after getting the expert's consent (see Annexure E). The researcher conducted a virtual session with the experts. The session focused on the research's objective, how the strategy and strategic activities were developed, how the validation process (Modified Delphi method) was designed, the draft strategy and strategic activities, and strategies/guides for addressing challenges. The experts were also invited to add strategic activities considering the local context. A short PowerPoint presentation was also sent to the experts describing the strategic activities. For each key strategy, additional activities suggested by the experts were included in the data collection tools. Table 6.1 provides the diabetes mHealth strategies, strategic objectives, and expected outcomes.

Table 6.1: Revised Strategic Areas for Diabetes mHealth After Round One.

Section I: mHealth opportunities/uses for diabetes management		
Strategy	**Objective**	**Expected Outcome**
Behavioural Change Communication	Provide behavioural intervention and education remotely for patients with T2DM.	Improve the patient's knowledge of diabetes management and enhance clinical outcomes.
Patient communication and support for DSM	Ensure the presence of adequate communication and support on the DSM	Enhance patient-HCP communication, and Improve DSM practice of patients with T2DM
Personal Health Record (PHR)	Collect, store, transmit and monitor data of patients with T2DM	Enhance data quality, and use; and improve clinical outcomes
Screening	Screen and identify T2DM cases	Improve T2DM screening rate, and reduce the proportion of undiagnosed diabetes.
Treatment/Therapy plan	Provide decision support for HCPs to design and communicate effective treatment/therapy plans.	Enhance treatment/therapy plans for managing T2DM and improve clinical care.
Section 2: Strategies to address challenges for diabetes mHealth implementation		
Challenges	**Strategic objectives**	**Expected Outcomes**
Interoperability	Employ effective and acceptable interoperability standards	Enhance interoperability between diabetes mHealth and other eHealth platforms
Security and Privacy	Employ acceptable standards for security and privacy	Ensure security and privacy of patient data in mHealth
Usability	Use acceptable strategies in designing and developing mHealth	Enhance the usability of mHealth by HCPs and patients
User-related	Provide educational support for HCPs on digital health	Improve HCPs' digital awareness and literacy
Resource	Provide resource support for primary healthcare settings and HCPs	Improve resources availability for diabetes mHealth implementations

6.2.3 Round Two

In this round, the researcher developed a data collection tool consisting of two major sections based on the experts' suggestions in round one. The first sections consist of strategies, actions, and 59 activities for mHealth use for T2DM management. The second section consists of 39 strategies to address challenges identified in the integrated finding (see Annexure F). The ten experts who participated in the Round One discussion were invited through email to rate their agreement on a four-point Likert scale, namely, 1=Not relevant, 2=Somehow relevant, 3=Relevant, and 4=Highly relevant.

Out of the ten, eight expert panel members responded. Out of these, six were male, and four had PhDs. Six of the participants were health informatics/health information system experts, one was a networking expert, and one expert was a software engineer. Regarding their organisations, two experts were from the Ministry of Health, and three were from Higher Education Institutes (HEI).

Table 6.2 provides the general characteristics of the panel of experts who participated in Round Two.

Table 6.2: General Characteristics of Round Two Experts.

Expert #	Gender	Age	Education level	Profession	Organization	Experience in mHealth (in years)
1	Male	30-40	Master's degree	Health Informatics	Non-governmental organization	10
2	Male	30-40	Doctoral Degree	Health Informatics	HIE	5
3	Male	41-50	Doctoral Degree	Health Informatics	HIE	6
4	Female	41-50	Master's Degree	Health Informatics	Ministry of Health	6
5	Male	30-40	Master's degree	Health Informatics	Ministry of Health	5
6	Female	51 and above 60 years	Doctoral Degree	Networking Expert	Governmental org	12
7	Male	41-50	Doctoral Degree	Software Engineer	HIE	10

8	Male	30-40	Master's Degree	Health Informatics	Addis Ababa city administration Health Bureau	7

Out of 59, 47 mHealth strategic activities for diabetes management were rated "relevant" or "very relevant" by more than 87.5% of the panel of experts (this meets the content validation criteria based on the I-CVI value, which is greater than 82%). 34 of the strategic activities achieved 100% consensus among panel experts.

Twelve strategic activities did not qualify for the next round (I-CVI ≤82%). Out of 12, seven strategic activities achieved the lowest panel expert consensus percentage. Only 62.5% agreed on the relevance of the strategic activities. The remaining five strategic activities achieved 75% of the panel expert consensus percentage.

Table 6.3 provides the number of experts, the percentage of consensus, and the decisions.

Table 6.3: Round Two: The Experts' Rating of the Relevance of mHealth Strategic Activities for T2DM Management

Strategy	Action	Activities	Number of experts in agreement	Percentage of Consensus	Decision
Strategy 1: Behavioural Change Communication Tool: SMS	Develop behavioural interventions and reminder messages for patients with type 2 DM	Develop Messages related to a healthy diet and nutrition	8	100%	Qualified
		Develop messages related to physical exercise	7	87.5%	Qualified
		Develop messages related to the prevention of disease complications	8	100%	Qualified
		Develop messages related to psychosocial supports*	5	62.5%	Not Qualified
	Maintain the quality of behavioural messages development	Involve experts, stakeholders, and patient associations during the SMS development	7	87.5%	Qualified
		Refer to national and international type 2 DM management guidelines	7	87.5%	Qualified
		Create a language switch option to provide a version based on the local language preference (translation to local languages)	8	100%	Qualified
		Create, revise, and update the SMS database	8	100%	Qualified
	Use messages tailoring techniques for behavioural intervention	3.1a. socio-demographic characteristics	8	100%	Qualified
		3.1b. previous DSM knowledge and practice	8	100%	Qualified
		3.1c. current health status	8	100%	Qualified
		3.1d. preferable time for receiving the SMS	8	100%	Qualified
		Use theory-based message tailoring techniques using theories with 4 to 5 constructs (Example: the trans-theoretical model of behavioural change (TTM))	7	87.5%	Qualified
	Implement behavioural interventions and	Design schedule for transmission of developed SMS to patients	8	100%	Qualified
		Start SMS content delivery from general informative messages	8	100%	Qualified

Strategy	Action	Activities	Number of experts in agreement	Percentage of Consensus	Decision
	reminders using SMSes	Continue the content delivery to develop self-management of specific behaviour	8	100%	Qualified
		The latent phase of content delivery shall focus on the maintenance of the behaviour	8	100%	Qualified
		Send At least one message/day during key behaviour change periods*	6	75%	Not Qualified
		Gradually decrease the SMS frequency to three to four SMSes per week during less acute phases (Moderate frequency)	7	87.5%	Qualified
	mHealth tool (SMS) features	SMSes to have 160 characters, including spaces, punctuations, and any branding or links to additional information	8	100%	Qualified
		Split into two text messages if necessary to accommodate additional content*	6	75%	Not Qualified
		Use well-known abbreviations sparingly*	6	75%	Not Qualified
		Consider the clients' literacy level	8	100%	Qualified
		The messages must be current (up-to-date)	8	100%	Qualified
		Use One-way (Person-to-person or P2P) SMS network trafficking	8	100%	Qualified
		Consider interactive, two-way (Application-to-person or A2P) SMS network trafficking ***(Long-term strategy)***	8	100%	Qualified
Strategy 2: Patient communication and support for Diabetes Self-management (DSM)	Remind for medication and clinical follow-up	Use voice calls to remind about compliance with medication	8	100%	Qualified
		Use voice calls to remind about compliance for clinical follow-up	8	100%	Qualified
	Create continuous communication with patients	Monitor patient progress by creating continuous communication using either voice calls or SMSes	8	100%	Qualified
		Use voice calls to communicate the treatment plan	7	87.5%	Qualified
		Use SMSes to communicate the treatment plan	7	87.5%	Qualified

Strategy	Action	Activities	Number of experts in agreement	Percentage of Consensus	Decision
		Provide patient counselling using voice calls	7	87.5%	Qualified
	Provide adequate decision support on DSM	Use SMSes to provide feedback based on patient clinical data.	7	87.5%	Qualified
		Use voice calls to provide feedback based on patient clinical data.	7	87.5%	Qualified
		Create a patient social support group to communicate and support each other through SMSes/social media*	5	62.5%	Not Qualified
		Use telemonitoring of blood glucose to support DSM*	5	62.5%	Not Qualified
Strategy 3: Maintain Personal Health Record (PHR)	Capture data (data collection)	Use biosensors to collect biomarkers from patients	7	87.5%	Qualified
		Use Bluetooth to connect mobile phones with biosensors	7	87.5%	Qualified
		Use other near-field communication tools as a backup for Bluetooth (Example: USB and WIFI) *	5	62.5%	Not Qualified
		Use voice calls to collect data remotely and transfer it to the central system using a mobile phone*	5	62.5%	Not Qualified
		Create a mobile interface for HCPs for data entry and integrate it with the Hospital EMR*	6	75%	Not Qualified
	Store patient data (data storage)	Use a central system of mHealth PHR to store data	8	100%	Qualified
		Use relational and non-relational databases for data storage at the central system	8	100%	Qualified
	Data transmission	Use SMSes for data transmission using the GSM (Cellular) transmission protocol*	6	75%	Not Qualified
		Use HTTP/HTTPS protocol to transfer collected data to the central platform in a web-based system	8	100%	Qualified
	Data monitoring (Use mHealth PHR application to monitor patients)	Create a data processing display system for data stored in the central database, allowing HCPs to monitor patients' data	8	100%	Qualified
		Create a graphical presentation for HCPs to track patterns and trends	8	100%	Qualified

Strategy	Action	Activities	Number of experts in agreement	Percentage of Consensus	Decision
		Provide statistics of collected patient data for HCPs to track patterns and trends	8	100%	Qualified
Strategy 4: Screening	Use the mHealth screening checklist	Develop a phone-based checklist for screening type 2 DM	8	100%	Qualified
		Use the phone-based screening checklist in a primary healthcare setting	8	100%	Qualified
	Use mHealth to improve screening and diagnostic rate	Use SMSes to remind the community of the importance of diabetes screening tests/early diagnosis*	5	62.5%	Not Qualified
		Use voice calls to remind patients to return for definitive screening tests*	5	62.5%	Not Qualified
Strategy 5: Treatment/Therapy plan	Implement a Clinical Decision Support System (CDSS)	Use mHealth PHR data processing system to plan treatment	8	100%	Qualified
		Provide knowledge-based support that could alert HCPs for critical issues (follow-up action and treatment plans)	8	100%	Qualified
		Use CDSS that allows HCPs to communicate the therapy plan through SMSes or mobile applications to the patients	8	100%	Qualified
	Create collaboration among healthcare professionals (HCPs)	Create health professionals' social group to communicate and support each other through SMSes/social media	8	100%	Qualified
		Create a teleconsultation service for HCPs to get consultations with senior experts/specialists (Using voice calls)	7	87.5%	Qualified
		Create access to an online referencing system for HCPs (for example, diabetes management guidelines)	8	100%	Qualified

**Strategic activities with I-CVI ≤82% (82% percentage of consensus) are not qualified for the Modified Delphi Round 3*

The panel of experts also rated the strategies suggested for addressing the challenges of implementing mHealth. Out of 39 strategies, 38 strategies were rated “very relevant” or “relevant” by more than 87.5% of the panel of experts (thus met the content validation criteria based on the I-CVI value, which is greater than 82%). Only one strategy under the usability challenge, *“The system design must be scalable,”* was not qualified for the Modified Delphi Round 3.

Table 6.4 provides the number of experts in consensus, percentage of consensus (I-CVI), and decisions.

Table 6.4: Round Two: The Experts' Rating of the Relevance of mHealth Strategies for Addressing Challenges

Challenges	Strategy	Number of experts in agreement	Percentage of Consensus	Decision
Address Interoperability Challenges	The system must be supported by IEEE 11073 Personal Health Devices (PHD) standard for data transmission from biosensors to the mobile phones	7	87.5%	Qualified
	Use Fast Healthcare Interoperability Resources (FHIR) using a Representational State Transfer (REST, often referred to as RESTful architectures) for structural interoperability	8	100%	Qualified
	The system shall use the HTTP protocol and the JSON (JavaScript Object Notation) data standard to exchange data between the mobile phones of health professionals and the central system	8	100%	Qualified
	The system shall support GSM (Cellular) data transmission protocol	8	100%	Qualified
	Employ HL7/FHIR standard for clinical messaging	8	100%	Qualified
	Provide basic interoperability with national e-health systems (EMR, DHIS2, LIS, HMIS, etc.)	8	100%	Qualified
	Employ open-software development standard	8	100%	Qualified
	Employ the International Classification of Diseases (ICD-11) standard for clinical terminology	8	100%	Qualified
	Employ Systemized Nomenclature of Medicine (SNOMED) standard for clinical data coding	8	100%	Qualified
	Integrate Logical Observation Identifiers Names and Codes (LOINC) standard for laboratories	8	100%	Qualified
	Integrate RxNorm for pharmacies	8	100%	Qualified
Address Security and Privacy Challenges (mHealth application for SMS/PHR/CDSS)	Use an authentication system for healthcare professionals and other users (three factors authentication) for access and data sharing	8	100%	Qualified
	Use advanced encryption standard (AES) for data sharing	8	100%	Qualified
	Use cryptographic mechanisms for maintaining data confidentiality	8	100%	Qualified
	The system shall include both synchronous and asynchronous data validation approaches	8	100%	Qualified
	Align with national eHealth security and privacy guidelines	8	100%	Qualified

Challenges	Strategy	Number of experts in agreement	Percentage of Consensus	Decision
Address usability challenges (mHealth application for SMS/PHR/CDSS)	The system must be easy to install	8	100%	Qualified
	The system must be easy to update	8	100%	Qualified
	The system must be easy to navigate	8	100%	Qualified
	The system must use an easy graphical interface	8	100%	Qualified
	The system must be easy to troubleshoot	8	100%	Qualified
	The system must be easy to exit either by uninstalling or unsubscribing	8	100%	Qualified
	The system must allow multilingual installation on a single application	8	100%	Qualified
	The user interface shall be kept simple by using the appropriate font type and size	7	87.5%	Qualified
	The system design must be scalable*	6	75%	Not Qualified
	Iterative development process to be used based on user feedback	8	100%	Qualified
Address user-related challenges	Usefulness: Increase awareness of HCPs related to the usefulness of diabetes-related mHealth	8	100%	Qualified
	Ease of Use: Capacitate health professionals' digital literacy on diabetes-related mHealth	8	100%	Qualified
	Create inter-professional relationships and collaboration in the utilization of diabetes-related mHealth	8	100%	Qualified
	Provide training and certification for health professionals in the application of diabetes-related mHealth as part of a continuous development programme (CPD)	8	100%	Qualified
	Make information on the diabetes-related mHealth application accessible to healthcare professionals and patients	8	100%	Qualified
	Prepare and disseminate the user guide for the developed mHealth system	8	100%	Qualified
	Prepare eLearning course on mHealth use and application	8	100%	Qualified
	Provide affordable internet incentives for HCPs to utilise mobile applications for diabetes management	7	87.5%	Qualified
Address resource challenges	Allocate adequate budget for mHealth implementation	8	100%	Qualified
	Expand the infrastructure for mHealth implementation	8	100%	Qualified

Challenges	Strategy	Number of experts in agreement	Percentage of Consensus	Decision
	Provide administrative support for HCPs to utilise mHealth for diabetes management	8	100%	Qualified
	Provide access to the internet for HCPs	8	100%	Qualified
	Provide incentives for HCPs to utilize mobile applications for diabetes management	7	87.5%	Qualified

**Strategies with I-CVI ≤82% (82% percentage of consensus) are not qualified for the Modified Delphi Round 3*

For some strategic activities, the experts provided remarks/reasons for providing the lowest rating for the strategic activities. For example, one of the strategic activities that achieved the lowest consensus percentage *was "Develop messages related to psychosocial support"* under strategy one. Two experts questioned the applicability of SMS to deliver psychosocial support since it required a complex intervention.

"Psychosocial supports are many and complicated to make them with short SMS and misunderstanding may happen." Panel Expert #2

Another strategic activity with a low agreement percentage was "*Send at least one message/day during key behaviour change periods"* under strategy one. One expert justified that by stating that a daily message could create fatigue for a patient considering the number of messages also received from Telcom vendors.

Table 6.5 provides the experts' remarks for strategic activities with a low agreement percentage.

Table 6.5: Panel of Experts' Remarks on the Strategic Activities with Low Rating

Disqualified activities	**Remarks from the experts**
Develop messages related to psychosocial support.	"Psychosocial supports are many and complicated to make them with short SMS and misunderstanding may happen." *Panel expert #2*
Send at least one message/day during key behaviour change periods.	"Concerned about fatigue with receiving dozens of SMS including telecom and other organisations SMS" *Panel expert #1*
Split into two text messages if necessary to accommodate additional content.	"I think one message content should be delivered with single text (splitting may vary the delivery time, and the patient may not receive adequate information to follow)" *Panel expert #2*
Use well-known abbreviations sparingly.	"It may not be feasible for customers" *Panel expert #3*
Use telemonitoring blood glucose to support DSM.	"There is the limitation on the telemonitoring on the availability of the smart application in local context and literacy level of patients" *Panel expert #5*

6.2.4 Round Three

In Round Three, the researcher revised the data collection tool used in Round Two by removing strategies with a low consensus percentage (I-CVI ≤82%). From the first section of the tool, 12 strategic activities were removed. Similarly, one strategy was removed from the second section. 47 strategic activities in the first section and 38 strategies in the second section were used to collect data in round three.

100 heterogenous experts were invited through email and face-to-face to rate their agreement on a five-point Likert scale, namely, 1= Strongly Disagree, 2=Disagree 3=Neutral, 4=Agree and 5=Strongly Agree.

Out of 100, 91 experts (87 professionals and four patients) responded to Round Three, with a 91% response rate. Most of the respondents were male, 58(63.7%), and in the 30-40 age group, 61 (67%). Regarding the educational level of professionals (n=87), 48 (55.2%) and 35 (40.2%) were holders of a BSc degree and an MSc degree, respectively. Out of 87 professionals, the majority were health informatics experts 31 (35.6%) and nurses 26 (29.9%). Most of the professionals (n=87) work in a health centre, 55 (63.2%), and in a Woreda Health Office, 12 (13.8%). Most of the experts had below 6 (60.9%) or 6-10 (32.2%) years of experience in mHealth-related activities. Table 6.6 provides the general characteristics of Round Three experts.

Table 6.6: General Characteristics of Round Three Experts

Variables	Response	Frequency	Percentage
Gender	Male	58	63.7%
	Female	33	36.3%
Age (in years)	20-30	13	14.3%
	30-40	61	67%
	41-50	14	15.4%
	Above 51	3	3.3%
Type of respondent	Professionals	87	95.6%
	Patients with T2DM	4	4.4%
Education level (Only for Professionals, n=87)	First Degree	49	56.3%
	Second Degree	35	40.2%
	Third Degree	3	3.4%
Profession (only for professionals, n=87)	Health informatics experts	31	35.6%
	Nurses	26	29.9%
	Public Health officers	9	10.3%
	Medical Doctors	14	16.1%

	ICT experts (Software engineering/networking)	7	8%
Organisation (only for professionals, n=87)	Health Centre	55	63.2%
	Woreda Health Office	12	13.8%
	Sub-city Health Office	9	10.3%
	Regional Health Bureau	4	4.6%
	Ministry of Health	2	2.3%
	HIEs	3	3.4%
	NGOs	2	2.3%
Years of experience in any mHealth/eHealth-related activities	Below 6 years	53	60.9%
	6-10 years	28	32.2%
	Above 10 years	6	6.9%

Out of 47, 45 mHealth strategic activities for diabetes management met the expected content validation criteria (I-CVI >80%) and were retained in the final strategies list. Twenty-eight of the strategic activities achieved 100% consensus among experts.

One of the strategic activities with the lowest consensus percentage was *"Consider interactive, two-way (A2P) SMS network trafficking" under strategy-1 (I-CVI=78%).* The other strategy with a low percentage consensus was ***"**Provide patient counselling using voice calls" under strategy-2 (I-CVI=75.8%).* These two strategic activities failed to meet the content validation criteria (I-CVI >80) and were removed from the final strategies list.

Table 6.7 provides the number of experts in consensus, the percentage of consensus, and the decisions.

Table 6.7: The Acceptability of mHealth Strategic Activities for T2DM Management

Strategy	Action	Activities	Number of experts in agreement	Percentage of Consensus	Decision
Strategy 1: Behavioural Change Communication Tool: SMS	Develop behavioural intervention and reminders messages for patients with type 2 DM	Develop messages related to a healthy diet and nutrition	91	100%	Qualified
		Develop messages related to physical exercise	91	100%	Qualified
		Develop messages related to the prevention of disease complication	91	100%	Qualified
	Maintain the quality of behavioural messages development	Involve experts, stakeholders, and patient associations during the SMS development	91	100%	Qualified
		Refer to national and international type 2 DM management guidelines	91	100%	Qualified
		Create a language switch option to provide a version based on the local language preference (translation to local languages)	91	100%	Qualified
		Create, revise, and update the SMS database	91	100%	Qualified
	Use messages tailoring techniques for behavioural intervention.	3.1a. socio-demographic characteristics	91	100%	Qualified
		3.1b. previous DSM knowledge and practice	89	97.8%	Qualified
		3.1c. current health status	91	100%	Qualified
		3.1d. preferable time for receiving the SMS	91	100%	Qualified
		Use theory-based message tailoring techniques using theories with 4 to 5 constructs (Example: the trans-theoretical model of behavioural change (TTM))	79	86.8%	Qualified
	Implement behavioural interventions and reminders using SMS	Design schedule for transmission of developed SMS to patients	91	100%	Qualified
		Start SMS content delivery from general informative messages	91	100%	Qualified
		Continue the content delivery to develop self-management of specific behaviour	91	100%	Qualified

Strategy	Action	Activities	Number of experts in agreement	Percentage of Consensus	Decision
		The latent phase of content delivery shall focus on the maintenance of the behaviour	91	100%	Qualified
		Gradually decrease the SMS frequency to three to four SMSes per week during less acute phases (moderate frequency)	91	100%	Qualified
	mHealth tool (SMS) features	SMSes to have 160 characters, including spaces, punctuations and any branding or links to additional information	91	100%	Qualified
		Consider the clients' literacy level	91	100%	Qualified
		The messages must be current (up-to-date)	91	100%	
		Use one-way (Person-to-Person or P2P) SMS network trafficking	91	100%	Qualified
		Consider interactive, two-way (Application-to-Person or A2P) SMS network trafficking*****	71	78%	Not Qualified
Strategy 2: Patient communication and support for Diabetes Self-management (DSM)	Remind for medication and clinical follow-up.	Use voice calls to remind compliance with medication	81	89%	Qualified
		Use voice calls to remind compliance for clinical follow-up	79	86.8%	Qualified
	Create continuous communication with patients.	Monitor patient progress by creating continuous communication using either voice calls or SMSes	91	100%	Qualified
		Use voice calls to communicate the treatment plan	83	91.2%	Qualified
		Use SMSes to communicate the treatment plan	79	86.8%	Qualified
		Provide patient counselling using voice calls*	69	75.8%	Not Qualified
	Provide adequate decision support on DSM.	Use SMSes to provide feedback based on patient clinical data.	91	100%	Qualified
		Use voice calls to provide feedback based on patient clinical data.	75	82.4%	Qualified
		Use biosensors to collect biomarkers from patients	73	80.2%	Qualified

Strategy	Action	Activities	Number of experts in agreement	Percentage of Consensus	Decision
Strategy 3: Maintain Personal Health Record (PHR)	Capture data (data collection)	Use Bluetooth to connect mobile phones with biosensors	81	89%	Qualified
	Store patient data (data storage).	Use a central system of mHealth PHR to store data	88	96.7%	Qualified
		Use relational and non-relational databases for data storage at the central system	82	90.1%	Qualified
		Use HTTP/HTTPS protocol to transfer collected data to the central platform in a web-based system	78	85.7%	Qualified
	Data monitoring (use mHealth PHR application to monitor patients).	Create a data processing display system for data stored in the central database, allowing HCPs to monitor patients' data	91	100%	Qualified
		Create a graphical presentation for HCPs to track patterns and trends	91	100%	Qualified
		Provide statistics of collected patient data for HCPs to track patterns and trends	91	100%	Qualified
Strategy 4: Screening	Use the mHealth screening checklist.	Develop a phone-based checklist for Screening type 2 DM	91	100%	Qualified
		Use the phone-based screening checklist in a primary healthcare setting	91	100%	Qualified
Strategy 5: Treatment/Therapy plan	Implement a Clinical Decision Support System (CDSS).	Use the mHealth PHR data processing system to plan treatment	87	95.6%	Qualified
		Provide knowledge-based support that could alert HCPs for critical issues (follow-up action and treatment plans)	91	100%	Qualified
		Use CDSS that allows HCPs to communicate the therapy plan through SMS or mobile application to the patients	79	86.8%	Qualified
	Create collaboration among Healthcare Professionals (HCPs).	Create health professionals' social group to communicate and support each other through SMS/social media	87	95.6%	Qualified

Strategy	Action	Activities	Number of experts in agreement	Percentage of Consensus	Decision
		Create a teleconsultation service for HCPs to get consultations with senior experts/specialists (using voice calls)	85	93.4%	Qualified
		Create access to an online referencing system for HCPs (for example, diabetes management guidelines)	91	100%	Qualified

**Strategies with I-CVI ≤80% (80% percentage of consensus) are removed from the final strategies list*

The experts also rated the strategies suggested for addressing the challenges of implementing mHealth. All 38 strategies met the content validation criteria based on the I-CVI value, which is greater than 80%. Thirty of the strategies achieved 100% consensus among experts.

