Assessing the Scale-Up of mHealth Interventions Based on Intervention Complexity Framework

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Katie Grinyer i6128597

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Internal supervisor Timo Clemens

Abstract

Background

More than 95% of the world's population has access to mobile networks. The use of mobile phones in healthcare (mHealth) has attracted attention because of its high penetration in society. Many mHealth interventions have not progressed further from their pilot status or small-scale level. The lack of large scale mHealth programs makes it difficult for decision makers to decide whether to "roll out" a project more widely. This review uses the Intervention complexity framework to investigate the implementation issues that large scale mHealth interventions experience on a regional and national level.

Methods

A literature review on large scale mHealth projects between 2009 and 2019 was carried out in the database Medline using PubMed. Data was synthesised using the four domains of the framework (intervention characteristics, delivery characteristics, governmental capacity requirement and usage characteristics). Results were grouped into these domains to assess specific aspects of mHealth implementation at a large scale.

Results

Twenty-six studies were found on large scale mHealth projects and are included in this paper. Most studies came from Africa or the United States (9/26), were published in 2016 (7/26) and were interventions that targeted patient education and awareness (7/26). Usage characteristics were found to have the high number of implementation issues (10/26), followed by delivery characteristics (6/26). mHealth implementation requires significant focus on the technical issues of end-user acceptability and usability. Successful programs are simple, allow the users to use their own mobile phones and are highly tailored to the individual and their needs.

Conclusions

mHealth is an innovative approach for providing healthcare services. Current research in mHealth struggles to keep up with the rapidly advancing technological field. Opportunities for future exploration include finding creative and novel ways to engage and incentivise all individuals within a whole population to adopt mHealth.

Key words: mHealth, mobile health, cell phones, smartphones, scaling up, national programs, implementation frameworks

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List of Abbreviations

BHBM	Be He@lthy be Mobile
CVD	Cardiovascular diseases
DOTS	Directly observed treatment short course
EC	European Commission
EHR	Electronic health record
ICT	Information and communication technologies
IMC	Internal memory capacity
INSA	International narrative systematic assessment tool
ITU	International Telecommunication Union
IVR	Interactive voice response
MeSH	Medical subject headings
NCD	Non-communicable diseases
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
SMS	Short message service
UK	The United Kingdom
US	The United States of America
WHO	World Health Organisation

1. Introduction

Information and communication technologies (ICTs) have influenced many aspects of society. Mobile technology has become one of the most significant forms of ICT delivery and is considered a necessity in modern life (Goswami & Singh, 2016). The use of mobile technology in healthcare has attracted much recent attention because of its unique advantage in being accessible, affordable and portable - as well as being both innovative and empowering (Steinhubl, Muse & Topol, 2015). It is commonly known as mobile health or mHealth and it includes any health intervention that uses mobile technologies such as mobile phones, wearable devices, personal digital assistants and tablets (Kay, Santos & Takane, 2011). mHealth is an important component of eHealth (use of ICT for health) and the World Health Organisation (WHO) defines it as any medical and public health practice supported by mobile phones, patient monitoring devices, and other wireless devices (WHO, 2011).

1.1 Setting the context

The potential applications for mHealth are extensive and expanding. Examples of mHealth include appointment reminders, community mobilisation, health promotion, patient monitoring, patient support systems and patient health records (Bousquet et al., 2017). In April 2014, the European Commission (EC) launched a green paper on mHealth which invited industry experts to comment on how mHealth could be optimised and discuss how the current barriers related to it in Europe could be addressed. The aim of the green paper was to identify how the use of mobile devices could enhance the health and wellbeing of European citizens as well as assessing the legal issues and risks that arise around patient safety and data protection. The green paper recognised that mHealth is a rapidly emerging field which has the capacity to play a leading role in transforming healthcare - for example, by facilitating the provision of high-quality care for patients or by enhancing the responsiveness or efficiency of health care delivery by professionals (EC, 2014).