Due to mHealth-related technical words and complex terms, the I-CVI for strategies under interoperability, security and privacy challenges are analysed based on the rating by 38 experts (excluding clinicians and patients). Table 6.8 provides the number of experts in consensus, percentage of consensus (I-CVI) and decisions.

Table 6.8: The Acceptability of mHealth Strategies to Address Challenges.

Challenges	Strategy	Number of experts in agreement	Percentage of Consensus	Decision
Address interoperability challenges (n=38)	The system be supported by IEEE 11073 Personal Health Devices (PHD) standard for data transmission from biosensors to the mobile phones	33	86.8%	
	Use Fast Healthcare Interoperability Resources (FHIR) using a Representational State Transfer (REST, often referred to as RESTful architectures) for structural interoperability	38	100%	
	The system shall use the HTTP protocol and the JSON (JavaScript Object Notation) data standard to exchange data between the mobile phones of health professionals and the central system	31	81.5%	
	The system shall support GSM (Cellular) data transmission protocol	38	100%	
	Employ HL7/FHIR standard for clinical messaging	38	100%	
	Provide basic interoperability with national e-health systems (EMR, DHIS2, LIS, HMIS, etc.)	38	100%	
	Employ open-software development standard	38	100%	
	Employ the International Classification of Diseases (ICD-11) standard for clinical terminology	38	100%	
	Employ Systemised Nomenclature of Medicine (SNOMED) standard for clinical data coding	38	100%	
	Integrate Logical Observation Identifiers Names and Codes (LOINC) standard for laboratories	36	94.7%	
	Integrate RxNorm for pharmacies	38	100%	
Address security and privacy challenges (mHealth application for SMS/PHR/CDSS) (n=38)	Use an authentication system for healthcare professionals and other users (three factors authentication) for access and data sharing	38	100%	
	Use advanced encryption standard (AES) for data sharing	38	100%	
	Use cryptographic mechanisms for maintaining data confidentiality	34	89.4%	
	The system shall include both synchronous and asynchronous data validation approaches	38	100%	
	Align with national eHealth security and privacy guidelines	38	100%	

Challenges	Strategy	Number of experts in agreement	Percentage of Consensus	Decision
Address usability challenges (mHealth application for SMS/PHR/CDSS) (n=91)	The system must be easy to install	91	100%	Qualified
	The system must be easy to update	91	100%	Qualified
	The system must be easy to navigate	91	100%	Qualified
	The system must use an easy graphical interface	91	100%	Qualified
	The system must be easy to troubleshoot	91	100%	Qualified
	The system must be easy to exit either by uninstalling or unsubscribing	91	100%	Qualified
	The system must allow multilingual installation on a single application	91	100%	Qualified
	The user interface shall be kept simple by using the appropriate font type and size	91	100%	Qualified
	Iterative development process to be used based on user feedback	89	97.8%	Qualified
Address user-related challenges (n=91)	Usefulness: Increase awareness of HCPs related to the usefulness of diabetes-related mHealth	91	100%	Qualified
	Ease of Use: Capacitate health professionals' digital literacy on diabetes-related mHealth	91	100%	Qualified
	Create inter-professional relationships and collaboration in the utilisation of diabetes-related mHealth	91	100%	Qualified
	Provide training and certification for health professionals in the application of diabetes-related mHealth as part of a continuous development programme (CPD)	91	100%	Qualified
	Make information on the diabetes-related mHealth application accessible to healthcare professionals and patients	91	100%	Qualified
	Prepare and disseminate the user guide for the developed mHealth system	91	100%	Qualified
	Prepare an eLearning course on mHealth use and application	89	97.8%	Qualified
	Provide affordable internet incentives for HCPs to utilise mobile applications for diabetes management	87	95.6%	Qualified
Address resource challenges (n=91)	Allocate adequate budget for mHealth implementation	91	100%	Qualified
	Expand the infrastructure for mHealth implementation	91	100%	Qualified
	Provide administrative support for HCPs to utilise mHealth for diabetes management	91	100%	Qualified

Challenges	Strategy	Number of experts in agreement	Percentage of Consensus	Decision
	Provide access to the internet for HCPs	91	100%	Qualified
	Provide incentives for HCPs to utilise mobile applications for diabetes management	85	93.4%	Qualified

**Strategies with I-CVI ≤80% (80% percentage of consensus) are removed from the final strategies list*

6.3 PRESENTATION OF FINAL STRATEGY AND DISCUSSION

This final strategy is based on scientific evidence and full expert opinion. It is meant to draw attention to technical and organisational factors that need to be considered when implementing mHealth initiatives.

6.3.1 Overall Aim

The overall aim of these strategies is to make a strong case for the implementation of mHealth to manage diabetes in primary healthcare facilities. The study assumes that these strategies could be a starting point for the policymakers and recognise that some related issues may need further exploration. Central to the proposed mHealth strategy is the effective management of diabetes.

6.3.2 Scope and Implementation of the Strategies

The strategies are designed for HCPs working in a primary healthcare setting in Addis Ababa, Ethiopia. The strategies could also be used for settings like Addis Ababa and urban primary healthcare settings in Ethiopia. Though, this required careful consideration of the setting and the infrastructure requirements.

It is evident that the implementation of mHealth falls within the mandate of the Federal or regional governments or NGOs in collaboration with the sub-city, Woreda Health Offices, and Health Centres.

6.3.3 Components of the Final Strategies.

The Final strategies are categorized into two components. The study's theoretical framework (TAM and IDT) guided the organisation of the structure of the strategies. The first component focuses on strategies to investigate the opportunities and use of mHealth for T2DM management by considering the evidence, perceived usefulness of HCPs, and validation of experts.

The second component is focuses on strategies for addressing challenges for effective implementation of mHealth to ensure ease of use and reduce the complexity of mHealth interventions (perceived ease of use/complexity). Table 6.9 provides the components and strategies of mHealth.

Table 6.9: Components and List of Validated Strategies

Component	Strategies
mHealth opportunities/uses for T2DM management	Strategy 1: Behavioural Change Communication
	Strategy 2: Patient communication and support for Diabetes Self-management (DSM)
	Strategy 3: Maintain Personal Health Record (PHR)
	Strategy 4: Screening
	Strategy 5: Treatment/Therapy plan
Addressing Challenges for effective mHealth implementations	Strategy 6: Enhance Interoperability of diabetes mHealth
	Strategy 7: Establish privacy and security features for diabetes-related mHealth
	Strategy 8: Enhance the usability of diabetes-related mHealth
	Strategy 9: Capacitate HCPs in the application of mHealth for T2DM management
	Strategy 10: Improve availability and adequacy of mHealth resources

6.3.4 Component One: mHealth Opportunities/uses for Diabetes Management

The overall strategic aim of component one is to improve the capacity of HCPs in T2DM management using mHealth interventions. The strategies, strategic action, and strategic activities validated to achieve this major aim are discussed here:

6.3.4.1 Strategy 1: Behavioural Change Communication

Patient behaviour toward overall T2DM management and DSM is a significant factor for positive clinical outcomes. Because T2DM management is primarily a behavioural issue that necessitates ongoing self-management practice, the importance of specific BCC in improving health outcomes cannot be overstated. (El-Gayar et al., 2021:2). BCC for diabetes is designed to "*reduce the burden of diabetes on individuals, families, communities and healthcare systems, and, by supporting good health, prevent or delay the onset of diabetes-related long-term complications*". (Mc Laughlin, Chaney, Belton & Garst, 2015:5).

Thus, the BCC strategy targeted provisions of BCC intervention remotely for patients with type 2 DM using mHealth. The expected outcome is to enhance the patients' knowledge of diabetes management and clinical outcomes. The mHealth tool identified for BCC intervention is SMSes to achieve the objectives. As indicated in the integrated findings, SMSes are the most applicable, convenient, and cheap tool for the provision of BCC for patients with T2DM. The strategic actions and activities under Strategy 1 are described here.

6.3.4.1.1 Strategic action 1.1: Develop behavioural intervention messages for patients with diabetes

The development of SMS behavioural change communication (BCC) messages for patients with Type 2 Diabetes Mellitus (T2DM) should address critical areas of diabetes management to bring the desired behavioural changes and subsequent improvement of health status. The BCC messages for patients with T2DM address three key areas: Healthy eating, physical activity, and prevention of diabetic complications.

Healthy eating is an essential component of diabetes self-management (DSM) behaviour (Banerjee, Chakraborty & Pal, 2020:352; Chester et al., 2018:642). It is recommended as the first step because it is the most difficult aspect of T2DM management (Sami, Ansari, Butt & Ab Hamid, 2017:68). Healthy eating and diet management improve glycemic control and prevent diabetic complications. Despite this fact, healthy eating habits are lacking among T2DM patients in developing countries (Stephani, Opoku & Beran, 2018:8; Suglo & Evans, 2020:13). Healthy eating (healthy diet and nutrition) includes food preparation, carbohydrates counting, label reading, food shopping, monitoring food portions, using a diet plan, and following nutritional guidelines.

Ethiopia also included patient education on healthy eating in the national noncommunicable disease (NCD) management guidelines. The guidelines stated that the guiding principles of BCC for healthy eating for patients with T2DM are:

- Energy balance.
- Maintaining adequacy and quality of micronutrients and macronutrients.
- Contextualising diet plans with culture, religion, and socioeconomic status.
- Making starchy foods the foundation of all meals and frequent use of high-fibre foods, such as vegetables and fruits, cereals, and whole grains, such as wheat, barley, rice, and corn.

- Reducing the intake of fatty foods (encouraging low animal fat) and discouraging the intake of simple sugars (Ministry of Health-Ethiopia, 2016:38).

Generally, these national and international guidelines and evidence-based recommendations should be considered in developing SMS messages related to healthy eating. The healthy eating SMS contents should include practical diets or meal planning methods like plate method and portion size rather than focusing on individual macro- or micronutrients.

Healthy eating SMS content development should also consider the socio-economic and food security status of patients with T2DM (Tezera et al., 2022). According to Tezera et al. (2022:6), around 50% (n=305) of patients with T2DM in Addis Ababa, Ethiopia, were food insecure, and it is challenging for the food-insecure patient to follow the recommended dietary plan (Gordon, 2022:178). Healthy eating SMS contents for food-insecure patients with T2DM should be tailored to their income and living situation (Gucciardi, Vahabi, Norris, Del Monte & Farnum, 2014:329; Ministry of Health-Ethiopia, 2016:38; Tezera et al., 2022:11).

Another SMS development area for BCC is physical activity content. Healthy eating and physical activities are the key BCC areas included in the American Association of Diabetes Educators' recommendations (Davis, Fischl, Beck, Browning, Carter, Condon, Dennison, Francis, Hughes & Jaime, 2022:S33) and Ethiopia's national NCD management guidelines (Ministry of Health-Ethiopia, 2016:38).

Physical activity is regarded as a keystone of DSM for patients with T2DM and especially if they are overweight or obese (Zhao, He, Zeng & Cheng, 2021:10). Physical activity has been demonstrated to improve glycemic control of patients with T2DM by increasing insulin sensitivity and glucose tolerance (American Diabetes Association, 2020:S33; International Diabetes Federation, 2019b:35).

A structured physical activity plan (physical exercise) includes aerobic and resistance exercises. Aerobic exercise is a repeated movement of large muscles with adequate oxygen supply, and resistance exercise is an intense-training workout in which some form of resistance is used (American Diabetes Association, 2020:S33; Hurst, Weston, McLaren & Weston, 2019:1711). Current guidelines recommend that patients with

T2DM conduct aerobic exercises at least 150 minutes per week and resistance training at least 60 minutes of two sessions per week (Harrington & Henson, 2021:35; World Health Organization, 2020:10). Similarly, the Ethiopian National NCD management guidelines outline recommendations for patient education for structured physical activity. The guide recommends aerobic exercise with moderate intensity for at least 3 to 5 days per week for 30 minutes or 150 minutes/per week. The guide also recommends resistance training three times per week specifically for patients with T2DM (Ministry of Health-Ethiopia, 2016:38). Thus, the physical activity SMS contents should be developed based on the above recommended aerobic and resistance exercises.

The third area of BCC content for SMSes is the prevention of diabetic complications. As clearly stated in clinical guidelines, improvement in glycemic control majorly contributes to reducing complications associated with T2DM (Beck, Riddlesworth, Ruedy, Ahmann, Haller, Kruger, McGill, Polonsky, Price & Aronoff, 2017:367; Davis et al., 2022:S33). That is why the SMS messages on preventing complications need to focus on mechanisms for continuous monitoring of glycemic levels.

The Ethiopian national guidelines recommend that patient education focuses on encouraging patients to practice self-blood glucose monitoring (SBGM) using a glucometer at home. The messages should be tailored to the glucometer's availability and the patient's living conditions. The guidelines also recommend including messages on control of hyperglycaemia and interpretation for the level of controlled glycemia (Ministry of Health-Ethiopia, 2016:39). This should be accompanied by additional messages on the importance of seeking clinical care in case of hyperglycaemia (increased blood sugar level). For example, the WHO 2017 guidelines outlined two BCC messages for the prevention of complications (World Health Organization, 2017:2):

1) If you discover that your blood sugar level is too high, see a doctor as soon as possible.
2) Even if you do not have any symptoms, organ damage is already occurring, which can lead to death.

The SMS BCC messages on preventing complications should also include signs and symptoms of T2DM complications and how to prevent the complications. The importance of medication and clinical follow-up compliance for preventing complications must also be included in the SMS BCC message.

6.3.4.1.2 Strategic action 1.2: Maintain the quality of behavioural messages development

The effectiveness of diabetes management and achieving expected behavioural change and clinical outcomes depend on the quality of SMS behavioural change communication (BCC) messages. According to pieces of evidence, there is a lack of rigour, evidence, and the inclusion of experts in SMS content development in mHealth interventions for T2DM management (Abroms et al., 2015:7-8; MacPherson, Cranston, Johnston, Locke & Jung, 2021:8; Willoughby & Furberg, 2015:362). Thus, different key activities must be completed to improve the quality of SMSes and the mHealth intervention for T2DM management.

One of the most important activities is to include senior experts, HCPs, policymakers, governmental and non-governmental organisations, Higher Education Institutes (HIEs), Professional Associations, and Ethiopian Diabetic Patients associations in developing SMS BCC messages. Another action point for maintaining quality is using different reference materials and evidence, including national and international clinical guidelines and literature, in developing SMS BCC messages. These inputs sought from the stakeholders, and reference materials enhance the SMS quality and ensure the validity of the SMS BCC contents.

Studies categorised the above SMS development approach as formative development. The formative development could be conducted in different phases. However, the centrepiece is that SMS messages are developed by a content experts team including senior clinicians, researchers, and patients with T2DM, and SMS messages are developed based on local/international guidelines and literature recommendations (Gatwood, Balkrishnan, Erickson, An, Piette & Farris, 2014:3; MacPherson et al., 2021:4; Owolabi, Goon & Ajayi, 2019:4-5). Sometimes end-users and additional stakeholders could be invited in the next phase to evaluate the developed messages and to make appropriate revisions (Gatwood et al., 2014:3). This means the development of SMS BCC messages development should be iterative and continuous.

In counties like Ethiopia, the presence of a multilingual population makes it difficult to design SMS BCC content in one common language. It is well known that most of the Addis Ababa population uses the Amharic language for communication; however, careful assessment should be conducted to identify the need to translate the SMS BCC messages to other common local languages. Development and translation of messages into local languages is common among studies conducted in multilingual populations or multiple countries (Buchholz, Sandi, Ingram, Welch & Ocampo, 2015:2-3; Leon, Namadingo, Cooper, Bobrow, Mwantisi, Nyasulu, Sicwebu, Crampin, Levitt & Farmer, 2021:3; Owolabi et al., 2019:4; Watterson, Rodriguez, Shortell & Aguilera, 2018:2-3). For example, a study conducted in sub-Saharan Africa translated the English version into three languages (Chichewa, isiXhosa, and Afrikaans) (Leon et al., 2021:3). Thus, before the development of SMS BCC messages, adequate assessment should be conducted among patients with T2DM in Addis Ababa to identify their language preference and to consider the translation of the message into the identified common languages. The pre-assessment is important to identify and invite language experts during development or to allocate a budget for translation by professional bodies.

The other key activity for maintaining quality SMS BCC messages development is creating an SMS bank/database. The SMS development activity should be conducted regularly and continuously, and the SMS output of each development phase should be organised by creating a database or SMS bank. Since T2DM management is continuously evolving, there is a need to make regular revisions to refine and update the SMS content database/bank. Figure 6.2 summarises the validated activities for maintaining the Quality of BCC SMS messages development.

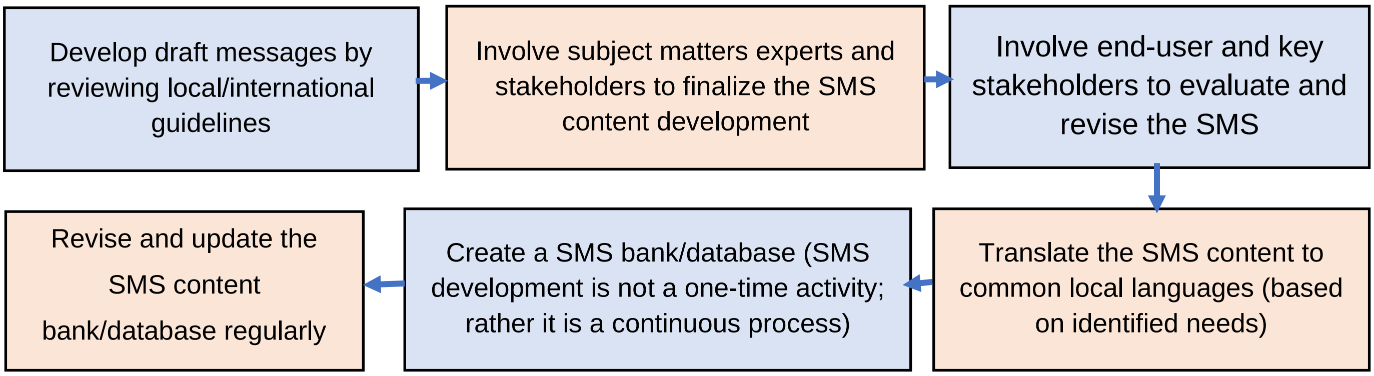

Figure 6.2: Maintaining the Quality of Behavioural Messages

6.3.4.1.3 Strategic Action 1.3: Use messages tailoring techniques for behavioural intervention

As discussed in Chapter 5, behavioural change communication (BCC) SMS messages tailored to theoretical constructs or non-theoretical characteristics outperformed SMSes not targeted at theoretical constructs or non-theoretical variables (El-Gayar et al., 2021:10; Liu, 2018:15). That is why the development of SMSes should be guided by behavioural theory and consider other important characteristics of patients with T2DM.

The non-theory variables/characteristics validated by this study for SMS tailoring are socio-demographic characteristics, previous DSM knowledge and practice, current health status, and preferable time for receiving the SMS. The SMS BCC messages tailored based on individual characteristics would motivate the patients to make the appropriate behavioural changes since the messages are directly related to their current conditions.

The significance of these tailoring techniques is unarguable since they target the actual individual gap in DSM behaviours, and tailored feedback could be easily disseminated to improve or maintain the patient's current health status. SMS tailoring based on the time preference of patients is also important since it improves readability and reduces the psychological burden for patients.

In addition to the non-theory tailoring, the BCC SMS message development in the local context for patients with T2DM should also use theory-based tailoring techniques to improve effectiveness in behavioural changes and clinical outcomes. The most difficult task for the content expert team during the development of SMSes using theory-based tailoring techniques is to select one or a combination of behavioural theories. To simplify the selection of specific or combination behavioural theory, the content experts' team should identify the primarily targeted behavioural changes. Then, the team should carefully review the appropriateness of each behavioural theory and its constructs (4 to 5 constructs are recommended) to achieve the targeted behavioural changes and associated clinical outcomes (El-Gayar et al., 2021:10; Michie & Prestwich, 2010:7; Noar, Benac & Harris, 2007:670).

Once the targeted outcome is determined and a specific behavioural theory is selected, the content expert team could adopt Kreuter's five-step tailored message development (Kreuter, Strecher & Glassman, 1999:276-281) or other applicable procedures. Kreuter's five-step process is effectively customised and used by Gatwood et al. (2014:3) for developing tailored SMS messages targeting T2DM management (Gatwood et al., 2014:3). Kreuter's five-step includes (1) Problem identification using the behavioural theory, (2) assessment tool creation on behavioural theory and predictors identified in Step 1, (3) tailored message creation, (4) message storage in electronic format (example Microsoft Excel), and (5) tailoring algorithm development on the software (example Microsoft Excel) using theory constructs and important characteristics identified for non-theory-based tailoring (Gatwood et al., 2014:3; Kreuter et al., 1999:280). These steps could be adopted and customised to develop tailored BCC SMS messages in local contexts.

6.3.4.1.4 Strategic Action 1.4: Implement behavioural interventions using SMSes

The next action point is the implementation of BCC SMS interventions among patients with T2DM. The initial activity that should be completed before implementing the interventions is developing an SMS transmission schedule. The schedule should consider the logical sequences and coherence of the SMS contents, the message frequency, and the preferable time for transmission.

The SMS strategies should be sequenced from low to high, considering the complexity of the concepts (Gatwood et al., 2014:9). As shown in this study, the transmission should start with simple general informative SMS messages. After that, the SMS contents developed to self-management of specific behaviour should be forwarded. The order of these SMS contents targeted specific behaviour, determined by the construct of the behaviour theories used for tailoring the SMS (Gatwood et al., 2014:9).

In the final stage of the intervention, the SMS content delivery should focus on maintaining the behaviour. The logical sequence should be designed separately for individual patients if non-theory-based tailoring is used in the SMS development.

The SMS transmission frequency is the other entity of the SMS schedule. As validated in this study, the SMS frequency should decrease gradually, and 3 to 4 SMSes per week should be transmitted during the less acute phase. Generally, a moderate SMS frequency should be considered during the schedule design and implementation of SMS intervention to avoid fatigue among patients due to a load of SMSes (Abroms et al., 2015:4).

6.3.4.1.5 Strategic Action 1.5: Enhance mHealth tool (SMS) features

The simplicity and appropriateness of the SMS feature significantly impact the usability and effectiveness of BCC SMS interventions. Careful considerations should be taken of the number of SMS characters, patient literacy level, message content and selection of SMS traffic networking during the development and implementation of the intervention.

The contents of the BCC SMS should not exceed 160 characters, including patient identification, spaces, punctuation and any branding or links to additional information. This restriction on the number of characters is critical in ensuring SMS delivery via a single mobile phone text message (Gatwood et al., 2014:8).

Adequate assessment should be conducted to identify the literacy level of patients with T2DM. In practice, the patient’s literacy level could be considered in the development tailoring algorithm; to ensure SMSes are developed and provided based on the understanding level of the patient. An alternative solution should be in place for a patient with no education or who cannot read text messages. For example, a literate family or anyone who can help the patient could be contacted to see if it is possible to send the SMS through a second person. This is also commonly used for a patient who does not own a mobile phone. Another strategy is to use a text-to-speech converter depending on the patient's mobile phone feature. Otherwise, voice calls could replace SMSes to provide BCC interventions.

As described in Chapter 5, the P2P (Non-Automated) messages are inexpensive and effective in improving glycemic control. The P2P SMS trafficking networking should be used for transmitting BCC SMS messages. This improves the strategy's feasibility since it only requires a basic mobile phone for implementation. Figure 6.3 provides a summary of strategy 1.

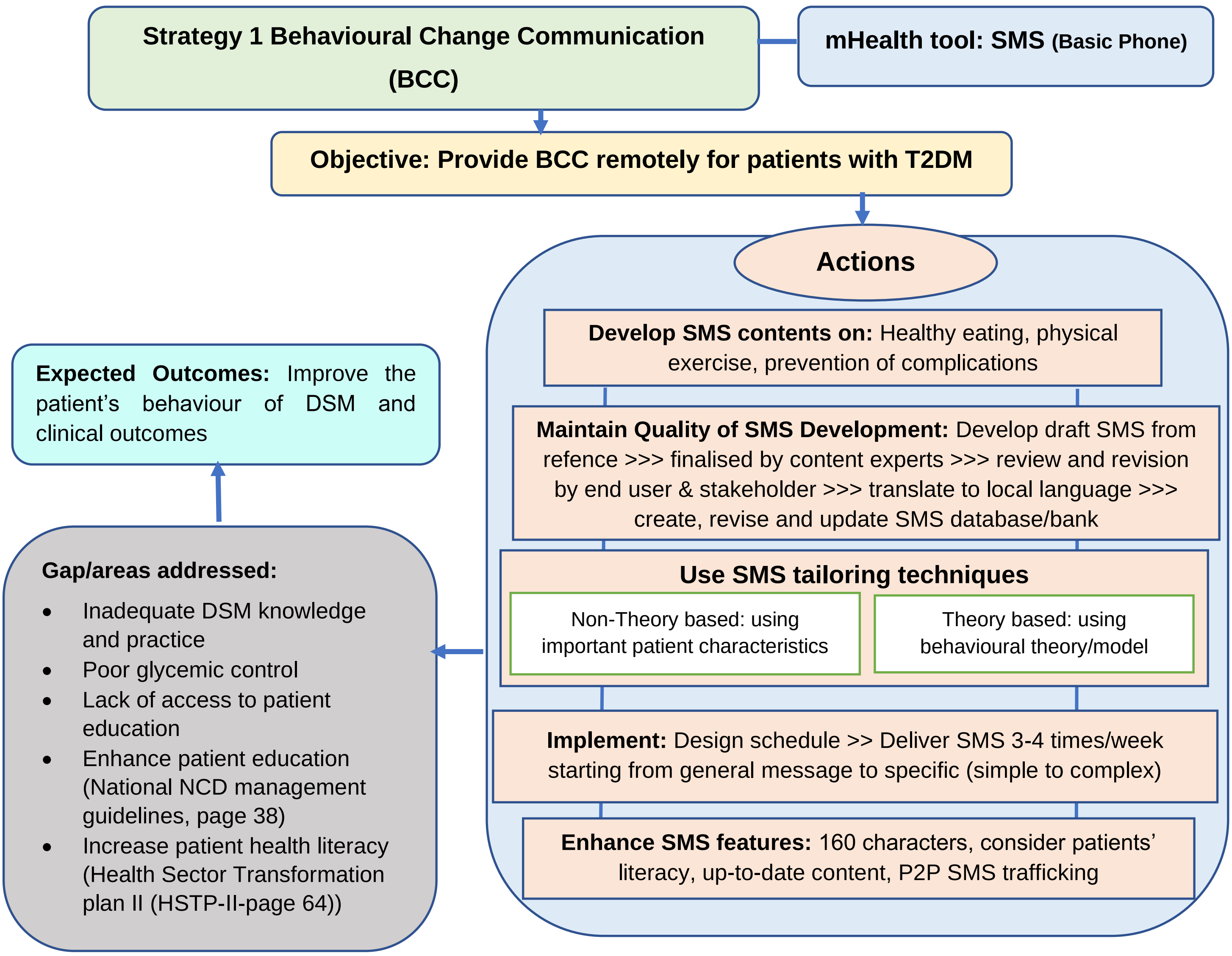

Figure 6.3: Strategy 1: Behavioural Change Communication

6.3.4.2 Strategy 2: Patient Communication and Support for Diabetes Self-management (DSM)

Despite different approaches to improve T2DM management, the diabetes self-management (DSM) level is still very low in low and middle-income countries. According to the systematic review in Ethiopia, the pooled prevalence of poor DSM practice among patients with T2DM was 51% (Ketema, Leshargie, Kibret, Assemie, Alamneh, Kassa & Alebel, 2020:4). Another similar systematic review study reported 49.8% of poor DSM practice among patients with T2DM in Ethiopia (Habebo et al., 2020:627). Poor communication between HCPs and patients (Adhikari, Devkota & Cesuroglu, 2021:13) and insufficient HCP support for patients are the major factors mentioned in studies (Alexandre, Campbell, Bugnon, Henry, Schaub, Serex, Elmers, Desrichard & Peytremann-Bridevaux, 2021:1110; Saunders, 2019:54). According to evidence, enhanced HCP-Patient communication and provision of tailored support is a key factor for creating collaboration, improving medication adherence, treatment follow-up, DSM practice and clinical outcomes (Greenwood et al., 2017:1020-1021; Holmen et al., 2017:9).

It is the role of HCPs to establish continuous communication and support to enhance patients' DSM practice. In Stragy-1, BCC interventions using SMSes were explored to improve DSM practice, though that could not be adequate alone to improve the DSM practice and clinical outcomes. Due to the stresses of daily life and information overload, patients are becoming increasingly distracted, making it easier than ever for patients to forget things. As a result, compliance with medication, clinical follow-up, and glucose monitoring could be poor unless an additional support mechanism is designed for patients with T2DM.

The patient communication and support strategy is targeted to ensure adequate communication and support on the DSM. The expected outcome is enhanced patient-HCP communication and improved DSM practice of patients with T2DM. To achieve the objectives, the mHealth tool identified for patient communication and support strategy are voice calls and SMSes. As indicated in integrated findings and supported by evidence, voice calls, and SMSes are the most appropriate, cost-effective tools for communicating and providing support for patients in T2DM. The strategic actions and activities in Strategy 2 are described below.

6.3.4.2.1 Strategic Action 2.1: Reminders for Medication and Clinical Follow-up

Poor compliance with medication worsens the disease and increases mortality, putting a significant financial burden on the patient with T2DM and the healthcare system (American Diabetes Association, 2018a:927). Thus, effective action should be taken to improve medication compliance. The validated action is to use voice calls to remind patients of their medication and the importance of medication adherence for T2DM management.

As discussed in Chapter 5 and supported by evidence, a voice call for reminders to take and refill medication is an effective strategy for improving medication compliance (Yasmin, Banu, Zakir, Sauerborn, Ali & Souares, 2016). One of the benefits of a voice call is that it does not require patients to be literate. The HCP could call the patient directly, or an automated call could be made using pre-recorded messages. According to evidence, human calls (calls by HCPs) are more effective in improving glycemic control (Hu et al., 2019:411; Huang et al., 2015:R99).

During the design and implementation of voice calls for a reminder of medication, the following points should be considered:

- Consider the voluntariness and time preference of patients with T2DM to receive the voice call reminder.
- Address the barriers (especially behavioural) for medication non-compliance during the voice call conversation.
- Rather than simply transmitting the reminder, the voice call should allow patients to pose questions or any concerns.
- Regularly monitor the voice call and collect feedback from the patients. The feedback should be used to revise the voice call implementations.

Consider the features of the patients' mobile phones to check the applicability of automated voice calls. Direct voice calls by HCPs increase motivation and a sense of responsibility to apply the recommendations effectively. In contrast, an automated call is cost-effective for reaching a large group of patients at once. A direct call by HCPs is preferable, although technological aspects and patients' preferences should be considered for choosing a direct voice call or an automated call.

Another action point is using voice calls to remind about clinical follow-ups. A voice call reminder for clinical follow-up is a telephone message that reminds patients of upcoming clinical care appointments. A voice call is a simple, effective, and cost-efficient method to improve compliance with clinical follow-ups and improve T2DM management. As discussed in the previous chapter and supported by evidence, a voice call reminder for clinical follow-up improves compliance with clinical care, "no-show" rates, and clinical outcomes (Ali-Ahmed & Halalau, 2016:235).

An automated call could be appropriate for clinical follow-up reminders to reduce the burden for HCPs. If an EMR is available or in long-term use, the automated call could be tethered with the EMR to detect subsequent appointments and make an automatic call. However, Vang et al. (2020:1318) argue that the HCP's direct reminder call enables patients to interact with the HCP, which could create a strong relationship between the patient and the HCP. Like the voice call reminder for medication, direct versus automated call selection depends on the patients' mobile phone features, preferences, and availability of resources.

The voice call reminders should be short and clear to reduce patient fatigue. Steiner et al. (2018:382) recommend using two voice call reminders. This includes one early reminder to allow patients to reschedule their activities (McLean, Booth, Gee, Salway, Cobb, Bhanbhro & Nancarrow, 2016:493) and another one day before to ensure the patients have scheduled appointments (Steiner et al., 2018:382). The voice call should be made during working hours. The patients' time and reminder frequency preference should be considered in designing the voice call intervention. Teo et al. (2021:127) recommend keeping the reminder messages short and simple and giving patients control over reminders.

6.3.4.2.2 Strategic Action 2.2: Create Continuous Communication with Patients

The use of voice calls and SMSes for enhancing communication is evident in the literature, and it is vital to create stronger bonds and collaboration between HCPs and patients with T2DM. This could lead to improved DSM and clinical outcomes.

The major activity validated in this study is using voice calls or SMSes to create continuous communications with patients with T2DM. This could create an opportunity for HCPs to monitor the patients' progress. It also enables HCPs to provide patient-centred and collaborative care by involving patients through SMSes/voice calls. Collaborative and patient-centric approaches are regarded as highly effective and modern for achieving the highest level of care (Asmat, Dhamani, Gul & Froelicher, 2022:14; Nurchis, Sessa, Pascucci, Sassano, Lombi & Damiani, 2022:8).

Implementing this strategic action does not require much investment since the basic mobile phones owned by HCPs and patients could be used. Though, administrative support, including airtime and allocating time for communication, should be provided for HCPs to implement the strategic action effectively.

6.3.4.2.3 Strategic Action 2.3: Provide Adequate Decision Support on Diabetes Self-management

Another action point for Strategy 2 is using mHealth by HCPs to provide decision support for patients with T2DM, also called tele-coaching. The use of mHealth decision support also positively affected DSM practice and clinical outcomes (Odnoletkova et al., 2016:7; Odnoletkova, Goderis, Nobels, Aertgeerts, Annemans & Ramaekers, 2014:8). The most used tools validated by this study are voice calls and SMSes.

The first aspect of mHealth decision support is gathering evidence depending on the patient's mobile phone features and the availability of a glucometer, and a system should be created to remotely collect clinical data and daily activities of patients, which is available for the HCP team for analysis and monitor patients' progress. After analysing the data either electronically or manually, the HCPs should develop tailored feedback based on the analysed patients' data. Alternatively, a comprehensive guide with feedback for each possible scenario could be developed and used to prepare tailored feedback. As discussed in Chapter 3, voice calls could be used by HCPs to collaborate with the patient, discuss their condition, and transmit tailored feedback.

Another alternative is SMSes, and once the tailored feedback is prepared, the HCPs could use an SMS to transmit feedback on how to manage their conditions. The SMS should only transmit feedback or decision support; a voice call is more appropriate if collaboration and further discussions are required with the patients. Additionally, HCPs could use the SMS service to receive remotely collected data from patients with T2DM (Shan, Sarkar & Martin, 2019:884).

The use of mHealth for decision support of patients with T2DM should consider the following points:

- The intervention should be contextualised based on the availability of resources: a glucometer, data analysis technology, and a guide for feedback preparations.
- Check the reliability and validity of data remotely collected by patients.
- Continuous monitoring and revision of the interventions by including feedback from patients.

Figure 6.4 summarizes strategy 2.

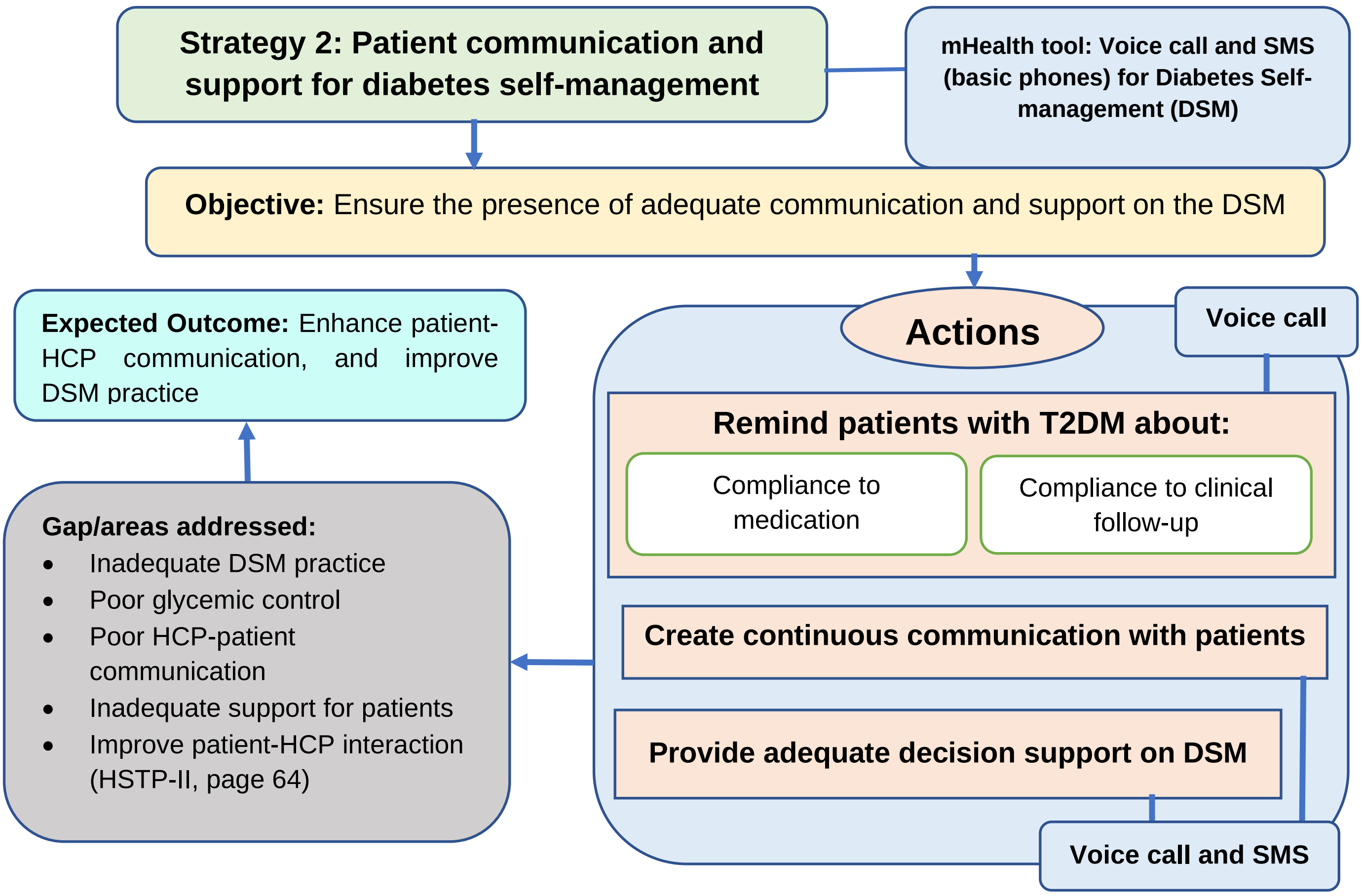

Figure 6.4: Strategy 2: Patient Communication and Support for DSM

6.3.4.3 Strategy 3: Maintain Personal Health Record (PHR)

As discussed in Chapters 5 and 3, mHealth PHR is health-related data captured by HCPs (or Patients) to help manage T2DM (Jung, 2021:98). The mHealth PHR purpose could vary depending on the development target. Some PHRs have only targeted the patients, and the patients are responsible for generating data and using the output for DSM. The other purpose of PHR is to create collaboration between the HCP team and patients. The data could be generated both by the HCPs and patients and even sometimes, it could be tethered to EMR. The purpose of such mHealth PHR is to assist HCPs in collecting, storing, and monitoring patients' data. The use of mHealth for maintaining patient data is crucial for developing countries like Ethiopia due to the poor quality of medical data (Endriyas, Kawza, Alano & Lemango, 2022:6; Getachew, Teka, Birhanu & Abraham, 2022:5).

The PHR strategy aims to use mHealth for data collection, storage, and monitoring in T2DM management. The expected outcome is improving data quality, use and clinical outcomes. The mHealth tool ranges from simple digital forms to more comprehensive PHR applications. As discussed in Chapters 3 and 5, the mHealth PHR has proven to be effective in maintaining data quality and improving the clinical outcomes of patients with T2DM. The strategic actions and activities validated by Strategy 3 are described below.

Since the comprehensive mHealth PHR requires advanced technologies and access to smartphones by HCPs and patients, the strategic activities should be considered a long-term strategy and could be implemented progressively by starting from simple digital forms.

6.3.4.3.1 Strategic Action 3.1: Capture Data (Data Collection)

The mHealth tool proposed for capturing data is a biosensor. An mHealth PHR with multi functionalities includes web-based and application-based data entry methods for collecting patients' data. This strategic action focuses on using biosensors connected to mHealth to capture clinical data (commonly glucose level). The biosensors should be able to connect with the mHealth tool or mobile devices using Bluetooth.

Patient data capturing using a biosensor enables HCPs to monitor patients' health status continuously and remotely. The HCP could also use a mHealth biosensor for capturing data, and in mHealth-PHR tethered with an EMR system, ease data collection and transmission. As discussed earlier, the data collection and transmission process could differ depending on the mHealth tool type. For example, Figure 6.5 describes two different processes or ways to use data captured by biosensors for patient monitoring and T2DM management. The first path requires advanced technologies. Once patients capture the data, it can be transmitted to the central database for storage and analysis and enables HCPs to monitor patients and develop and transmit treatment plans using the internet. The second way is simple: patients could use an SMS to send data captured by biosensors, and as outlined in Strategy 2, HCPs could also use an SMS to tailor treatment plans developed based on remotely collected data. Without a central database, a simple digital form could also be used to transmit data captured by patients using a biosensor.

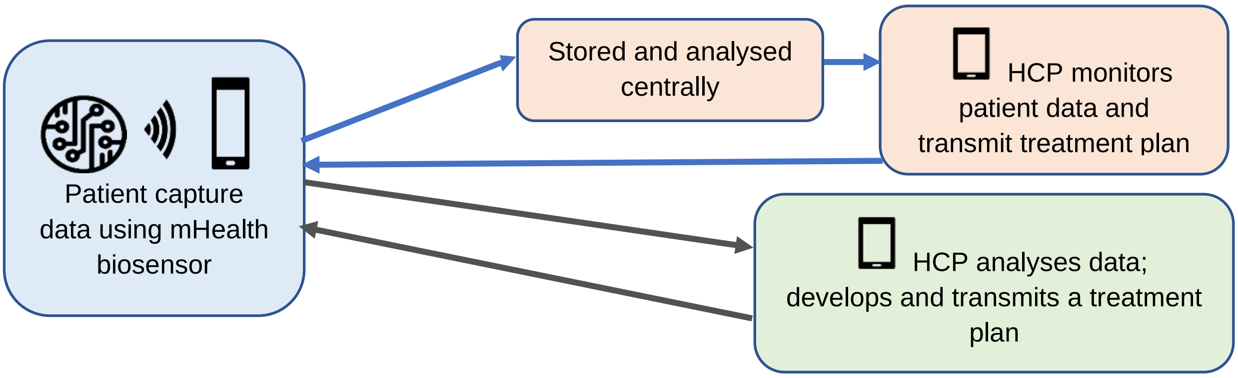

Figure 6.5: Use of Data Captured by mHealth Biosensor

As indicated in Strategy 2, the use of biosensors in the local setting should consider the availability of biosensor equipment and the patient's living conditions. Additionally, the following points should be considered for implementing Strategic Action 3.1:

- Availability of resources.
- Training for patients on biosensor use and data quality.
- Quality of the biosensor equipment.
- Presence of continuous evaluation by involving patients.