Currently, there are over seven billion mobile subscriptions and 95% of the world's population is covered by mobile networks (International Telecommunication Union, 2019). Therefore, mobile devices can be particularly important for those who have limited access to their healthcare system. This might include the marginalized, disadvantaged and those living in rural areas. It can provide a platform which is always available and can contribute to a more efficient way of delivering care. It can open and extend communication channels

between other healthcare professionals and patients which could lead to more accurate and timelier clinical decisions, advice, diagnosis and support (Ali, Chew & Yap, 2016).
In terms of target diseases, mHealth has particularly focused on chronic diseases (Chow, Ariyarathna, Islam, Thiagalingam & Redfern, 2016) because it can help detect the development of chronic conditions at an early stage through self-assessment tools and remote diagnosis, whilst sharing data with care providers. Further, mobile phone technology can be harnessed to influence behaviours that can help to prevent non-communicable diseases (NCDs) such as cardiovascular diseases (CVD), cancers, and diabetes (WHO, 2014b). Prominent examples of this are through applications (hereafter "apps") which provide communication, information and motivation tools, such as medication reminders or fitness and dietary recommendations. Therefore, the use of apps can encourage individuals to adhere to healthier lifestyles (EC, 2014).

The main driver towards using mHealth in Europe is its potential to provide new cost-effective ways to support healthcare (EC, 2014). Healthcare systems are under strain and face challenges, such as maintaining the financial sustainability of health services, the ageing population and increased citizens' expectations (Borgonovi, Adinolfi, Palumbo & Piscopo, 2018). These challenges impact immensely on health care budgets and make health services less affordable and accessible for European citizens. However, all these challenges can be tackled and transformed with the use of innovation and digital technology and therefore the use of mHealth has become an increasingly attractive solution (EC, 2014).

Many mHealth initiatives have been found to be successful in improving health-related outcomes as well as gaining a high level of acceptance in local communities and healthcare settings. Despite the widespread enthusiasm for the use of mHealth, there has been much concern around its effectiveness. While well-established mHealth interventions exist, scientific evidence regarding effectiveness is constantly being challenged due to methodological issues (Labrique, Vasudevan, Chang & Mehl, 2013). For example, systematic reviews on diabetes management using mHealth have reported positive associations between mHealth and the reduction of risky behaviours among diabetic patients, while others have found no association and show that the results have critical limitations – such as, insufficient sample size or risk of bias (Arambepola et al., 2016).

Challenges in implementation and scaling up of mHealth initiatives are widely documented. There is a lack of evidence on the social, organisational and cultural implications that influence the successful implementation of mHealth in all settings (Leon, Schneider & Daviaud, 2012). Recent reviews have also drawn attention to the lack of knowledge that exists on the impact of mHealth initiatives at scale. This is because many mHealth projects exist on a small scale and very few are on a national scale. Moreover, most mHealth projects are still in or have not progressed out of their pilot phase and so, their duration is too short to accurately predict their impacts when brought to scale (Aranda-Jan, Mohutsiwa-Dibe & Loukanova, 2014).

The term scaling-up is now widely used in the public health literature and according to Mangham and Hanson (2010), it refers to a process that expands the coverage of health interventions. The WHO defines it as the deliberate effort to increase the impact of a successfully tested health innovation in the pursuit to benefit more people (WHO, 2018b). Key words associated with scalability include 'expand' and 'replication'. The former refers to growth within an established organisational structure, for example, hiring more employees and the latter, relates to good practices in one setting that can be transferred and adapted into a new one. Scalability does not always mean enlargement, it can also include reduction – as scale just means size (WHO, 2010). The scaling-up rarely happens automatically which is often assumed. It is an iterative process, which requires focused attention, strategic planning and management (WHO, 2010).

The process of scaling up mHealth projects requires careful consideration. It is evident that the enthusiasm for mHealth has grown and that innovative and effective mHealth initiatives do exist. Yet little is known about the successful scale-up of mHealth interventions (L'Engle, Plourde & Zan, 2017). Often interventions that are tested in pilot projects have substantial organizational and financial support but lose this investment when taken to scale. Consequently, project managers responsible for enlarging projects face great challenges. They must implement the intervention within health systems that are fragile and faced with many pressing priorities and few resources. Successful scaling up requires a balancing act between desired outcomes and practical realities and constraints (WHO, 2010). The mHealth field has arrived at a point in its progression where it now needs case studies to guide successful scale-up of mHealth interventions to benefit whole populations rather than smaller groups.