6.3.4.3.2 Strategic Action 3.2: Store Patient Data (Data Storage)

As depicted in Figure 6.4, comprehensive mHealth PHR includes a central database for storage and further processing and analysis of patient data. The feasibility of such an mHealth system for the local setting could be challenging in the short term, though such strategic action could be crucial to prepare and progressively implement in the long term.

This study validated the use of relational and non-relational databases for data storage in the central system. The 2021 Ethiopian Digital Health Blueprint also set a central repository strategy. However, the standard or types of databases is not clearly described (Ministry of Health-Ethiopia, 2021:44). The use of relational and non-relational databases depends on the structure of data to be captured, scalability, security and on the need how the patient data are to be accessed, stored, and used. A previously relational database, MySQL, was commonly used to store data captured by mHealth PHR. However, currently, due to the presence of different unstructured data, a non-relational database, NoSQL, was explored and considered effective for the medical database (El-Sappagh et al., 2018:21932; Ndlovu et al., 2021b:10; Sánchez-de-Madariaga, Muñoz, Castro, Moreno & Pascual, 2018:2). Thus, both relational and non-relational data could be used in the local setting depending on the structure of T2DM data generated at primary healthcare, scope, scalability, type of CDSS and level of security.

6.3.4.3.3 Strategic Action 3.3: Data Monitoring (use mHealth PHR Application to Monitor Patients)

This action depends on previous Strategic Actions 3.1 and 3.2, which are the availability of a central database for data storage and analysis and the connection between mHealth PHR and EMR.

One of the validated activities under this strategic action is a processing display system for data stored in the central database, allowing HCPs to monitor patients' data. Depending on the types of databases, such systems use different data processing techniques and big data analysis machine learning to provide information for monitoring patient health status.

In this study, a graphical and statistical approach should be used to display analysed or processed data. A display of a few statistics using a simple digital form could also be implemented as an initial step. The graphs and statistics used to display should assist the HCP in tracking patterns and trends of patients with T2DM. Thus, during the design and development of comprehensive mHealth PHR or a simple digital form, the important information required for effective patient monitoring should be included and provided in graphics and statistics.

Using current and previous data for patient monitoring should also be considered for the long-term implementation of mHealth tethered with PHR. The Ethiopian eHealth strategy also proposed an eHealth architecture to mHealth to connect with different eHealth solutions, including EMR (Ministry of Health-Ethiopia, 2014:15). Though the eHealth architecture is not supported by detailed strategy and action plans, the use of mHealth is not identified for noncommunicable disease (NCD), including diabetes. Thus, a detailed action plan should be developed and implemented to use mHealth PHR for data collection, storage, and monitoring for managing patients with T2DM. Figure 6.6 provides a summary of Strategy 3.

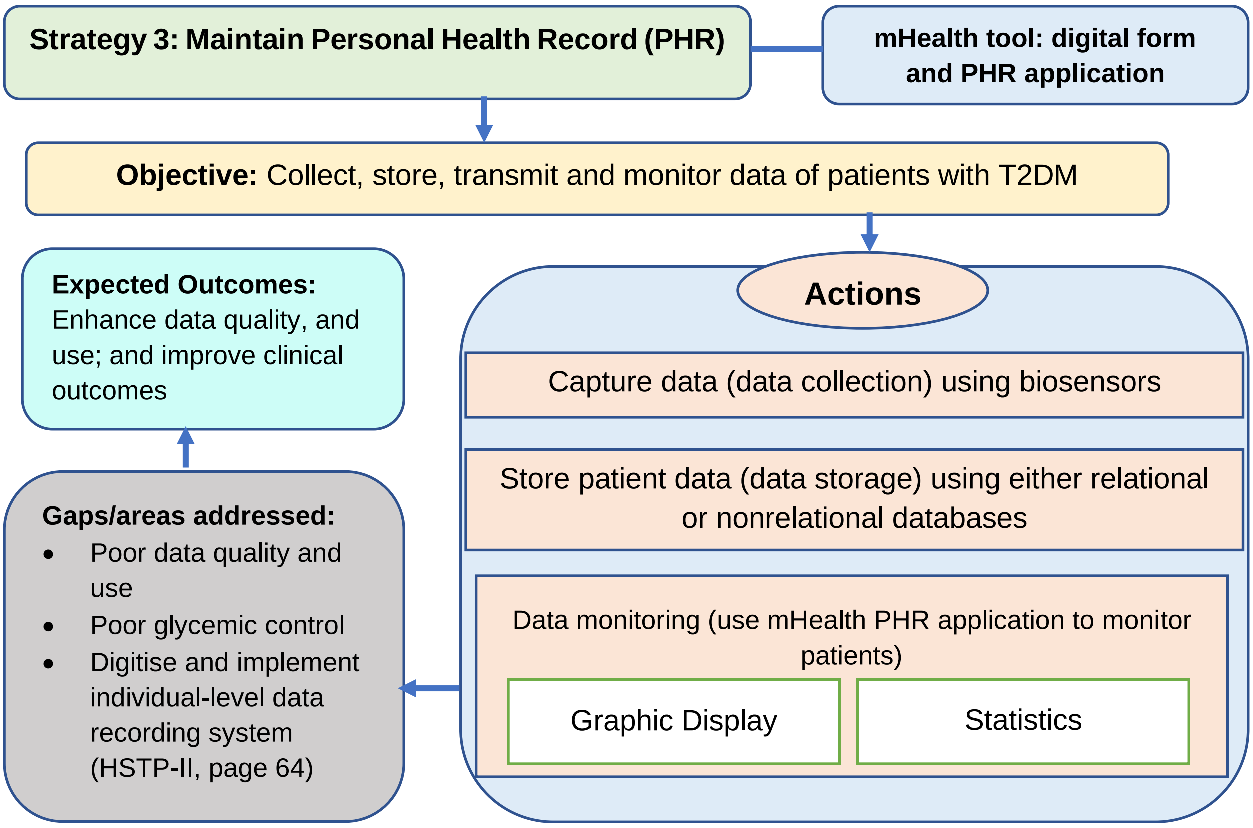

Figure 6.6: Strategy 3: Maintaining PHR

6.3.4.4 Strategy 4: Screening

The prevalence of undiagnosed diabetes is high in low and middle-income countries, especially in Africa (54% of prevalence) (International Diabetes Federation, 2021:74). Similarly, the estimated proportion of undiagnosed diabetes in 2020 was 57.6% (International Diabetes Federation, 2021:104). This creates an unnecessary burden by increasing mortality due to complications and increasing healthcare costs. That is why early detection and diagnosis of T2DM is crucial for timely patient management, preventing complications, disability, mortality and reducing healthcare costs.

The screening strategy is targeted to use an mHealth checklist for screening individuals at risk of developing T2DM. The expected outcome is to increase the T2DM screening rate and reduce the proportion of undiagnosed diabetes. As discussed in Chapter 5, the mHealth digital form delivered positive outcomes in screening and detecting T2DM cases. Since the mHealth reminder for screening follow-up is not considered irrelevant by the Modified Delphi experts, only one strategic action with activities is discussed here.

6.3.4.4.1 Strategic Action 4.1: Use the mHealth Screening Checklist

The development of the mHealth screening checklist ranges from simple web-based digital forms to comprehensive applications. Studies tested the web-based digital forms for screening interventions (Johari, Dabaghmanesh, Zare, Safaeian & Abdollahifard, 2018:290; Prabhune et al., 2019:2043). For example, one study used Open Data Kit (ODK) software to develop a simple web-based checklist for rapid screening (Prabhune et al., 2019:2043). The rapid screening digital checklists are prepared based on national/international screening criteria used to identify individuals at higher risk of developing T2DM.

The digital rapid screening checklist should be prepared based on the nationally agreed screening criteria in the local context. The screening criteria for diabetes are clearly outlined in the Clinical and Programmatic Management of Major Non-Communicable Disease Guidelines of the Ministry of Health (MoH), Ethiopia (Ministry of Health-Ethiopia, 2016:34-35). The WHO step checklist is also commonly used for developing a digital rapid screening checklist (World Health Organization, 2021:1-4).

For example, in Figure 6.7, the researcher developed an example of a web-based rapid screening checklist using KoboCollect software that HCPs could use for screening individuals. The checklist could be accessed online or using the mobile KoboCollect application. The checklist automatically analyses and interprets data, computes, and categorises Body Mass Index (BMI), computes and categorises risk scores, and provides decision support for HCPs on the subsequent action.

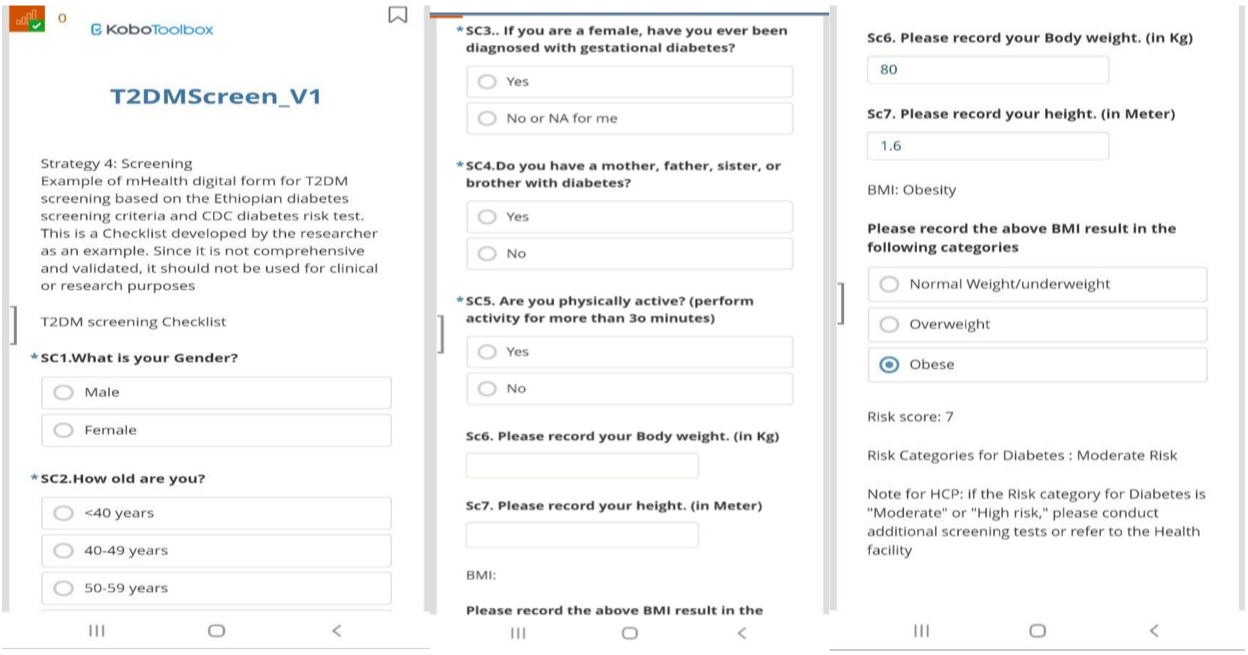

Figure 6.7: Examples of Digital Screening Form for Diabetes Developed Using KoboCollect Software. (Available for test at: https://ee.humanitarianresponse.info/x/7fLuOhJx). *Note: This is a checklist developed by the researcher as an example for Strategy 4. Since it is not comprehensive and validated, it should not be used for clinical or research purposes.*

The presence of such an online available screening checklist would make it easy for HCPs to screen the patients using their mobile phone devices.

Another tool is a comprehensive mobile application with a screening checklist. This could be mobile applications linked with a central database or tethered with EMR and have CDSS to support HCPs in analysing screening checklist scores and glucometer measurements to detect T2DM cases. Since this requires advanced technologies, its implementation in local settings should be considered a long-term strategy. Figure 6.8 summarises Strategy 4.

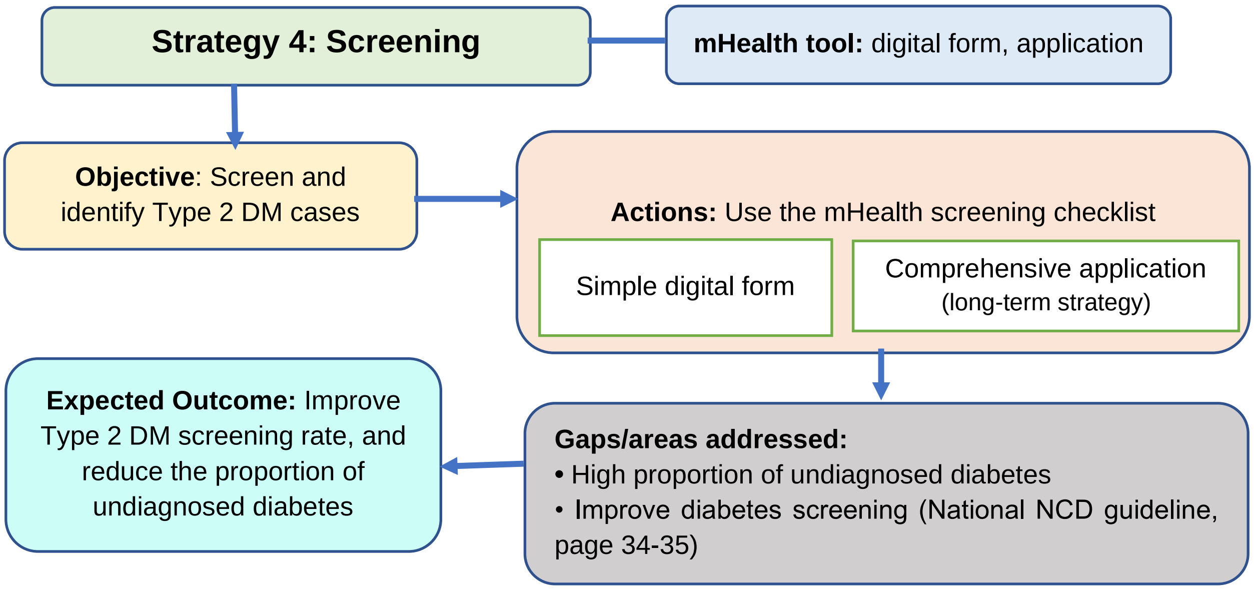

Figure 6.8: Strategy 4: Screening

6.3.4.5 Strategy 5: Treatment/Therapy Plan

The clinical outcomes of T2DM management highly depend on the quality and effectiveness of the treatment and therapy plan provided by the HCPs. The poor quality of treatment plans is also a feature of diabetes care in developing countries which negatively affects the quality of care (Russo et al., 2022:11; Zimmermann, Bunn, Namadingo, Gray & Lwanda, 2018:11) and patient satisfaction with the treatment (Abebe, Berhane & Worku, 2014:5; Getie, Geda, Alemayhu, Bante & Aschalew, 2020:7).

The treatment/therapy plan strategy targets decision support for HCPs to develop and conduct effective treatment/therapy plans. The expected outcome is improving the quality and effectiveness of the treatment plan for managing T2DM and enhancing clinical outcomes. The strategic actions and activities of Strategy 5 are described below.

6.3.4.5.1 Strategic Action 5.1: Implement a Clinical Decision Support System (CDSS)

The mHealth CDSS can be (1) a separate entity that can be used at one point in time, or (2) where the current and previous records of the patient are used to generate decision support using an algorithm or rule, which is part of longitudinal PHR (Orton, Agarwal, Muhoza, Vasudevan & Vu, 2018:S65). The second type is closely related to

Strategy 2, in which CDSS are integrated into the mHealth PHR or mHealth application used to collect, store and process data. This should also be considered for long-term implementations.

The CDSS system should provide knowledge-based support based on the current and previous patient data history for HCPs to develop evidence-based and tailored treatment plans. The presence of automated algorithms or rule-based instructions in CDSS ensures that HCPs follow a set of guidelines (Labrique et al., 2013:166; Tian, Zhang & Zhang, 2020:S21). The availability of a CDSS tool integrated with clinicians' workflow that identified gaps in glycemic control and management and offered evidence-based management recommendations enhanced practice results and led to fewer hyperglycaemic incidents (Pichardo-Lowden, 2022:772-773).

For short-term use in the local context, simple mHealth checklists could be developed for different scenarios supporting HCPs at the point of care. For example, a protocol or step-by-step guide on managing a patient with dyslipidaemia could be developed using mHealth (mobile phones), which HCPs could easily use to support their decisions. The availability of such a checklist, protocol, or step-by-step guide for scenarios and conditions could improve HCP performance at the point of care or in the design of an effective treatment plan (Agarwal et al., 2021:7). According to the WHO, this digital protocol and checklists are merely job aids that support clinical care delivery and are not necessarily linked to digital medical records (World Health Organization, 2019b:xvi). These checklists should be prepared cautiously and based on national and international T2DM management guidelines. The presence of errors or deviations from the locally implemented clinical workflow could create unnecessary confusion and barriers to adoption and use by HCPs.

As depicted in Figure 6.7 in Strategy 4 screening, a checklist could be used by HCPs to enter clinical information, and the system can automatically analyse and provide support on the treatment plan or the subsequent action. This concludes that CDSS is not only about complex algorithms or advanced mHealth applications; it could be started from simple mobile phone-based guides and checklists and progressively advance to complex algorithms and knowledge-based support.

The CDSS should also include an alert system to notify HCPs of critical features or data changes. A decision should also be supported for HCPs on how to act or manage these critical changes. The alert system is crucial for HCPs to provide treatment promptly and reduce clinical errors due to lack of information, and it also results in effective clinical outcomes.

The future adoption and use of CDSS should be based on an extensive evaluation using available checklists. These checklists could also be used to identify the features of comprehensive and effective CDSS which guide T2DM management (Van de Velde, Kunnamo, Roshanov, Kortteisto, Aertgeerts, Vandvik & Flottorp, 2018:3). The availability of digital resources, the clinical care workflow, and the presence of national guidelines also need to be considered during implementation.

6.3.4.5.2 Strategic Action 5.2: Create Collaboration among Healthcare Professionals (HCPs)

Compared to Strategic Action 5.1, this could be easily implemented in the short term considering the local context and simplicity of the proposed mHealth tool. The presence of collaboration among HCPs enhances the decision support among HCPs in designing effective treatment plans and improving the quality of care (Johnson & Carragher, 2018:21; Lee, McCutcheon, Fazel, Cooley & Slack, 2021:14-15; Nurchis et al., 2022:9).

The first strategic activity that should be considered for implementation in the local context is creating a social group (SMS group/social media) that facilitates communication and support among HCPs. The presence of an SMS group enhances collaborations and communication among HCPs, and it can be used for coordinating clinical care. HCPs from primary healthcare settings could also easily get senior expert assistance by using the SMS/group or social media for teleconsultation (Labrique et al., 2013:166; Manocha, Spiegelman, Miller & Solomon, 2020:41). Interprofessional practice and effective communication between HCPs is critical for positive clinical outcomes and digital technologies like an SMS group could enhance this (Bates, 2015:14; Yoshimoto, Nawa, Uemura, Sakano & Fujiwara, 2022:239). The SMS group does not require advanced technology and could easily be implemented in basic phones, which makes it convenient and cost-effective. SMS/social groups should be monitored and controlled to correct misuse or remove any discussion unrelated to patient care.

Another validated activity is implementing a teleconsultation (using voice calls) service for HCPs to get assistance from senior experts. This was also clearly outlined in the WHO and Ethiopian Digital Health Strategy (Ministry of Health-Ethiopia, 2021:15; World Health Organization, 2019b:xv). According to evidence, teleconsultation is an effective mechanism to get decision support and a second opinion on the development of treatment plans by HCPs working in primary healthcare settings, which also improves clinical outcomes (Aberer, Hochfellner & Mader, 2021:634; de Kreutzenberg, 2022:323; World Health Organization, 2019b:xv). Voice calling is not the only tool for teleconsultation; as discussed above, SMSes, social groups and other digital technologies like videocalls, email and social media could be used for teleconsultation. Voice calls, however, have many advantages over these digital tools, including synchronised/real-time interaction without requiring an internet connection. Teleconsultation requires only a basic mobile phone, making it convenient and cheap (Sarveswaran, Rangamani, Ghosh, Bhansali, Dharmalingam, Unnikrishnan, Vikram, Mathur & Misra, 2021:2).

As depicted in Figure 6.9, teleconsultation could be implemented in two ways in the local context. The first method is establishing a central call centre that serves all health centres in Addis Ababa. The centre would include senior experts for the provision of consultations, and HCPs working in the primary healthcare setting (health centres) could contact the call centre to get assistance and second opinions on T2DM management. It is also possible to make the call centre comprehensive, including other clinical services for communicable and non-communicable diseases, ensuring effective resource use. This could be less feasible since hiring senior experts for the call centre is expensive, but it could be considered for long-term implementation.

The second method is to use the three-tier health system of Ethiopia. According to this system, the lowest tier in the health system, the primary healthcare setting (including health centres), has a referral linkage with second-tier health systems (comprehensive hospitals). This referral linkage could be used for teleconsultation by creating a linkage that enables the HCP in the primary healthcare setting to get assistance/consultation from senior experts at the second-tier system (comprehensive hospitals) through mobile phones. Compared to the first method, this is relatively cheap since it utilises the available human resources and could be implemented by providing a small incentive for mobile service (airtime). This could also support referrals and follow-ups (Maria, Serra & Heleno, 2022:2).

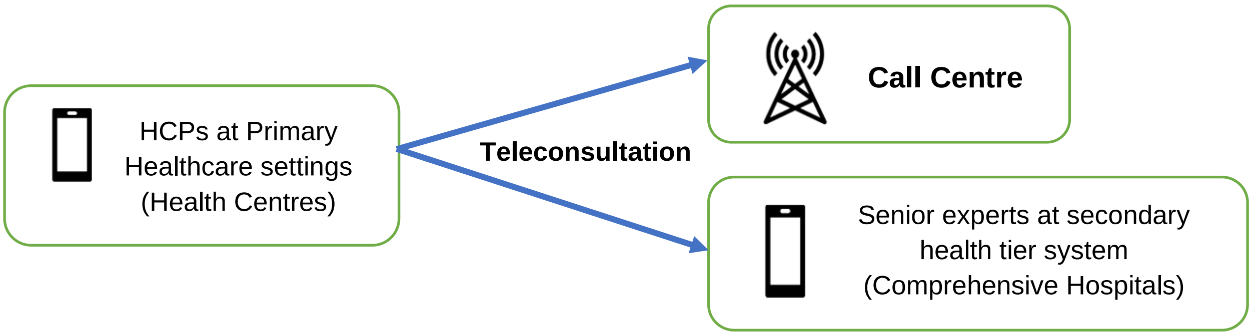

Figure 6.9: Teleconsultation for HCPs

The other activity under this strategic action is to make online referencing systems accessible on mobile phones for HCPs. The presence of adequate online references enhances accessibility through mobile phones and creates an opportunity for HCPs to improve their knowledge and skills in T2DM management. Establishing national or regional knowledge repositories could be crucial to increase access to online reference materials not only for T2DM management but also for other diseases. Fig 6.10 summarises Strategy 5.

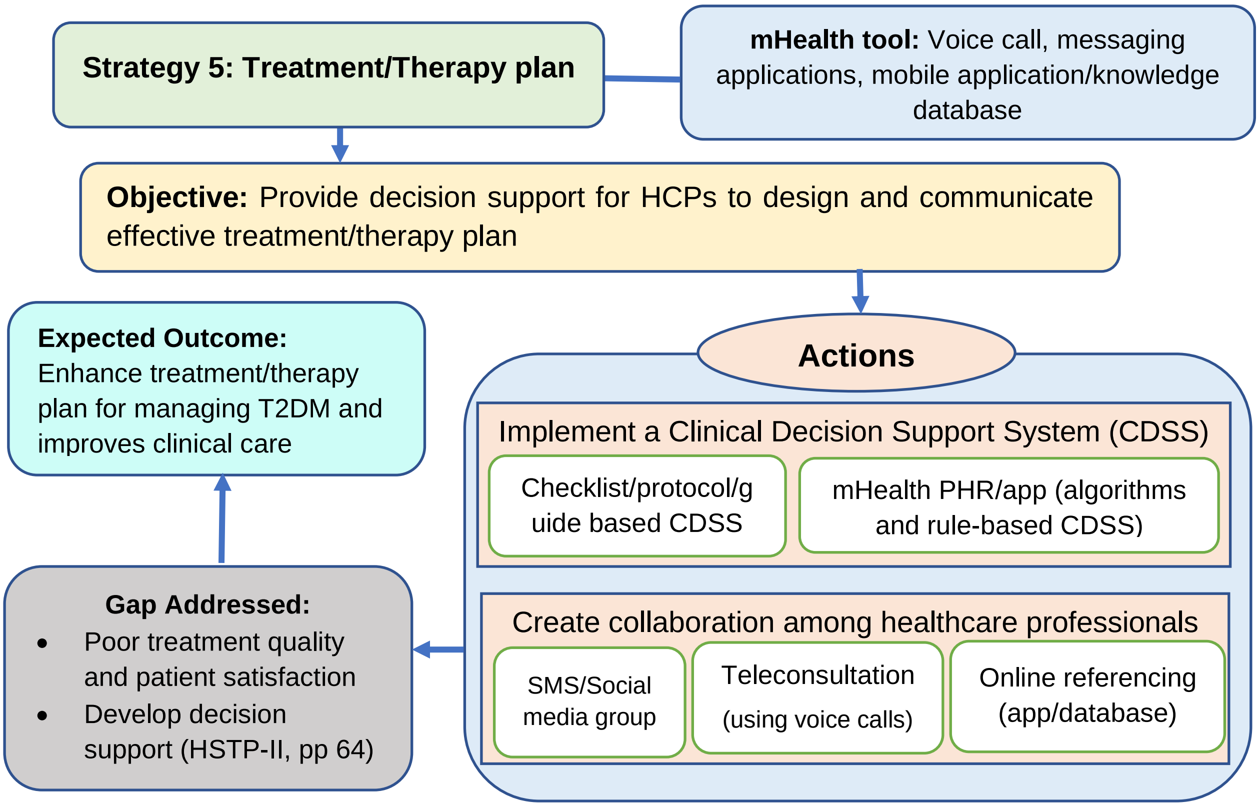

Figure 6.10: Strategy 5: Treatment Plan

6.3.5 Component Two: Addressing Challenges for Effective mHealth Implementation

The overall strategic aim of Component One was to tackle the challenges of implementing mHealth for T2DM management. The strategies validated to achieve this major aim are discussed here:

6.3.5.1 Strategy 6: Enhance Interoperability of Diabetes mHealth

As discussed in Chapter 3, the major challenge that hinders the effective implementation of mHealth for T2DM management in low and middle-income countries is the lack of a regulatory framework and standard for interoperability. This finding was supported by studies conducted in Ethiopia (Biru et al., 2022:6; Kebede, Gebremeskel & Shivers, 2021:16; Precise Consult International, 2021:9). For example, a recent study on the performance of health information systems found that data standards, including data exchange, are not supported in Ethiopia (Biru et al., 2022:6). Despite the presence of national eHealth strategies and a digital blueprint, the adopted data standards are not specified, which may affect diabetes mHealth interoperability with other locally available eHealth solutions.

Strategy 6 aims to adopt an acceptable interoperability standard for diabetes mHealth solutions. The expected outcome is to enhance interoperability between diabetes mHealth and other nationally available eHealth platforms. The validated strategic activities are described below.

In Ethiopia, there is no identified standard for mHealth devices. Though, for future use of mHealth biosensors, the data standards for mHealth devices should be determined. This study proposed the IEEE 11073 PHD standard for data transmission from biosensors to mobile phones. As discussed in Chapter 5, the IEEE 11073 PHD standard creates flexibility and enhances security features for logically connecting mHealth devices.

In the eHealth strategy 2014 of Ethiopia, the importance of adopting applicable standards for the structural layer was mentioned as a main strategic issue, but it failed to identify an appropriate standard for the country's eHealth architecture. This was improved, and a clear action plan was included in the Digital Blueprint of Ethiopia, developed in 2021, which outlined an Open Health Information Mediator (OpenHIM) as a middleware mediator to enhance interoperability between different health information systems. The document also broadly suggested the adoption of international standards for data structure and messaging, including LOINC, SNOMED, and FHIR, as appropriate for different eHealth domains to enhance interoperability (Ministry of Health-Ethiopia, 2021:58).

This study validated the adoption of FHIR using a Representational State Transfer (REST, often referred to as RESTful architectures) for structural interoperability. The FHIR structural standard appropriateness and importance for mHealth application is discussed in Chapter 5, and positive results are reported on the interoperability with OpenHIM proposed as a middleware mediator in Ethiopia. According to evidence, FHIR is becoming a preferred method for communication with OpenHIM platforms

(Kasthurirathne, Mamlin, Kumara, Grieve & Biondich, 2015:6; Kebede et al., 2021:14). The system uses the HTTP protocol and the JSON data standard to exchange data between mobile phones of HCPs and the central system which is also validated by this study. Efforts should be made to integrate GSM (Cellular) data transmission protocol.

The FHIR is also the most recommended messaging standard for integration with OpenHIM, a middleware mediator proposed by this study for diabetes mHealth. The diabetes mHealth development process should follow an open-software development standard. The use of the FHIR standard for messaging and an open-software development standard is also supported by the 2021 digital blueprint of Ethiopia and the eHealth strategic study conducted in Ethiopia (Ministry of Health-Ethiopia, 2021:58; Precise Consult International, 2021:18).

As outlined earlier in this strategy, the 2021 Digital Blueprint of Ethiopia also suggested the adoption of LOINC and SNOMED for semantic interoperability (Ministry of Health-Ethiopia, 2021:58). Regarding semantic interoperability, this study proposed ICD-11 standard for clinical terminology, SNOMED standard for clinical data coding, LOINC standard for laboratories and RxNorm for pharmacies. These standards were also used in some local mHealth interventions. For example, Kebede et al. (2021:16) used the ICD-10 (previous version of ICD-11) standard for developing EMR.

6.3.5.2 Strategy 7: Establish Privacy and Security Features for Diabetes mHealth

Another challenge that requires an effective strategy is the lack of a mHealth regulatory framework for patients' data privacy and security. As discussed in earlier chapters, this was evident in Ethiopia, there is no clear strategy and standard for digital health security, and eHealth security is not patient-centric (Precise Consult International, 2021:10).

This strategy aims to adopt an acceptable standard and features for the security and privacy of diabetes mHealth solutions. The expected outcome ensures mHealth data security and privacy of patients with T2DM. The strategies are described below.

One of the features that should be considered in the mHealth implementation for diabetes is using a three-factor authentication system for HCPs, patients, and other users of the mHealth system. This system should be employed for data capturing, access and sharing. The three factors' authentications are a 4-digit personal identification number (PIN) and password (something-users-know), biometrics such as fingerprint, iris, and facial recognition (something-users-are), and smartwatch/Bluetooth device (something-users-have) (Kennedy & Olmsted, 2017:212). The PIN or passwords and biometrics are commonly used for authentications, and the others should be considered for long-term implementations. The authentication system could start from two-factor authentication and progressively advance to three-factor authentications for the local context. Evidence also suggests employing at least a two-factor authentication to ensure the security and privacy of patient data (Grindrod, Khan, Hengartner, Ong, Logan, Vogel, Gebotys & Yang, 2018:14; Spigel et al., 2018:9).

Data sharing is inevitable in diabetes mHealth applications, and effective measures should be taken to ensure patient data security and confidentiality during data communication. Different measures could be taken to ensure data sharing security, and this study proposed adopting cryptographic mechanisms, including AES, for data sharing. The system should also include synchronous and asynchronous data validation approaches.

Whether diabetes mHealth applications are implemented in the short or long term, a multi-layer structure should be employed to ensure mHealth security and privacy like authentication, authorization, cryptography, and data validation (Jusob, George & Mapp, 2022:43; Takenga et al., 2014:4). This was also a priority in the Digital Health Blueprint, some of the above features are included in long- and short-term strategies to improve system security and protect the digital health systems of Ethiopia (Ministry of Health-Ethiopia, 2021:58; Precise Consult International, 2021:18).

6.3.5.3 Strategy 8: Enhance the Usability of Diabetes mHealth

As discussed in previous chapters, some of the challenges that affect mHealth usability by HCPs include a lack of mHealth initiatives in local languages, a poor user interface, complexity to install and use, poor scalability and a complex troubleshooting and maintenance system. Appropriate actions should be taken during design and development to enhance mHealth solutions' usability. Local leaders should consider the following usability features, as should policymakers and mHealth implementers during the design, development, adoption, and implementation of mHealth (most of these features are also included as criteria in some studies for the usability of the evaluation of mHealth solutions):

- The system must be easy to install (Stoyanov, Hides, Kavanagh, Zelenko, Tjondronegoro & Mani, 2015:5).
- The system must be easy to update (Stoyanov et al., 2015:5).
- The system must be easy to navigate (Kasali, Taiwo, Akinyemi, Alaba, Awodele & Kuyoro, 2019:21; Stoyanov et al., 2015:5; Zhou, Bao, Setiawan, Saptono & Parmanto, 2019a:8).
- The system must use an easy graphical interface (Kasali et al., 2019:21; Schnall, Cho & Liu, 2018; Stoyanov et al., 2015:5; Zhou et al., 2019a:8).
- The system must be easy to troubleshoot (Schnall et al., 2018:4; Stoyanov et al., 2015:5).
- The system must be easy to exit by uninstalling or unsubscribing (Stoyanov et al., 2015:5).
- The system must allow multilingual installation for common local languages on a single application.
- The user interface shall be kept simple by using the appropriate font type and size (Kasali et al., 2019; Schnall et al., 2018:4; Stoyanov et al., 2015:5; Zhou et al., 2019a:8).

An effective way to address the above usability features is to employ an iterative development process based on continuous user feedback.

6.3.5.4 Strategy 9: Capacitate HCPs in the Application of mHealth for T2DM Management

The adoption and use of mHealth applications are significantly affected by digital health literacy and awareness of HCPs. Digital health literacy is defined as "the ability to search, find, understand and evaluate health information from electronic resources and to use the knowledge gained to solve health-related problems" (Krausz, Westenberg, Vigo, Spence & Ramsey, 2020:3). Capacity building is vital for improving the digital awareness and literacy of HCPs which also improves the usability of mHealth. As discussed in Chapter 4, most of the HCPs who participated in this study did not get formal education or training in digital health, including mHealth. This could affect the implementation of mHealth for T2DM management. Lack of support for digital health implementation was also reported among HCPs who participated in Phase II of this study.

This strategy is targeted through the digital health capacity building of HCPs using pre-service education and training. The expected outcome is to enhance HCPs' digital awareness and literacy. The validated strategic activities are described below.

As discussed in Chapter 5, the strategic ways for improving digital literacy and awareness are pre-service education by including digital health competencies in the formal curriculum and CPD/in-service training modules when designing digital health courses.

The integration of digital health in the Ethiopian health professional education curriculum should go beyond providing basic ICT courses. The course contents in health informatics and other digital health courses should address the full aspect of digital health, from design to the application of eHealth solutions, including mHealth. The integration of digital health in Ethiopia's health professional training curriculum should be based on adequate need assessment of digital health services and should also consider digital health training frameworks implemented regionally (Alunyu, Munene & Nabukenya, 2020:51-52) and internationally (Frank, 2005:5; Huang, 2007:90; Slovensky, Malvey & Neigel, 2017:4).

Accredited CPD providers in Addis Ababa or Ethiopia, professional associations, higher education institutes and training organisations should pay attention to designing and developing digital health CPD courses. Especially eLearning courses should be considered to increase accessibility and add many HCPs in primary healthcare settings.

Since the scope of this study is to capacitate the digital health literacy of HCPs for improving the adoption and use of mHealth for T2DM management, the following educational contents/areas should be considered for curriculum integration and development of CPD courses:

- Basic ICT skills.
- Contents on the types and applications of mHealth for disease management (including T2DM). This should focus on simple, cheap, convenient mHealth interventions for disease management.
- Introductory content on the design and development of mHealth for disease management (including T2DM).
- Use of mHealth for interprofessional practice, clinical care, and consultation.
- Usability evaluation theory and tools of mHealth applications (including diabetes mHealth).
- Regulatory and compliance issues (ethical, legal, privacy and security-related issues of mHealth).
- Digital communications skills.

Another strategic activity is to create interprofessional collaboration to share best practices and experience in implementing mHealth for T2DM management. This enhances awareness of HCPs in the mHealth application and scalability across primary healthcare settings. Digital technologies and forums could effectively create collaboration and knowledge-sharing platforms. Policymakers, local leaders and mHealth implementers could also use these collaboration platforms to provide information on the diabetes-related mHealth application for HCPs. Before implementing diabetes mHealth, programme owners or mHealth developers should develop user guides and provide adequate training for HCPs on using the developed mHealth solution.

6.3.5.5 Strategy 10: Improve Availability and Adequacy of mHealth Resources

Availability and adequacy of resources are primary requirements for effective implementation, and it is a common challenge for low and middle-income countries. As outlined in Chapter 3, the mHealth resource scarcity and lack of support for HCPs are the key challenges for mHealth implementations in developing countries. Inadequacy of mHealth resources and support is also a challenge in Ethiopia (Bogale et al., 2022:1507; Jemere et al., 2019:9). Expanding mHealth resources is inevitable for improving the quality and accessibility of clinical care. This strategy provides resource support for primary healthcare settings and HCPs. The expected outcome is to enhance resource availability for diabetes mHealth implementations.

Local and regional leaders and policymakers should include mHealth in the priority health agendas and adequate budgets could be allocated for mHealth implementation. A sufficient budget is a cornerstone for expanding digital health infrastructure and providing administrative support. Since digital health is a national agenda and priority in Ethiopia's health policy, its implementation at the lower level of the healthcare system should be supported by allocating adequate budget by federal and regional governments. An adequate monitoring and evaluation system should also be in place to ensure budgets are utilised for expanding mHealth infrastructures in primary healthcare settings.

More investment could be used to establish strong digital resources centrally at the regional level. The presence of central digital infrastructure ensures resource sharing among Health centres and enhances cost-effectiveness. Collaboration between MoH, regional health offices, health centres, Telecom vendors and NGOs is crucial for improving infrastructure. The public-private partnership could also be established for expanding infrastructure (African Development Bank, 2022:21; Latif et al., 2017:11).

The federal and regional government should develop strategic plans to identify mHealth interventions that could be implemented with locally available and cost-effective resources (Latif et al., 2017:10). Administrative support like internet access and incentives should be in place to support HCPs' use of mHealth for clinical care.

6.4 SUMMARY

This chapter described the developed and expert-validated strategies for implementing mHealth that support HCPs for T2DM management in the primary healthcare setting of Addis Ababa, Ethiopia. The effective implementation of the strategies could enhance the usability and ease of use of mHealth for T2DM management and enable HCPs to provide quality clinical care enhanced by mHealth technologies. This could improve the quality of clinical care, DSM behaviour and clinical outcomes.

Chapter 7 presents the study's conclusion, recommendations, limitations, and contribution.

CHAPTER 7

CONCLUSIONS, RECOMMENDATIONS, AND LIMITATIONS

7.1 INTRODUCTION

This chapter presents the conclusion of this study. It provides a summary of key findings and makes recommendations based on the major findings. It also describes the study's contributions, recommendations, limitations, and conclusions. The study's purpose was to investigate opportunities for the development of mHealth intervention for diabetes management and design strategies for their implementation in Ethiopia.

The study was executed in three phases, using a sequential, explorative, and mixed-methods research. In Phase I, an integrative literature review was conducted to identify the opportunities and challenges of mHealth for T2DM management in low and middle-income countries. The Phase I findings were used to develop the data collection tool for Phase II, and a quantitative survey was conducted among 272 HCPs working at health centres in Addis Ababa, Ethiopia. The findings from Phases I and II were integrated, and a joint display using tables was used, followed by a detailed discussion of combined findings. Based on the integrated findings, draft strategies were developed for mHealth implementation for T2DM management. In Phase III, the strategies were validated using three rounds of the Modified Delphi Technique. A theoretical framework guided the integration of both data sets and interpretation of meta-inferences, including the development of strategies, to lay the foundation for further action in developing mHealth for diabetes management in Addis Ababa.

7.2 SUMMARY OF INTEGRATED FINDINGS

The study findings are based on integrating Phase I and II (Qualitative results) and Phase II (Quantitative results). The findings are categorised into opportunities/uses of mHealth for T2DM management and challenges that may hinder the effective implementation of mHealth. These opportunities include the uses of mHealth and the critical features of the design and functionality of the application, plus acceptance of mHealth by healthcare professionals. Challenges involve barriers to mHealth implementation in low and middle-income countries. The strategies to mitigate these challenges are included to strengthen the case for the use of mHealth for diabetes management in Ethiopia. The significance of the involvement of stakeholders and recognition of the regulatory framework is acknowledged (MacPherson et al., 2021:4; Whittemore et al., 2020:520)

7.2.1 Use of mHealth in Low and Middle-income Countries

This study revealed evidence of how mHealth is used in different low and middle-income countries (LMICs). This was considered a good start to create an understanding of what worked and what did not in other contexts. The assumption was that this new knowledge would provide concrete evidence for developing strategies for the implementation of mHealth for diabetes management in Addis Ababa.

Several mHealth approaches that focused on behavioural change communication (BCC) between patients and healthcare professionals were presented. This study showed that most healthcare professionals were in favour of such initiatives. 82% and 89% of HCPs perceived mHealth as useful and an easy platform to provide BCC for patients with T2DM, respectively. There was also an intention by the majority (84.9%) of the HCPs to use mHealth for BCC in the future. Furthermore, SMSes were identified as the most applicable, convenient and inexpensive mHealth tool for providing BCC for patients with T2DM (Whittemore et al., 2020:521). Most HCPs rated the use of SMSes as a critical feature of mHealth.

The findings highlighted the use of mHealth (SMS) for BCC through health promotion messages related to healthy eating, physical exercise, and prevention of complications. The patients' needs, literacy level, language, length, simplicity, and frequency of these messages were critical factors, as elaborated in Chapters 3 and 5. Voice calls were also used as reminder systems to ensure treatment adherence and follow-up. Communication and support create collaboration through continuous interaction (Riangkam et al., 2021:886) and provide timely and tailored feedback remotely based on the patients' current health statuses (Greenwood et al., 2017:1019). The emphasis in all the reviewed studies was on supporting diabetes self-management (DSM) by patients.

mHealth could be used by HCPs to communicate and support patients for DSM. HCPs positively perceived this opportunity; most of the HCPs believed that mHealth would make it easy to reach patients and rated it useful for improving care delivery for patients. Most HCPs also indicated their intention to use mHealth. Such intentions provide a good supportive network for the effective implementation of digital innovations.

The possibility of using mHealth for the collection, storage, transmission, and monitoring of patient data was highlighted in some studies that were reviewed. 90.5% of HCPs agreed that these features were critical for proper data management. Around 91% of HCPs also showed their future intention to use mHealth to capture, store and share patient data.

Data revealed the capabilities of mHealth to capture remote data through a biosensor embedded in the application or be used as a stand-alone functionality to provide tailored use by the HCPs (El-Rashidy et al., 2021:5). For this functionality to work effectively, a central database for data storage needs to be established, this would enhance data access through mHealth. In support, most HCPs (89%) believed that a central database in mHealth would make it easy to store patient data. A relational or non-relational database could be used depending on the type of patient data (Ndlovu et al., 2021b:10).

Other technical aspects revealed were the internet or GSM protocol that could be used for data transmission and data monitoring systems, and 89.3% of HCPs perceived mHealth-based data transmission as potentially helpful in enhancing patient data transmission. Most HCPs showed support for mHealth and indicated intentions to use it should it be implemented in Addis Ababa.

7.2.2 Design of the mHealth Application

The findings showed the importance of getting the design correct right from the planning to the implementation stages. The structure and organisation of the information system affect its functionality. What seemed to work well in other contexts was the architecture of the application, what it can offer and the satisfaction of users with its interface. Chapters 3 and 5 elaborated on how this architecture involving P2P trafficking that supports the transmission of communication interventions such as SMS. However, the study also showed that such complex functionalities require digital literacy and support by policy makers. A high number of HCPs believed that this would be a better health investment and were willing to try the technology out. Their focus was on improving health outcomes for diabetes patients. These communication capabilities of mHealth need to be used effectively and tailored according to patients' and other users' needs. In addition, the prevalence of the disease is also a factor to be considered in designing digital innovations, considering the costs involved.

A clinical decision support system (CDSS), for example, allows HCPs to design evidence-based and tailored treatment plans for patients with T2DM. This was considered critical by 87.5% of HCPs. The CDSS embedded in the mHealth personal health records (PHR) application could provide knowledge-based and non-knowledge-based support for HCPs based on the current and previous patient data (Ndlovu et al., 2021a:7). According to the HCPs, using mHealth would make the CDSS beneficial for designing treatment plans and avoiding errors.

7.2.3 Barriers to Effective Implementation of mHealth

7.2.3.1 Interoperability

This study revealed the importance of having government regulations and standards on interoperability. It is important for mHealth to be incorporated into the Health Information System (HIS) in Ethiopia. The lack of such regulatory frameworks was identified as a significant barrier to the effective implementation of mHealth. Most HCPs agreed and acknowledged the significance of guidelines and protocols for mHealth initiatives. Ethiopia has no clear standard and framework for the integration of mHealth with other eHealth systems (Biru et al., 2022:4-5; Harding et al., 2018:5; Wondwosen et al., 2018:8).

The following interoperability standards were identified in this study:

- The Institute of Electrical and Electronics Engineers (IEEE) 11073 Personal Health Devices (PHD) standard for medical devices like biosensors.
- The Fast Healthcare Interoperability Standards (FHIR) for messaging standards.

- The FHIR, a Representational State Transfer (REST, often referred to as RESTful architectures) for structural interoperability.
- Logical Observation Identifiers Names and Codes (LOINC), Systematised Nomenclature of Medicine Clinical Terms (SNOMED), Digital Imaging and Communications in Medicine (DICOM), Unified Medical Language System (UMLS), RxNorm, and International Classification of Diseases (ICD) for semantic interoperability.

The FHIR is recommended for structural interoperability for integration with OpenHIM, a standard adopted as a middleware mediator for an eHealth system in Ethiopia (Ministry of Health-Ethiopia, 2021:58). The Ethiopia digital health blueprint also suggested LOINC and SNOMED for semantic interoperability (Ministry of Health-Ethiopia, 2021:58). The study assumed that there is an opportunity to develop mHealth for diabetes management in Ethiopia.

7.2.3.2 Security and Privacy

Another challenge was the lack of standards and frameworks for the security and privacy of patient data in low and middle-income countries like Ethiopia (Biru et al., 2022:5; Harding et al., 2018:6). Most HCPs (86%) also believed that security and privacy are critical in data management. The development of mHealth architecture should consider different features such as authentication (Kennedy & Olmsted, 2017:212), authorisations data (Grindrod et al., 2018:14), encryption, and data validation (Jusob et al., 2022:43; Takenga et al., 2014:4), to mitigate risks in data security.

7.2.3.3 mHealth System Usability

Some of the usability challenges identified in this study included the absence of indigenous languages in mHealth content, poor interface, complex system, poor scalability, and a complex troubleshooting and maintenance system. The findings showed that the complexity of the mHealth system negatively affected the adoption of mHealth systems by users. Data showed HCPs perceived ease of use of mHealth interventions as a predictor for future intention to use. However, it is acknowledged that the complexity of the mHealth system could be improved by using user-centric technology, keeping the user interface simple such as the appropriate font type and size, and making it scalable (Gurupur & Wan, 2017:1; Katusiime & Pinkwart, 2019:944). Customisation of local languages in the mHealth system could also be important considering the local context.

Lower digital awareness and literacy among HCPs was another challenge that negatively affected the usability of the mHealth system in low and middle-income countries (LMICs). The reason was a lack of education and training related to digital health. In this study, most HCPs did not take courses or attend formal in-service training in eHealth/mHealth. Taking a course during undergraduate/postgraduate study was also a positive predictor for mHealth acceptance by HCPs. The strategy for addressing these challenges could be inculcating eHealth education in preservice education (Munene, Egwar & Nabukenya, 2020:40) and providing short-term in-service training in different areas of eHealth/mHealth (World Health Organization, 2019a:83). The involvement of HCPs during the design and development of mHealth, the availability of a user guide and training could also be important to improve digital awareness and literacy (Ikwunne, Hederman & Wall, 2022:300; World Health Organization, 2019a:84-86). These solutions are crucial to increase awareness of the usefulness of mHealth, and as revealed in this study, perceived usefulness was a predictor for mHealth acceptance.

7.2.3.4 mHealth Resources and Infrastructure

Inadequate digital infrastructure was also presented as a great challenge for effective mHealth implementations in low and middle-income countries (LMICs). This study found that most HCPs lacked internet access in Health Centres and did not browse the internet on their cell phones. One of the reasons could be competing health priorities and lack of mHealth strategies in the national health policies. Incorporating mHealth into national policy is essential in establishing financial stability for expanding resources and infrastructure for the digital health system (Nsor-Anabiah et al., 2019:2900).

Lack of support by the government was another issue that should be addressed for effective mHealth interventions. Provision of affordable airtime, increased access to the internet, availability of an adequate budget, intersectoral collaboration and the presence of an incentive system are all necessary to improve mHealth resources in the primary healthcare settings (African Development Bank, 2022:21). Identifying locally available resources and progressive implementation of mHealth could also be key in resource-limited settings (Latif et al., 2017:10).

7.3 DEVELOPMENT OF STRATEGIES

The strategies were developed to improve Type 2 diabetes mellitus (T2DM) management of healthcare professionals (HCPs) by mHealth implementation. The proposed strategies were validated in three rounds using the Modified Delphi Technique, as presented in Chapter 6. As shown in Table 7.1, the mHealth strategies focused on opportunities for mHealth for T2DM management and addressing challenges that could negatively affect mHealth implementation.

Table 7.1: mHealth Strategies for T2DM Management

Component	Strategies	mHealth tools
mHealth opportunities/ uses	Strategy 1: Behavioural Change Communication	SMSes
	Strategy 2: Patient communication and support for Diabetes Self-management (DSM)	SMSes, voice calls
	Strategy 3: Maintain Personal Health Record	Digital forms, mHealth application
	Strategy 4: Screening	Digital forms, application
	Strategy 5: Treatment/Therapy plan	Voice calls, messaging applications, mobile applications, knowledge-based database
Addressing challenges	Strategy 6: Enhance Interoperability of Diabetes mHealth	
	Strategy 7: Establish privacy and security features for diabetes-related mHealth	
	Strategy 8: Enhance the usability of diabetes-related mHealth	
	Strategy 9: Capacitate HCPs in the application of mHealth for T2DM management	
	Strategy 10: Improve availability and adequacy of mHealth resources	

The strategies are intended for primary healthcare providers in Addis Ababa, Ethiopia. The strategies could be used in Ethiopia's rural primary healthcare settings after further considerations and validations.

7.4 RECOMMENDATIONS

Based on the findings, the study put the following recommendations for stakeholders from different levels of the healthcare system:

7.4.1 Healthcare Professionals

The study result showed that Health care professionals (HCPs) have a positive attitude toward mHealth opportunities and positive perceptions of its usefulness and ease of use. Most HCPs also intend to use mHealth for T2DM management, but there is inadequate support for HCPs. HCPs could advocate implementing mHealth strategies that do not require advanced technologies, high costs, and technical support in their Health Centres. HCPs should also be supported through education and short-term in-service training to enhance their digital awareness and literacy. Administrative support, like internet access, affordable airtime, and reasonable incentives, should be provided for HCPs. The support should include allocating time and enabling environments for HCPs to implement mHealth for T2DM management. The health informatics experts at health centres also need to collaborate with HCPs to utilize the identified opportunities of mHealth for T2DM management.

7.4.2 Health Centre Leaders

The study identified the mHealth opportunity for improving T2DM management and clinical care in primary healthcare settings. Health centres could collaborate with stakeholders to implement the proposed strategies. Lack of internet access and support was also identified as a detrimental factor, which could be addressed by allocating an adequate budget. The budget could also address the infrastructure gap that hinders mHealth implementation and support, including capacity-building activities for HCPs.

7.4.3 Regional Health Bureaus and the Ministry of Health

The study identified the potential of mHealth in improving the quality of clinical care in primary healthcare settings. Thus, the regional leaders, including the sub-city and Woreda leaders, should consider the implementation of the validated strategies in collaboration with the Ministry of Health. This study also identified a lack of strategic implementation as a challenge, and regional offices could design a detailed action plan for the strategic and progressive implementation of the proposed mHealth strategies. This should include the integration of mHealth in the strategic action plan, allocating budgets, and creating collaboration among stakeholders. Regional health bureaus should also consider providing support and enhancing the capacity of HCPs.

The ministry could support the implementation of mHealth for T2DM management among Health centres in Addis Ababa. The implementation could be expanded to other regions based on the outcomes. This research identified competing interests in health priorities as a challenge, and mHealth should be integrated into the national health priorities. Lack of infrastructure was another identified challenge, and the Ministry of Health should support the regional health bureaus to expand infrastructure in primary healthcare settings. The Ministry of Health should also adopt/develop a clear standard and framework for interoperability, security, and privacy.

7.4.4 mHealth Developers

The mHealth developers could be a separate entity or group of entities like Health centres, regional health bureaus, the Ministry of Health, NGOs, and HEIs. The mHealth developers could consider the proposed strategic activities presented during the development and implementation of mHealth strategies for T2DM management. Especially the strategies proposed to address system usability

7.4.5 Non-Governmental Organizations

NGOs could collaborate with governmental entities to support the implementation of mHealth for T2DM management. NGOs could support health facilities in expanding digital infrastructure and resources. NGOs could also provide training to improve the digital awareness and literacy of HCPs.

7.4.6 Ministry of Education

This result showed that most HCPs did not take eHealth/mHealth-related courses during their undergraduate/postgraduate, which was a predictor for mHealth acceptance by HCPs. Thus, in collaboration with the Ministry of Health and HEIs, the

Ministry of Education should integrate mHealth into the curriculum. The proposed content of this study could be considered during curriculum integrations.

7.4.7 Continuous Professional Development (CPD) Programs

This result showed that most HCPs did not attend eHealth/mHealth-related training. Thus, CPD programs related to eHealth/mHealth should be designed by different stakeholders to increase training access for HCPs.

7.4.8 Higher Education Institutes

The lack of quality data on the effectiveness and efficiency of mHealth was a challenge identified by this study. The HIEs should support mHealth implementers in generating evidence of the effectiveness and efficiency of the validated strategies for implementing mHealth for T2DM management. The HEIs should integrate eHealth courses into their curricula.

7.4.9 Further Research

The following issues should be considered for further research:

- Testing the effectiveness of the proposed mHealth strategies in improving glycemic control and other clinical and non-clinical outcomes.
- Generating evidence of the cost-effectiveness of the proposed mHealth strategies.
- Assessing the challenges for effective implementation of proposed mHealth strategies from the perspectives of leaders.
- Conducting a detailed study to develop a framework for interoperability, security, and privacy of mHealth.

7.5 CONTRIBUTION OF THE STUDY

This study has made significant contributions to research in three critical areas: synthesis of the existing literature on the use of mHealth in low and middle-income countries (LMICs), and findings from this phase identified possibilities for mHealth in Ethiopia. Secondly, validating the literature with data from the surveys of health care professionals, and thirdly, using the theoretical framework that combines perceived usefulness and perceived ease of use/complexity to measure their level of acceptance of the envisaged mHealth technology. The framework guided accurate measurement of perceived usefulness and perceived ease of use/complexity and found that these were the direct predictors of intention to use mHealth for T2DM management. The identified mHealth opportunities were also well supported by HCPs; almost all possibilities were perceived as useful, and HCPs intended to use mHealth in the future. The perceived usefulness, perceived ease of use, and attitude of HCPs toward mHealth opportunities provided scientific evidence on acceptance, which is essential for the successful implementation of digital innovations.

The study also revealed complex issues involved in the development of mHealth technology. These become more relevant in resource-constrained countries. However, evidence-based strategies were developed, including specific issues that need to be taken into consideration in developing mHealth innovations in low and middle-income countries. It was also evident that with just enough political willingness, digital innovations could be incorporated into the country's digital strategy to support data transmission and management.

Health systems across low and middle-income countries face myriad challenges, including rising costs related to health care, the burden of disease, increased prevalence of long-term conditions, poverty, and inequality. Digital innovations that are affordable and well-accepted by users may strengthen these health systems, as evidenced in this study. Control of chronic conditions could benefit from low-cost digital innovations. However, the study showed that all stakeholders need to be involved, from the initial phases of the development till implementation, to increase acceptance and a sense of ownership.

According to evidence in Ethiopia, despite increasing Type 2 diabetes mellitus (T2DM) prevalence, the quality of T2DM management is poor (Dagnew et al., 2021:8). There is poor glycemic control and an increase in the prevalence of diabetes-related complications among patients. Patients are engaged in self-management activities due to poor access to patient education, poor communication between HCPs and patients, and inadequate support for DSM. The treatment plan quality is poor, and patients are not satisfied. There is also a problem in clinical data quality and use, and the country's health policy outlines the need to digitize individual-level data to address this challenge. The increased proportion of undiagnosed diabetes also worsens the situation (Yitbarek et al., 2021:3). The proposed strategies, especially behavioural change Communication using SMS, patient communication and support using voice calls, use of digital checklist and applications, clinical decision support system and presence of digital screening checklist could help alleviate the challenges described above.

The study identified the opportunities and use of mHealth to enhance T2DM management by HCPs. Various interventions executed in different countries demonstrated that mobile technology has the capability to improve access of patients to care, collect health-related data, monitor patients' health and link patients with health care professionals, who can access the patient data and provide interventions or feedback.

Despite the potential benefits of mHealth, the study revealed possible reasons why the implementation of mHealth continues to be challenging. There were many challenges identified, including a lack of infrastructure, a lack of government regulations, economic difficulties, a lack of an interoperability standard, poor security and privacy of health data, a lack of digital awareness and literacy, and poor usability of the mHealth system.

Different tools are proposed in the strategies. SMS is one of the tools proposed in behavioural change communication and patient support strategies. SMS is the most practical, practical, and affordable tool. Voice calls are the most effective means of patient communication, support, and teleconsultation because they enable real-time interaction and collaboration between patients and healthcare professionals. Voice call is also a cheap and simple tool. Digital forms were suggested to maintain personal health records. These digital forms also could be used for diabetes screening.

These strategies could guide future implementation and enhance the effectiveness of the implementation of the innovation.

7.6 LIMITATIONS OF THE STUDY

The study revealed some crucial data on implementing mHealth for consideration by policy makers in Ethiopia. However, there were also limitations. The Integrated literature review had a small number of qualitative studies. However, this weakness was overcome by the grey literature which was included. The Phase II survey focused only on the key concepts of the combined theories that guided the study. The study was conducted in one region and only in public primary healthcare settings, which could affect its generalizability. However, the findings could serve as a baseline for further exploration of favourable factors for mHealth in other settings.

7.7 CONCLUSION

This study aimed to investigate opportunities for the development of mHealth intervention for diabetes management and design strategies for their implementation in Ethiopia. The integrative literature review identified interventions that can be executed using mHealth applications in low and middle-income countries. These interventions focused on domains like patient education, communication, support for diabetes self-management (DSM), maintaining personal health records (PHRs), screening, and clinical decision support system (CDSS) for treatment/therapy plans, using structured SMS and voice calls. The mHealth interventions were found to improve glycemic control, clinical outcomes, diabetes knowledge, and adherence to treatment and clinical follow-up. In addition, mobile phone interventions have proven beneficial in terms of rapid data collection, storage, and general health information management. The HCPs' access to patient data on mobile devices will lead to timely identification and control of diabetes complications.

The study confirmed that users need to see potential in mobile technology, most of the HCPs had a positive attitude toward the possibility of adopting mHealth and it was perceived as having significant potential to benefit health service delivery to patients with diabetes mellitus. The HCPs considered all the mHealth opportunities identified in Phase I valuable and would be easy to use in a primary healthcare setting. HCPs demonstrated an intention to use mHealth for early diagnosis, provision of patient education, maintaining PHR, patient monitoring, patient communication, DSM support, patient tracking, and clinical decision support system (CDSS).

The advanced statistical analysis showed that the indices of the measurement models reached the recommended acceptable model fitness values. The perceived usefulness and ease of use/complexity significantly affected HCPs’ behavioural intention to use mHealth for T2DM management. Perceived complexity/ease of use also significantly affected the perceived usefulness of mHealth for T2DM management by HCPs. In the regression analysis, attitude towards mHealth opportunities and attending eHealth/mHealth courses also positively affected HCPs' behavioural intention to use mHealth for T2DM management. Their approval is vital in being able to measure the success of the mobile application in future.

The study assumes that the drive towards adopting mobile technology demands an adjusted approach towards diabetes care and documentation of such care. Central to the argument for this innovation is the improvement of patient care in primary healthcare settings. Health providers' decisions can, therefore, be guided by timely, accurate and comprehensive real-time information generated from mobile technology. HCPs will need adequate skills to enable them to execute some unique functionalities such as capturing, entering, storing, retrieving, analysing, interpreting, and using data to manage diabetes.

Despite the opportunities presented in various studies, the implementation of mHealth still faces several challenges. This included research and evidence-related, government-related, infrastructural, economic, users-related, and system application- and interface-related issues. The absence of a framework to regulate mHealth initiatives in Ethiopia could also be a potential barrier. However, the researcher believes that the existing eHealth landscape in the country could support the initiative.

The evidence-based strategies outline a detailed strategy for the implementation of mHealth. These strategies could address the identified challenges that have been found to be barriers to the implementation of mHealth in other similar settings. The study also acknowledges the need to align mHealth with organizational objectives, digital strategy, and end-user needs and paying attention to issues of usability and security of information.

The study concluded that there are opportunities for using mHealth to manage chronic conditions such as diabetes in Ethiopia. Successful implementation of mobile technologies requires a positive attitude and acceptance by HCPs to enhance the quality of diabetes management in primary healthcare settings.

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ANNEXURE A: DATA EXTRACTION TOOL

Item	Description	Remark
About the article		
Title of the article		
Title of the Journal		
Authors		
Country		
Language		
Year of publication		
Type of article	1. Empirical evidence 2. Review article 3. report 4. Other, please specify	
Study aim/hypothesis/purpose of the article		
Methodology		
Study setting and period		
Study design		
Study population (please include for the control group, if any)		
Sample size (please include for the control group, if any)		
Sampling techniques (please include for the control group, if any)		
Variables under study (dependent)		
Variables under study (independent)		
Intervention (type and duration) and Strategies for strengthening DM		
Description of the mHealth platform/application/intervention		
Information architecture		
Interoperability		
Theoretical framework		
Measurement and Data analysis		
Result and Conclusion		
Findings		
Outcomes for DM management		
Implication		
Conclusions		

ANNEXURE B: RISK OF BIAS ASSESSMENT

Articles	Joanna Briggs Institute Critical Appraisal Tools for RCT studies													%Y (Risk)
	Q 1	Q 2	Q 3	Q 4	Q 5	Q 6	Q 7	Q 8	Q 9	Q 10	Q 11	Q 12	Q 13	
Shetty et al. 2011	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	U	84.6% (Low)
Tamban et al. 2013	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	U	84.6% (Low)
Takegna et al. 2014	Y	U	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Y	76.9% (Low)
Shahid et al. 2015	Y	Y	Y	N	N	N	Y	Y	Y	Y	Y	Y	Y	76.9% (Low)
Kumar et al. 2015	Y	Y	Y	U	N	N	Y	Y	Y	Y	Y	Y	Y	76.9% (Low)
Shariful et al. 2015	Y	U	Y	N	N	N	Y	N	Y	Y	Y	Y	U	53.8% (Moderate)
Olmen et al 2017	U	U	Y	U	N	N	Y	U	Y	Y	Y	Y	U	46.2% (High)

Y=yes, N=No, U=Unclear; Q1) Was true randomization used for assignment of participants to treatment groups; Q2) Was allocation to treatment groups concealed? Q3) Were treatment groups similar at the baseline; Q4) Were participants blind to treatment assignment? Q5) Were those delivering treatment blind to treatment assignment; Q6) Were outcomes assessors blind to treatment assignment; Q7) Were treatment groups treated identically other than the intervention of interest; Q8) Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analysed? Q9) Were participants analysed in the groups to which they were randomized? Q10) Were outcomes measured in the same way for treatment groups; Q11) Were outcomes measured in a reliable way; Q120 Was appropriate statistical analysis used; Q13) Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?

Articles	Joanna Briggs Institute Critical Appraisal Tools for Quasi-experimental /Interventional Studies									
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	%Y (Risk)
Zolfaghari et al. 2011	Y	Y	Y	N	Y	Y	Y	Y	Y	88.9% (Low)
Pastakia et al. 2011	Y	U	Y	N	Y	N	U	N	U	33.3% (High)
Rotheram-Borus et al. 2012	Y	Y	Y	N	Y	N	Y	N	Y	66.7% (Moderate)
Haddad et al. 2014	Y	Y	Y	N	Y	N	Y	Y	Y	77.8% (Low)
Sujeet et al 2016	Y	Y	Y	Y	U	N	Y	Y	U	66.7% (Moderate)

Q1) Is it clear in the study what is the ‘cause’ and what is the ‘effect’; Q2) Were the participants included in any comparisons similar? Q3) Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest; Q4) Was there a control group? Q5) Were there multiple measurements of the outcome both pre and post the intervention/exposure; Q6) Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analysed; Q7) Were the outcomes of participants included in any comparisons measured in the same way? Q8) Were outcomes measured in a reliable way? Q9) Was appropriate statistical analysis used?

Article	Joanna Briggs Institute Critical Appraisal Tools for Qualitative studies										%Y (Risk)
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	
Watkins et al, 2018	U	U	U	Y	Y	N	N	Y	Y	Y	50% (Moderate)

Q1) Is there congruity between the stated philosophical perspective and the research methodology; Q2) Is there congruity between the research methodology and the research question or objectives; Q3) Is there congruity between the research methodology and the methods used to collect data; Q4) Is there congruity between the research methodology and the representation and analysis of data? Q5) Is there congruity between the research methodology and the interpretation of results? Q6) Is there a statement locating the researcher culturally or theoretically? Q7) Is the influence of the researcher on the research, and vice- versa, addressed? Q8) Are participants, and their voices, adequately represented? Q9) Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body? Q10) Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?

ANNEXURE C: CONSENT FORM FOR HEALTHCARE PROFESSIONALS

Purpose of the Study

This study aims to investigate opportunities for the development of the mHealth intervention for diabetes management and design strategies for their implementation in Ethiopia.

Purpose of your Participation

As a Healthcare professional managing patients with Type-2 Diabetes mellitus, you will be requested to complete a questionnaire focused on the opportunities of mobile health in supporting your performance in managing patients. The questionnaire will not take more than 50 minutes to complete.

Potential Benefits and Harms

No direct or indirect harm could come from your participation in this study; the only potential risk is minimal psychological discomfort from the questions being asked. The benefit of your participation is that your views and experiences will assist the researcher in recommending and developing strategies for improving the implementation of mHealth to support your and your colleague's diabetes management.

Anonymity:

Your identity will always remain anonymous. None of the information you share with me today will be traced back to you as an individual. Any information reported will be grouped with the responses of others. All data will be stored confidentially and securely during the study (i.e., on a password-protected laptop) and destroyed once the study is over.

Types of Participation

Your participation in this study is voluntary. You have the right to withdraw from the study at any stage should you decide to participate, and you will not be penalized. All information provided will be treated in the strictest confidence.

For More Information/any Enquiries

If you require any information or have any questions about the study, please get in touch with me (Robel Tezera Zegeye) by Telephone: at +251911930408 or by email: 58554246@mylife.unisa.ac.za or robeltezera@gmail.com

The Department of Health Studies' Ethics Committees, University of South Africa, has approved this research. If you wish to report any problems you have experienced concerning the study, please contact Prof Margaret Ramukumba, the Research Supervisor, on Tel: 072 6302 504 or email: mokholelana@gmail.com.

Consent by Participant

I, ____ (interviewee's name), understand that I am being asked to participate in a study to answer questions related to the mobile health (mHealth) technology uses for diabetes management and to identify barriers that hinder (as well as facilitators for) acceptance of this kind of technology.

I understand that it is my choice to participate in this study and that I may refuse to participate or stop/withdraw from it at any time.

I also understand that a summary of the results will be made available to me at the end of the study if I request a copy. My signature below indicates that I understand this study and I agree to participate. Also, I have been given a copy of this signed consent form.

____

Signature of Participant

Declaration by Investigator

I, Robel Tezera Zegeye declare that:

- This document contains information that I have explained.
- I encouraged them to ask questions and answered them thoroughly
- As previously discussed, I am confident that he/she comprehends all aspects of the research.
- I did not use an interpreter.

____________________________ ____________________________

Investigator Signature *Date*

ANNEXURE D: DATA COLLECTION INSTRUMENT PHASE II

Dear Participants

You are invited to participate in this study on strategies to Implement Mobile Health Interventions for Diabetes Management in Ethiopia

The main objective of this study is to examine potential barriers and facilitators for diabetes mHealth intervention in Ethiopia.

Considerable value is highly given to the fact that your input will contribute to designing mobile health strategies for diabetes.

Kindly note that your name will not be written in this form, and all information you give will be kept strictly confidential. Your participation is voluntary, and you are not obliged to answer any question you do not wish to answer. If you feel discomfort completing the questionnaire, please feel free to drop it off whenever you want.

The questionnaire should take thirty minutes to complete if you decide to participate. Please answer the questions in the space provided. Try to honestly complete the questions when you are most unlikely to be distributed. There are no reimbursements associated with completing the questionnaire.

If you require any further Information, please do not hesitate to contact me on my cell phone number, **+251-911930408,** or My E-mail address, 58554246@mylife.unisa.ac.za. Should you have any questions regarding the ethical aspects of the study, you can contact the study's supervisor at UNISA, Professor Margaret Ramukumba, during office hours at telephone number 012 4296719 or e-mail: mokholelana@gmail.com.

The researcher appreciates your time in completing this questionnaire as well as your contribution to the successful completion of the study. A copy of my completed research report can be made available to you upon request.

Researcher: Robel Tezera Zegeye

Supervisor: Professor Margaret Ramukumba

Guide to Answering the Questions:

- Read the statement or question carefully to ensure understanding.
- Select the appropriate response.

Section A General Information			
Part I: Socio-demographic Data			
No.	Question	Response	Code
101	What is your Gender?	Male Female	1 2
102	How old are you? (in years)		
103	What is your highest level of education?	Master's degree Bachelor's degree Diploma	1 2 3
104	What is your working position in the health institution	Healthcare Manager Specialist General Practitioner Nurse Other, Please Specify ________________	1 2 3 4 5
105	Did you study any course related to eHealth/mHealth during your undergraduate or postgraduate study?	Yes No	1 2
106	Did you attend any formal training related to eHealth or mHealth?	Yes No	1 2
Part II: Mobile Phone Experiences			
107	Do you own a cell phone?	Yes No	1 0
108	Type of mobile phone	Smartphone (install and use applications) Basic (only used for voice and text messages)	
109	How many years have you been using a cell phone?		
110	Do you have access to the internet at the health center?	Yes No	1 2

No.	Questions	Responses/Code				
	How often do you use your cell phone for the following activities?	**All the time**	**Regularly**	**Occasionally**	**Rarely**	**Never**
111	For making phone calls	1	2	3	4	5
112	For text messaging	1	2	3	4	5
113	For checking data stored on your cell	1	2	3	4	5
114	For checking e-mail	1	2	3	4	5
115	For browsing internet	1	2	3	4	5
116	For reading books, articles, or any reading materials	1	2	3	4	5

117	For capturing data, memos, or events	1	2	3	4	5

Section B Perception regarding the Use of mHealth

Statements in this section intend to examine the Health Professional perceptions of the potential of mHealth for Diabetes Management

No.	Statement	Responses/Code				
	Indicate your views regarding the following Statements	Strongly Disagree	Disagree	Neutral	Agree	Strongly agree
201	Using mHealth application will allow health professionals to disseminate prevention strategies	1	2	3	4	5
202	Using mHealth application will make it easier for early diagnosis of fluctuations in blood glucose	1	2	3	4	5
203	Using mHealth will increase healthcare reach to patients with diabetes	1	2	3	4	5
204	Using mHealth will allow health professional to capture and share data	1	2	3	4	5
205	mHealth application will make it easier for monitoring diabetes patients					
206	mHealth will empower diabetes patient to self-manage their condition	1	2	3	4	5
207	mHealth will empower diabetes patients to improve their glycemic control	1	2	3	4	5
208	Using mHealth will enable health professionals to communicate with diabetic patients in real-time	1	2	3	4	5
209	mHealth will allow health professional to disseminate health education easily	1	2	3	4	5
210	Using mHealth application will make it easier to prevent complications	1	2	3	4	5
211	mHealth application will make it easier for patient tracking system	1	2	3	4	5
212	mHealth application will make the decision support system helpful	1	2	3	4	5

Section C Perception of usefulness of diabetes mHealth application

Statements in this section intend to look at the Health Professionals perceptions toward the usefulness of mobile application in management of diabetes.

No.	Statement	Responses/Code				
	Indicate your views regarding the following mHealth Application	Strongly Disagree	Disagree	Neutral	Agree	Strongly agree
301	Using mobile phone would improve my performance in communicating with diabetic patients	1	2	3	4	5
302	Using mobile phone would improve my performance in maintaining patients' health records (collecting, storing, monitoring, transmitting data for diabetes patients)					
303	Using mobile phone would support my performance in increasing patients Self-Management practice					

304	Using mobile phone would improve my performance in maintaining patient adherence to treatment regimen (medication and diet)					
305	Using mobile phone would be cost effectives in diabetes management					
306	Using mobile would improve patient satisfaction on the provided healthcare					

Section D Critical Features of the mHealth applications The question is about features of mHealth application for diabetes management						
No.	Statement	Responses/Code				
	The following mHealth functionalities would be useful in diabetes management:	Strongly Disagree	Disagree	Neutral	Agree	Strongly agree
401	SMS features	1	2	3	4	5
402	Voice call features					
403	Mobile Biosensor for collecting Biomarkers (example blood glucose levels)					
404	Personal Health Record features (for data collection, storage, and communication)					
405	Bluetooth that links to mobile phones to blood glucose meter					
406	Mobile connected to central database (like hospital information system or HMIS or Electronic Health record)					
407	Mobile diary application					
408	Alarm features to indicate critical features					
409	Remote patient monitoring system					
4010	Decision support system to design appropriate intervention for diabetic patients					
4011	Security features with restricted access system					
4012	Interoperable system that easily interact with other software					

Section E Perceptions on complexity/ease of use of mHealth applications		
	Rate your confidence for each situation with a percentage from the following scale Zero being no confidence while 10 is reflecting highest confidence level.	0 1 2 3 4 5 6 7 8 9 10
501	I would find it easy to use a mobile phone to communicate and counsel diabetic patients	0 1 2 3 4 5 6 7 8 9 10
502	I would find it easy to use a mobile phone to collect and store data and communicate intervention plans (to maintain PHR)	0 1 2 3 4 5 6 7 8 9 10
503	Using mobile phones to manage diabetic patients would be easy for me	0 1 2 3 4 5 6 7 8 9 10
504	I would find it easy to get a diabetes mobile health application to support my tasks	0 1 2 3 4 5 6 7 8 9 10

505	My interaction with the diabetes mobile health application would be satisfying	0 1 2 3 4 5 6 7 8 9 10
506	I would find the diabetes mobile health application to be flexible to interact with	0 1 2 3 4 5 6 7 8 9 10
507	It would be easy for me to become skilful at using a diabetes mobile health application	0 1 2 3 4 5 6 7 8 9 10

Section F Health Professional Intention to Use Diabetes Mobile Health System						
No.	Statement	Responses/Codes				
	Indicate your views regarding the intention to use the listed mHealth applications (I would use mHealth for):	Strongly Disagree	Disagree	Neutral	Agree	Strongly agree
601	Early diagnosis and treatment of diabetes	1	2	3	4	5
602	Provision of health education	1	2	3	4	5
603	Maintaining PHR (capturing storing, and sharing patient data)	1	2	3	4	5
604	Monitoring diabetic patient data	1	2	3	4	5
605	Communicating in real-time with diabetic patients	1	2	3	4	5
606	Empowering patients on self-management of diabetes	1	2	3	4	5
607	Tracking diabetic patients	1	2	3	4	5
608	Using for decision support system	1	2	3	4	5
609	I believe that I would use the mobile health application to manage diabetic patients in the future.	1	2	3	4	5
610	I intend to use the functions and content of diabetes mHealth application as often as possible	1	2	3	4	5

Thank you for your time and participation!

ANNEXURE E: CONSENT FORM FOR EXPERTS

Introduction

This is research being conducted by Robel Tezera Zegeye as part of a PhD in Public Health at the University of South Africa (UNISA). You are invited to participate in this study as a digital health/mobile health expert at different levels of the healthcare system and higher education institutes. The purpose of the study is to Design strategies for diabetes-related mHealth interventions in Addis Ababa, Ethiopia.

Purpose of your Participation

As a digital health/mobile health expert, you will be requested to complete a questionnaire consisting of questions related to the study for two or three rounds. The answers will be based on your knowledge and views, which do not require prior preparation.

Anticipated Risks

The study procedures involve no foreseeable risks to you. You have the right to refuse to answer any question that makes you feel uncomfortable. However, if you feel that you are psychologically affected, please feel free to talk to me anytime.

Benefits for Participation

This research will have a very small reimbursement to you as a participant in the Delphi panel. However, the important benefits are that your views and experiences will assist the researcher in recommending and developing strategies for improving the implementation of mHealth for diabetes management.

Types of Participation

Your participation in this study is voluntary. You have the right to withdraw from the study at any stage should you decide to participate, and you will not be penalized. All information provided will be treated in the strictest confidence, and your name will not be reflected anywhere.

For More Information/any Enquiries

If you require any information or have any questions about the study, please get in touch with me (Robel Tezera Zegeye) by Telephone: at +251911930408 or by email: 58554246@mylife.unisa.ac.za or robeltezera@gmail.com

The Department of Health Studies' Ethics Committees, University of South Africa, has approved this research. If you wish to report any problems you have experienced concerning the study, please contact Prof Margaret Ramukumba, the Research Supervisor, on Tel: 072 6302 504 or email: mokholelana@gmail.com.

Declaration by Expert

I .... voluntarily consent to participate in the research project mentioned above. The background, purpose, risks, and benefits of the study have been explained to me. I also understand that I may withdraw from the study at any time without consequences. I know that my participation in the study will be acknowledged, although my identity and my organization's identity will be withheld.

Participant's Signature	*Date*

Declaration by Investigator

I, Robel Tezera Zegeye declare that:

- This document contains information that I have explained.
- I encouraged them to ask questions and answered them thoroughly
- As previously discussed, I am confident that he/she comprehends all aspects of the research.
- I did not use an interpreter.

Investigator Signature	*Date*

ANNEXURE F: QUESTIONNAIRE MODIFIED DELPHI ROUND 2

Dear Participants

You are invited to participate in this study on strategies to Implement Mobile Health Interventions for Diabetes Management in Ethiopia

The main objective of this study is to examine potential barriers and facilitators for diabetes mHealth intervention in Ethiopia.

Considerable value is highly given to the fact that your input will contribute to designing mobile health strategies for diabetes.

Kindly note that your name will not be written in this form, and all information you give will be kept strictly confidential. Your participation is voluntary, and you are not obliged to answer any question you do not wish to answer. If you feel discomfort completing the questionnaire, please feel free to drop it off whenever you want.

The questionnaire should take thirty minutes to complete if you decide to participate. Please answer the questions in the space provided. Try to honestly complete the questions when you are most unlikely to be distributed.

If you require any further Information, please do not hesitate to contact me on my cell phone number, **+251-911930408,** or My E-mail address, 58554246@mylife.unisa.ac.za. Should you have any questions regarding the ethical aspects of the study, you can contact the study's supervisor at UNISA, Professor Margaret Ramukumba, during office hours at telephone number 012 4296719 or e-mail: mokholelana@gmail.com.

The researcher appreciates your time in completing this questionnaire as well as your contribution to the successful completion of the study. A copy of my completed research report can be made available to you upon request.

Researcher: Robel Tezera Zegeye

Supervisor: Professor Margaret Ramukumba

Section I: General Information of Experts

Carefully read the statement or question to ensure comprehension, and kindly answer all sociodemographic by inserting an X in the column for response options.

No.	Question	Response	Code
101	What is your Gender?	Male Female	1 2
102	In which age category do you fall?	30-40 years 41-50 years 51 and above 60 years	1 2 3
103	What is your highest level of education?	Master's degree PhD	1 2
104	Please indicate your professional qualification	Health information system experts (Health Informatics experts) Networking Expert (IT expert) Software Developer (Software Engineer	1 2 3
105	Please indicate your organization/institute	Addis Ababa Regional Health Bureau Ministry of Health Higher education Institute Other Governmental organization Non-governmental Organization Other, please specify:	1 2 3 4 5 6
106	How many years did you participate in designing and developing any mHealth application or mobile application system?		

Section II: Strategies of mHealth for diabetes management

Instruction for the Inventory

Dear Experts,

This section contains 59 strategic activities under 5 strategies. The included activities are focused on mHealth interventions/features, which are important for healthcare professionals working in Health Centres to manage patients with Type 2 DM.

The strategies in this section are based on previous research and modified Delphi round one. We require your expert opinion on the appropriateness of each strategy for the mHealth platforms intended for use by health professionals in diabetes management.

Please be as objective and constructive as possible in your judgment and use the following rating scale:

Rating scale	Description
1= the strategy is not relevant to mHealth for diabetes management	The strategic activity has no relevance in designing, developing, and implementing mHealth for diabetes management.
2= the strategy is somehow relevant to mHealth for diabetes management	The strategic activity has some relevance but does not have a significant impact on the design, development, and implementation of the mHealth for diabetes management
3= the strategy is relevant to mHealth for diabetes management	The strategic activity has relevance in designing, developing, and implementing the mHealth for diabetes management.
4= the strategy is highly relevant to SMS-mHealth for diabetes management	The strategic activity has high relevance in designing, developing, and implementing mHealth for diabetes management. The absence of strategic activity will significantly negatively affect the development and implementation of mHealth for diabetes management.
Remark	The expert could provide additional comments, revise the strategies and activities, and propose additional/alternative strategies and activities

Strategy 1: Behavioural Change Communication Objective: Provide behavioural intervention and education remotely for patients with type 2 DM mHealth tool: **SMS**						
Expected Outcome: Improve the patient's knowledge of diabetes management and enhance clinical outcomes						
Actions	**Activities**	**Not relevant**	**Somehow relevant**	**Relevant**	**Highly relevant**	**Comments**
1. Develop Behavioural Intervention and reminders messages for patients with type 2 DM	1.1. Develop Messages related to a healthy diet and nutrition	1	2	3	4	
	1.2. Develop messages related to physical exercise					
	1.3. Develop messages related to the prevention of disease complication					
	1.4. Develop messages related to psychosocial supports					
2. Maintain the Quality of Behavioural Messages development	2.1. Involve experts, stakeholders, and patient associations during the SMS development					
	2.2. Refers to national and international type 2 DM management guidelines					
	2.3. Create a language switch option to provide a version based on the local language preference (translation to local languages)					
	2.4. Create, revise, and update the SMS database					
3. Use messages tailoring techniques for behavioural intervention	**3.1. Use non-theory-based message tailoring techniques based on the following:**	**1**	**2**	**3**	**4**	**Comments**
	3.1a. sociodemographic characteristics					
	3.1b. previous DSM knowledge and practice					
	3.1c. current health status					
	3.1d. preferable time for receiving the SMS					
	3.2. Use **theory-based** message tailoring techniques using theories with 4 to 5 constructs (Example: the trans-theoretical model of behavioural change (TTM))					

4. Implement behavioural interventions and reminders using SMS	4.1. Design schedule for transmission of developed SMS to patients					
	4.2. Start SMS content delivery from general informative messages					
	4.3. Continue the content delivery to develop self-management of specific behaviour					
	4.4. The latent phase of content delivery shall focus on the maintenance of the behaviour					
	4.5. Send At least one message/day during key behaviour change periods.					
	4.6. Gradually decrease the SMS frequency to three to four SMS per week during less acute phases (Moderate frequency)					
5. mHealth tool (SMS) features	5.1. SMS to have 160 characters, including spaces, punctuation, and any branding or links to additional information					
	5.2. Split into two text messages if necessary to accommodate additional contents					
	5.3. Use well-known abbreviations sparingly					
	5.4. Consider the clients' literacy level					
	5.5. The messages must be current (up-to-date)					
	5.6. Use One-way (Person-to-person or P2P) SMS network trafficking					
	5.7. Consider interactive, two-way (Application-to-person or A2P) SMS network trafficking *(Long-term strategy)*					
Overall Comments on Strategy 1 (please provide comments or additional feedback):						

Strategy 2: Patient communication and Support for Diabetes Self-management (DSM) Objective: Ensure the presence of adequate communication and support on DSM mHealth tool: **Voice call, SMS, and telemonitoring**						
Expected Outcome: Enhance patient-HCP communication, and Improve DSM practice of Patients with Type 2 DM						
Actions	**Activities**	**Not relevant**	**Somehow relevant**	**Relevant**	**Highly relevant**	**Comments**
6. Remind for medication and clinical follow-up	6.1. Use voice calls to remind compliance with medication					
	6.2. Use voice calls to remind compliance for clinical follow-up					
7. Create continuous communication with patients	7.1. Monitor patient progress by creating continuous communication using either voice calls or SMS					
	7.2. Use voice calling to communicate the treatment plan					
	7.3. Use SMS to communicate the treatment plan					
	7.4. Provide patient counselling using voice calls					
8. Provide adequate decision support on DSM	8.1. Use SMS to provide feedback based on patient clinical data.					
	8.2. Use voice calls to provide feedback based on patient clinical data.					
	8.3. Create patient social support group to communicate and support each other through SMS/social media					
	8.4. Use telemonitoring blood glucose to support DSM					
Overall Comments on Strategy 2 (please provide comments or additional feedback):						

Strategy 3: Personal Health Record (PHR) Objective: Collect, store, transmit and monitor data of patients with Type 2 DM mHealth tools: **PHR (form-based) application, biosensors, voice calls, SMS**							
Expected Outcome: Enhance data quality, and use; and improve clinical outcomes							
Actions	**Activities**		**Not relevant**	**Somehow relevant**	**Relevant**	**Highly relevant**	**Comments**
9. Capture Data (Data collection)	9.1.	Use biosensors to collect biomarkers from patients	1	2	3	4	
	9.2.	Use Bluetooth to connect mobile phones with biosensors					
	9.3.	Use other near-field communication tools as a backup for Bluetooth (Example: USB and WIFI)					
	9.4.	Use voice calls to collect data remotely and transfer it to the central system using a mobile phone					
	9.5.	Create a mobile interface for HCPs for health professionals for data entry and integration it with the Hospital EMR					
10. Store Patient data (Data storage)	10.1.	Use a central system of mHealth PHR to store data					
	10.2.	Use relational and non-relational databases for data storage at the central system					
11. Data transmission	11.1.	Use SMS for data transmission using the GSM (Cellular) transmission protocol					
	11.2.	Use HTTP/HTTPS protocol to transfer collected data to the central platform in a web a based system					
12. Data Monitoring (Use mHealth PHR application to monitor patients)	12.1.	Create a data processing display system for data stored in the central database, allowing HCPs to monitor patients' data					
	12.2.	Create a graphical presentation for HCPs to track patterns and trends					
	12.3.	Provide statistics of collected patient data for HCPs to track patterns and trends					
Overall Comments on Strategy 3 (please provide comments or additional feedback):							

Strategy 4: Screening
Objective: Screen and identify Type 2 DM cases
mHealth tools: **SMS, Phone-based checklist, Voice calls**

Expected Outcome: Improve Type 2 DM Screening rate, and reduce the proportion of undiagnosed diabetes

Actions	Activities		Not relevant	Somehow relevant	Relevant	Highly relevant	Comments
13. Use the mHealth screening checklist	13.1.	Develop a phone-based checklist for Screening type 2 DM	1	2	3	4	
	13.2.	Use the phone-based screening checklist in a primary healthcare setting					
14. Use mHealth to improve screening and diagnostic rate	14.1.	Use SMS to remind the community of the importance of diabetes screening tests/early diagnosis					
	14.2.	Use voice calling to remind patient to return for definitive screening tests					

Overall Comments on strategy 4 (please provide comments or additional feedback):

Strategy 5: Treatment/Therapy plan
Objectives: provide decision support for HCPs to design and communicate effective treatment/therapy plan
mHealth tool: **Clinical Decision Support System (CDSS), Voice calls, SMS**

Expected Outcome: Enhance treatment/therapy plan for managing Type 2 DM and improves clinical care

Actions	Activities		Not relevant	Somehow relevant	Relevant	Highly relevant	Comments
15. Implement a Clinical Decision Support system (CDSS)	15.1.	Use the mHealth PHR data processing system to plan treatment	1	2	3	4	
	15.2.	Provide knowledge-based support that could alert HCPs for critical issues (follow-up action and treatment plans)					
	15.3.	Use CDSS that allows HCPs to communicate the therapy plan through SMS or mobile application to the patients					
	16.1.	Create health professionals' social group to communicate and support each other through SMS/social media					

16. Create collaboration among healthcare professionals (HCPs)	16.2. Create a teleconsultation service for HCPs to get consultations with senior experts/specialists (Using voice calls)					
	16.3. Create access to an online referencing system for HCPs (for example, diabetes management guidelines)					
Overall Comments on Strategy 5 (please provide comments or additional feedback):						

Section III: Framework/Guide to Address challenges of mHealth implementation for diabetes management

Instruction for the Inventory

Dear Experts,

This section contains strategic guides/frameworks to address challenges for implementing mHealth for diabetes management. Totally 39 items are extracted from the previous research phase, and modified Delphi round one. Your expert opinion on the appropriateness of each guide is required to address the mentioned challenges for the effective implementation of mHealth for type 2DM management.

Please be as objective and constructive as possible in your judgment and use the following rating scale:

Rating scale	Description
1= not relevant	The guide has no relevance in addressing the challenges
2= somehow relevant	The strategy has some relevance but does not have a significant impact on addressing the challenges
3= relevant	The strategy has relevance in addressing the challenge.
4= highly relevant	The strategy has high relevance and is the only solution to addressing the challenges
Remark	**The expert could provide additional comments, revise the guide, and propose additional/alternative guide**

F1. Guide to Address Interoperability Challenges		1=Not relevant	2=Somehow relevant	3=Relevant	4=Highly relevant	Comments
F1a	The system be supported by IEEE 11073 Personal Health Devices (PHD) standard for data transmission from biosensors to the mobile phones					
F2b	Use Fast Healthcare Interoperability Resources (FHIR) using a Representational State Transfer (REST, often referred to as RESTful architectures) for structural interoperability					
F2c	The system shall use the HTTP protocol and the JSON (JavaScript Object Notation) data standard to exchange data between the mobile phones of health professionals and the central system					
F1d	The system shall support GSM (Cellular) data transmission protocol					
F1e	Employ HL7/FHIR standard for clinical messaging					
F1f	Provide basic interoperability with national e-health systems (EMR, DHIS2, LIS, HMIS, etc.)					
F1g	Employ open-software development standard					
F1h	Employ the International Classification of Diseases (ICD-10) standard for clinical terminology					
F1i	Employ Systemized Nomenclature of Medicine (SNOMED) standard for clinical data coding					
F1j	Integrate Logical Observation Identifiers Names and Codes (LOINC) standard for laboratories					
F1k	Integrate RxNorm for pharmacies					
F2. Guide to Address Security and Privacy Challenges (mHealth application for SMS/PHR/CDSS)		**1=Not relevant**	**2=Somehow relevant**	**3=Relevant**	**4=Highly relevant**	**Comments**
F2a	Use an authentication system for healthcare professionals and other users (three factors authentication) for access and data sharing					
F2b	Use advanced encryption standard (AES) for data sharing					
F2c	Use cryptographic mechanisms for maintaining data confidentiality					
F2d	The system shall include both synchronous and asynchronous data validation approaches					
F2e	Align with national eHealth Security and privacy guidelines					
F3. Guide to address usability challenges (mHealth application for SMS/PHR/CDSS)		**1=Not relevant**	**2=Somehow relevant**	**3=Relevant**	**4=Highly relevant**	**Comments**
F3a	The system must be easy to install					
F3b	The system must be easy to update					
F3c	The system must be easy to navigate					
F3d	The system must use an easy graphical interface					

F3e	The system must be easy to troubleshoot					
F3f	The system must be easy to exit either by uninstalling or unsubscribing					
F3g	The system must allow multilingual installation on a single application					
F3h	The user interface shall be kept simple by using the appropriate font type and size					
F3i	The system design must be scalable					
F3j	Iterative development process to be used based on user feedback					
F4. Guide to Address User-related Challenges		**1=Not relevant**	**2=Somehow relevant**	**3=Relevant**	**4=Highly relevant**	**Comments**
F4a	Usefulness: Increase awareness of HCPs related to the usefulness of diabetes-related mHealth					
F4b	Ease of Use: Capacitate health professionals' digital literacy on diabetes-related mHealth					
F4c	Create inter-professional relationships and collaboration in the utilization of diabetes-related mHealth					
F4d	Provide training and certification for health professionals in the application of diabetes-related mHealth as part of a continuous development program (CPD)					
F4e	Make information on the diabetes-related mHealth application accessible to healthcare professionals and patients					
F4f	Prepare and disseminate the User guide for the developed mHealth system					
F4g	Prepare eLearning course on mHealth use and application					
F4i	Provide affordable internet incentives for HCPs to utilize mobile applications for diabetes management					
F5. Guide to Address resource Challenges		**1=Not relevant**	**2=Somehow relevant**	**3=Relevant**	**4=Highly relevant**	**Comments**
F5a	Allocate adequate budget for mHealth implementation					
F5b	Expand the infrastructure for mHealth implementation					
F5c	Provide administrative support for HCPs to utilize mHealth for diabetes management					
F5d	Provide access to the internet for HCPs					
F5e	Provide incentives for HCPs to utilize mobile applications for diabetes management					
Comments (please provide comments or additional feedback):						

Thanks for your time and support!

ANNEXURE G: QUESTIONNAIRE MODIFIED DELPHI ROUND 3

Dear Experts,

You are invited to participate in this study on strategies to Implement Mobile Health Interventions for Diabetes Management in Addis Ababa, Ethiopia

The main objective of this study is to Design strategies for diabetes-related mHealth interventions in Addis Ababa, Ethiopia

The fact that your input contributes to the development of diabetes mobile health strategies is highly valued.

Please keep in mind that your name will not be written on this form and that all information you provide will be kept strictly confidential. Your participation is entirely voluntary, and you are under no obligation to answer any questions that you do not wish to answer. If you are uncomfortable completing the questionnaire, you may discontinue it at any time. Try to honestly complete the questions when you are most unlikely to be distributed. There is a small reimbursement associated with completing the questionnaire. Your name and contribution will be mentioned in the acknowledgment section of all papers produced from this paper based on your permission.

If you require further information, please do not hesitate to contact me on my cell phone number, +251-911930408, or My E-mail address, 58554246@mylife.unisa.ac.za. Should you have any questions regarding the ethical aspects of the study, you can contact the supervisor of the study at UNISA, Professor Margaret Ramukumba, during office hours at telephone number 012 4296719 or e-mail: mokholelana@gmail.com

The researcher appreciates your time in completing this questionnaire and your expertise and contribution to the successful development of mHealth strategies for Diabetes management. A copy of my completed research report can be available upon request.

Researcher: Robel Tezera Zegeye

Supervisor: Professor Margaret Ramukumba

Section I: General Information of Experts

Carefully read the statement or question to ensure comprehension, and kindly answer all sociodemographic by inserting an X in the column for response options.

No.	Question	Response	Code
101	What is your Gender?	Male Female	1 2
102	In which age category do you fall?	20-30 years 30-40 years 41-50 years Above 51 years	1 2 3 4
	Types of respondents	Professionals Patients with T2DM	1 2
103	What is your highest level of education? *Only for Professionals*	First Degree (BSc) Second Degree (MSc) Third Degree (PHD)	1 2 3
104	Please indicate your professional qualification *Only for Professionals*	Health information system experts (Health Informatics experts) Nurse Public Health officer Medical Doctor ICT expert (Software engineering/networking)	1 2 3 4 5
105	Please indicate your organization/institute *Only for Professionals*	Health Centre Woreda Health Office Sub-city Health office Regional Health Bureau Ministry of Health Higher education Institute Other Governmental organization Non-governmental Organization Other, please specify:	1 2 3 4 5 6 7
106	How many years did you participate in designing and developing any mHealth application or mobile application system?		

Section II: Strategies of mHealth for diabetes management

Instruction for the Inventory

Dear Experts,

This section contains 47 strategic activities under 5 strategies. The included activities are focused on mHealth interventions/features, which are important for healthcare professionals working in Health Centres to manage patients with Type 2 DM.

The strategies in this section are revised based on the round two findings. We require your expert opinion on the appropriateness of each strategy for the mHealth platforms intended for use by health professionals in diabetes management.

Please be as objective and constructive as possible in your judgment and use the rating scale from strongly agree (5) to strongly disagree (1)

Strategy 1: Behavioural Change Communication Objective: Provide behavioural intervention and education remotely for patients with type 2 DM mHealth tool: **SMS**						
Expected Outcome: Improve the patient's knowledge of diabetes management and enhance clinical outcomes						
Actions	**Activities**	**1=Strongly disagree**	**2=Disagree**	**3=Neutral**	**4=Agree**	**5=Strongly agree**
17. Develop Behavioural Intervention and reminders messages for patients with type 2 DM	17.1. Develop Messages related to a healthy diet and nutrition					
	17.2. Develop messages related to physical exercise					
	17.3. Develop messages related to the prevention of disease complication					
18. Maintain the quality of behavioural messages development	18.1. Involve experts, stakeholders, and patient associations during the SMS development					
	18.2. Refers to national and international type 2 DM management guidelines					
	18.3. Create a language switch option to provide a version based on the local language preference (translation to local languages)					
	18.4. Create, revise, and update the SMS database					
19. Use messages tailoring techniques for behavioural intervention	**19.1. Use non-theory-based message tailoring techniques based on the following:**	**1**	**2**	**3**	**4**	**5**
	3.1a. sociodemographic characteristics					
	3.1b. previous DSM knowledge and practice					
	3.1c. current health status					
	3.1d. preferable time for receiving the SMS					
	19.2. Use **theory-based** message tailoring techniques using theories with 4 to 5 constructs					

	(Example: the trans-theoretical model of behavioural change (TTM))					
20. Implement behavioural interventions and reminders using SMS	20.1. Design schedule for transmission of developed SMS to patients					
	20.2. Start SMS content delivery from general informative messages					
	20.3. Continue the content delivery to develop self-management of specific behaviour					
	20.4. The latent phase of content delivery shall focus on the maintenance of the behaviour					
	20.5. Gradually decrease the SMS frequency to three to four SMS per week during less acute phases (Moderate frequency)					
21. mHealth tool (SMS) features	21.1. SMS to have 160 characters, including spaces, punctuation, and any branding or links to additional information					
	21.2. Consider the clients' literacy level					
	21.3. The messages must be current (up-to-date)					
	21.4. Use One-way (Person-to-person or P2P) SMS network trafficking					
	21.5. Consider interactive, two-way (Application-to-person or A2P) SMS network trafficking					

Strategy 2: Patient communication and Support for Diabetes Self-management (DSM)
Objective: Ensure the presence of adequate communication and support on DSM
mHealth tool: **Voice call, SMS, and telemonitoring**

Expected Outcome: Enhance patient-HCP communication, and Improve DSM practice of Patients with Type 2 DM

Actions	**Activities**	**1=Strongly disagree**	**2=Disagree**	**3=Neutral**	**4=Agree**	**5=Strongly agree**
22. Remind for medication and clinical follow-up	22.1. Use voice calls to remind compliance with medication					
	22.2. Use voice calls to remind compliance for clinical follow-up					
23. Create continuous communication with patients	23.1. Monitor patient progress by creating continuous communication using either voice calls or SMS					
	23.2. Use voice calling to communicate the treatment plan					
	23.3. Use SMS to communicate the treatment plan					
	23.4. Provide patient counselling using voice calls					

24. Provide adequate decision support on DSM	24.1. Use SMS to provide feedback based on patient clinical data.					
	24.2. Use voice calls to provide feedback based on patient clinical data.					

Strategy 3: Personal Health Record (PHR) Objective: Collect, store, transmit and monitor data of patients with Type 2 DM mHealth tools: **PHR (form-based) application, biosensors, voice calls, SMS**						
Expected Outcome: Enhance data quality, and use; and improve clinical outcomes						
Actions	**Activities**	**1=Strongly disagree**	**2=Disagree**	**3=Neutral**	**4=Agree**	**5=Strongly agree**
25. Capture Data (Data collection)	25.1. Use biosensors to collect biomarkers from patients					
	25.2. Use Bluetooth to connect mobile phones with biosensors					
26. Store Patient data (Data storage)	26.1. Use a central system of mHealth PHR to store data					
	26.2. Use relational and non-relational databases for data storage at the central system					
	26.3. Use HTTP/HTTPS protocol to transfer collected data to the central platform in a web a based system					
27. Data Monitoring (Use mHealth PHR application to monitor patients)	27.1. Create a data processing display system for data stored in the central database, allowing HCPs to monitor patients' data					
	27.2. Create a graphical presentation for HCPs to track patterns and trends					
	27.3. Provide statistics of collected patient data for HCPs to track patterns and trends					

Strategy 4: Screening Objective: Screen and identify Type 2 DM cases mHealth tools: **SMS, Phone-based checklist, Voice calls**						
Expected Outcome: Improve Type 2 DM Screening rate, and reduce the proportion of undiagnosed diabetes						
Actions	**Activities**	**1=Strongly disagree**	**2=Disagree**	**3=Neutral**	**4=Agree**	**5=Strongly agree**
28. Use the mHealth screening checklist	28.1. Develop a phone-based checklist for Screening type 2 DM	1	2	3	4	
	28.2. Use the phone-based screening checklist in a primary healthcare setting					

Strategy 5: Treatment/Therapy plan Objectives: provide decision support for HCPs to design and communicate effective treatment/therapy plan mHealth tool: **Clinical Decision Support System (CDSS), Voice calls, SMS**						
Expected Outcome: Enhance treatment/therapy plan for managing Type 2 DM and improves clinical care						
Actions	**Activities**	**1=Strongly disagree**	**2=Disagree**	**3=Neutral**	**4=Agree**	**5=Strongly agree**
29. Implement a Clinical Decision Support system (CDSS)	29.1. Use the mHealth PHR data processing system to plan treatment	1	2	3	4	
	29.2. Provide knowledge-based support that could alert HCPs for critical issues (follow-up action and treatment plans)					
	29.3. Use CDSS that allows HCPs to communicate the therapy plan through SMS or mobile application to the patients					
30. Create collaboration among healthcare professionals (HCPs)	30.1. Create health professionals' social group to communicate and support each other through SMS/social media					
	30.2. Create a teleconsultation service for HCPs to get consultations with senior experts/specialists (Using voice calls)					
	30.3. Create access to an online referencing system for HCPs (for example, diabetes management guidelines)					

Section III: Framework/Guide to Address challenges of mHealth implementation for diabetes management

Instruction for the Inventory

Dear Experts,

This section contains strategic guides/frameworks to address challenges for implementing mHealth for diabetes management. 38 items are extracted based on Modified Delphi round two findings. Your expert opinion on the appropriateness of each guide is required to address the mentioned challenges for the effective implementation of mHealth for type 2DM management.

Please be as objective and constructive as possible in your judgment and using the rating scale, from strongly agree (5) to Strongly disagree (1)

F1. Guide to Address Interoperability Challenges *For Health informatics and ICT experts only*		**1=Strongly disagree**	**2=Disagree**	**3=Neutral**	**4=Agree**	**5=Strongly agree**
F1a	The system be supported by IEEE 11073 Personal Health Devices (PHD) standard for data transmission from biosensors to the mobile phones					
F2b	Use Fast Healthcare Interoperability Resources (FHIR) using a Representational State Transfer (REST, often referred to as RESTful architectures) for structural interoperability					
F2c	The system shall use the HTTP protocol and the JSON (JavaScript Object Notation) data standard to exchange data between the mobile phones of health professionals and the central system					
F1d	The system shall support GSM (Cellular) data transmission protocol					
F1e	Employ HL7/FHIR standard for clinical messaging					
F1f	Provide basic interoperability with national e-health systems (EMR, DHIS2, LIS, HMIS, etc.)					
F1g	Employ open-software development standard					
F1h	Employ the International Classification of Diseases (ICD-10) standard for clinical terminology					
F1i	Employ Systemized Nomenclature of Medicine (SNOMED) standard for clinical data coding					
F1j	Integrate Logical Observation Identifiers Names and Codes (LOINC) standard for laboratories					
F1k	Integrate RxNorm for pharmacies					

F2. Guide to Address Security and Privacy Challenges (mHealth application for SMS/PHR/CDSS) *For Health informatics and ICT experts only*		1=Strongly disagree	2=Disagree	3=Neutral	4=Agree	5=Strongly agree
F2a	Use an authentication system for healthcare professionals and other users (three factors authentication) for access and data sharing					
F2b	Use advanced encryption standard (AES) for data sharing					
F2c	Use cryptographic mechanisms for maintaining data confidentiality					
F2d	The system shall include both synchronous and asynchronous data validation approaches					
F2e	Align with national eHealth Security and privacy guidelines					
F3. Guide to address usability challenges (mHealth application for SMS/PHR/CDSS)		**1=Strongly disagree**	**2=Disagree**	**3=Neutral**	**4=Agree**	**5=Strongly agree**
F3a	The system must be easy to install					
F3b	The system must be easy to update					
F3c	The system must be easy to navigate					
F3d	The system must use an easy graphical interface					
F3e	The system must be easy to troubleshoot					
F3f	The system must be easy to exit either by uninstalling or unsubscribing					
F3g	The system must allow multilingual installation on a single application					
F3h	The user interface shall be kept simple by using the appropriate font type and size					
F3j	Iterative development process to be used based on user feedback					
F4. Guide to Address User-related Challenges		**1=Strongly disagree**	**2=Disagree**	**3=Neutral**	**4=Agree**	**5=Strongly agree**
F4a	Usefulness: Increase awareness of HCPs related to the usefulness of diabetes-related mHealth					
F4b	Ease of Use: Capacitate health professionals' digital literacy on diabetes-related mHealth					
F4c	Create inter-professional relationships and collaboration in the utilization of diabetes-related mHealth					
F4d	Provide training and certification for health professionals in the application of diabetes-related mHealth as part of a continuous development program (CPD)					
F4e	Make information on the diabetes-related mHealth application accessible to healthcare professionals and patients					
F4f	Prepare and disseminate the User guide for the developed mHealth system					
F4g	Prepare eLearning course on mHealth use and application					

F4i	Provide affordable internet incentives for HCPs to utilize mobile applications for diabetes management					
F5. Guide to Address resource Challenges		**1=Strongly disagree**	**2=Disagree**	**3=Neutral**	**4=Agree**	**5=Strongly agree**
F5a	Allocate adequate budget for mHealth implementation					
F5b	Expand the infrastructure for mHealth implementation					
F5c	Provide administrative support for HCPs to utilize mHealth for diabetes management					
F5d	Provide access to the internet for HCPs					
F5e	Provide incentives for HCPs to utilize mobile applications for diabetes management					

Thanks for your time and support!

ANNEXURE H: ETHICAL CLEARANCE

UNISA university of south africa

RESEARCH ETHICS COMMITTEE: DEPARTMENT OF HEALTH STUDIES
REC-012714-039 (NHERC)

15 February 2017

HSHDC/609/2017
Mr RT Zegeye
Student: 5855-424-6

Supervisor: Dr M Ramukumba
Qualification: PhD
Joint Supervisor: -

Dear Mr RT Zegeye

Decision: Ethics Approval

Name: Mr RT Zegeye

Proposal: Strategies to implement mobile health interventions for diabetes management in Ethiopia.

Qualification: DPCHS04

Thank you for the application for research ethics approval from the Research Ethics Committee: Department of Health Studies, for the above mentioned research. Final approval is granted for the duration of the research period as indicated in your application.

The application was reviewed in compliance with the Unisa Policy on Research Ethics by the Research Ethics Committee: Department of Health Studies on 15 February 2017.

The proposed research may now commence with the proviso that:

1) *The researcher/s will ensure that the research project adheres to the values and principles expressed in the UNISA Policy on Research Ethics.*

2) *Any adverse circumstance arising in the undertaking of the research project that is relevant to the ethicality of the study, as well as changes in the methodology, should be communicated in writing to the Research Ethics Review Committee, Department of Health Studies. An amended application could be requested if there are substantial changes from the existing proposal, especially if those changes affect any of the study-related risks for the research participants.*

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City Government of Addis Ababa Health Bureau

Ref.No. ዐ/ሐ/47427/227
Date 5/4/13

TO:

- ARADA SUBCITY HEALTH OFFICE
- AKAKI KAILTY SUB-CITY HEALTH OFFICE
- BOLE SUB-CITY HEALTH OFFICE
- KIRKOS SUB-CITY HEALTH OFFICE
- NIFAS SILK LAFTO SUB-CITY HEALTH OFFICE
- YEKA SUB-CITY HEALTH OFFICE
- GULELLE SUB-CITY HEALTH OFFICE
- KOLFE KERANIO SUB-CITY HEALTH OFFICE
- LIDETA SUB-CITY HEALTH OFFICE
- ADDIS KETEMA SUB-CITY HEALTH OFFICE

Subject: Request to access Facilities to conduct approved research

The letter is to support **Robel Tezera Zegeye** of **"Strategies to Implement Mobile Health Interventions for Diabetes Management in Ethioiopia."** The study proposal was duly reviewed and approved by Addis Ababa Health Bureau IRB, and the principal investigator is informed with a copy of this letter to report any changes in the study procedures and submit an activity progress report to the Ethical Committee as required. Therefore we request the facility and staffs to provide support to the principal investigator.

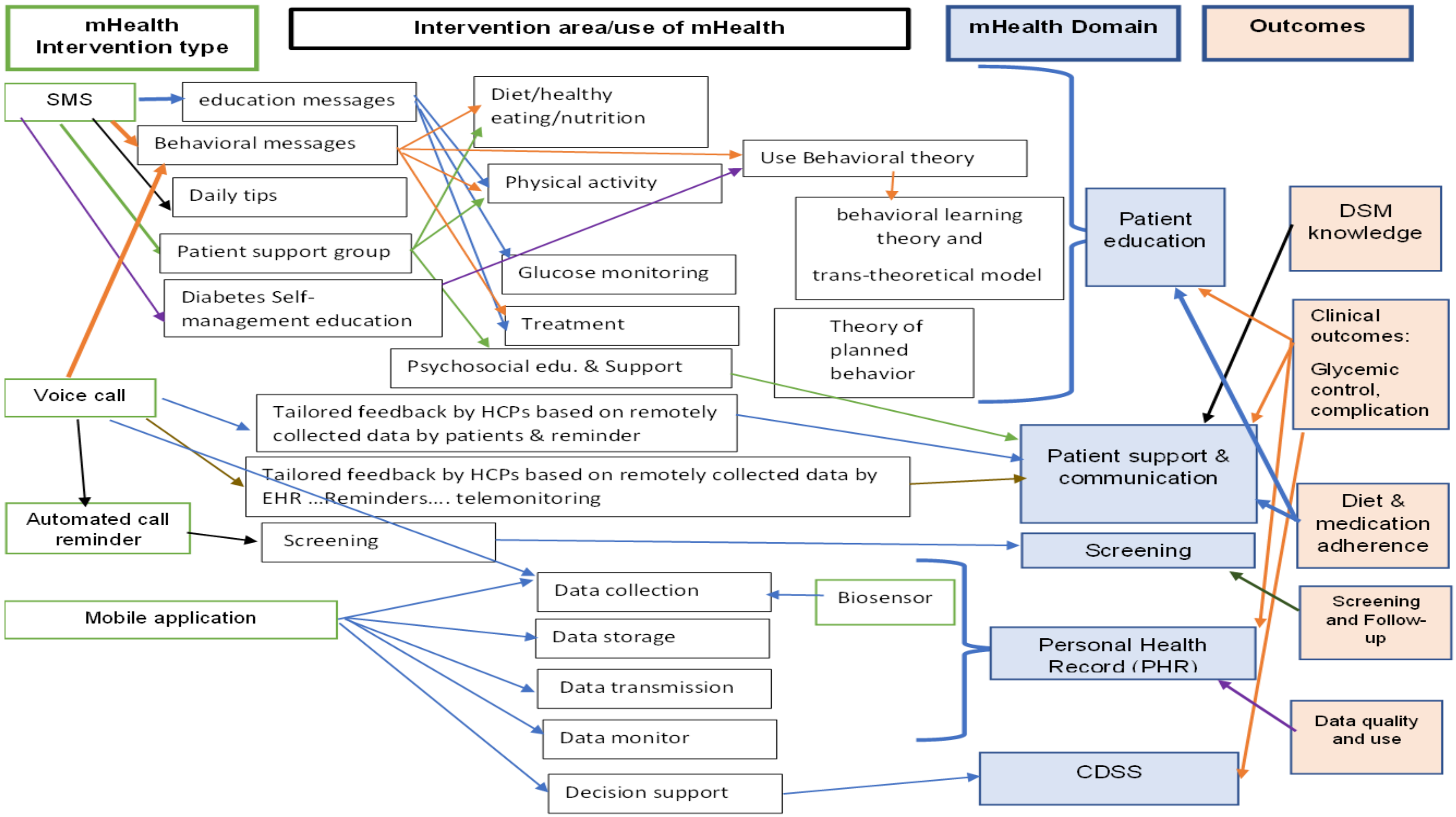
With Regards

Ethical Clearance Committee

Cc

- **Robel Tezera Zegeye**
- **To Ethical Clearance Committee**

ANNEXURE I: DATA REDUCTIONS EXAMPLE



ANNEXURE J: CERTIFICATE OF LANGUAGE EDITING

I, the undersigned, declare that I have edited the PhD (Public Health) thesis of Robel Tezera Zegeye, titled: **STRATEGIES TO IMPLEMENT MOBILE HEALTH INTERVENTIONS FOR DIABETES MANAGEMENT IN ETHIOPIA.**

Some sections of the thesis, such as questionnaires used in the research phases, were not corrected since they form part of the recording documentation.

Signed: 

Prof P.J. Botha (emeritus)

(Member of the South African Translator's Institute)

Date: 21st January 2023