In response to this issue, the WHO and International Telecommunication Union (ITU) launched in 2012 the programme 'Be He@lthy be Mobile' (BHBM). It was set up as a four-year initiative across eight countries to determine the impact of large scale mHealth projects on whole populations. These countries were selected because of their high burden of NCDs and political commitment to technology. Each country concentrated on one NCD they aimed to tackle, including, mTobaccoCessation in Costa Rica, India, Philippines and Tunisia, mDiabetes in Senegal, mCervicalCancer in Zambia and mHealth for NCDs in the United Kingdom (UK) and Norway (WHO, 2014a). According to ITU (2019) initial results from BHBM programs have been promising - for example, India has launched two nation-wide mHealth programs because their first one (mTobaccoCessation) program was proven to be highly successful (International Telecommunication Union, 2019).

1.3 Research Objectives

If the EU is serious about unlocking the potential of mHealth and committed to improving the health of its citizens and whole populations; then more investigation is required into how mHealth projects can be effectively developed at scale. Considering the widespread enthusiasm for the mHealth field and growing research base, information about the successful scale-up of mHealth interventions has not kept pace (L'Engle, Plourde & Zan, 2017). Therefore, due to the lack of evidence on how initiatives can be successfully scaled-up, the purpose of this paper will be to explore why mHealth projects face constraints in going to scale. This study will aim to review literature on the mHealth's scalability to identify best practices and provide recommendations on scaling up mHealth interventions. It will focus on mHealth initiatives that have been delivered on a wide geographical scale, including: regional, state, national or international level. This will also include the BHBM projects because they have demonstrated large scale mHealth implementation at a national level. A critical assessment will then be undertaken on each intervention to determine how they were able to launch their initiatives at scale. This will help to determine where the challenges lie in scaling up mHealth programs. The Intervention complexity framework will be used to provide themes on the factors that influence scalability (see **Table 1** in the next chapter).

Without models of successful mHealth program scale-up, the field remains stifled and at risk of "pilotitis" that can plague implementers for several years (Labrique, Vasudevan, Chang &

Mehl, 2013). The overarching research question of this paper is what are the main factors that need to be considered by implementers when scaling up mHealth initiatives?

Additional sub-questions will be addressed to help answer the main research question. These include:

- Which factors have led to successful scaling up of mHealth programs?
- Which factors have challenged the scaling up of mHealth programs?
- What are the most common themes of mHealth scaling up?

2. Conceptual Framework

In order to answer the research questions, this thesis has used the Intervention complexity framework to help identify themes within the literature. The following chapter will outline how the framework will be applied throughout the research.

Frameworks and models help those involved in scaling up projects take a pragmatic approach to the implementation process. They are based on previous evidence and experience which can be helpful for implementers identifying factors that might promote and hinder the complex process of scaling up interventions. Recent literature reviews have shown that the number of articles published on scaling-up interventions have grown rapidly (Indig, Lee, Grunseit, Milat & Bauman, 2018). The WHO and other international bodies have created frameworks to support countries enlarging public health initiatives (WHO, 2010; WHO, 2018b). Whilst there are many public health implementation frameworks and models, there are very few that focus on mHealth implementation specifically.

Noordam et al. (2015) successfully applied the Intervention complexity framework, which is a non-mHealth specific framework, to assess the scale-up of two children based mHealth innovations in Malawi and Zambia. Gericke and colleagues (2005) created the Intervention complexity framework to help them assess the technical feasibility of scaling up public health interventions (see **Table 1**). According to Gericke et al. (2005) this framework can be applied to analyse the complexity of any health intervention because it is comprehensive and general enough to capture all the possible constraints in scaling up. The framework asserts that the feasibility of an intervention depends on the degree of the intervention's technical complexity in four domains. Technical complexity is defined as the quality and quantity of non-financial resources required for implementing and sustaining an intervention. The four domains are: characteristics of the basic intervention; characteristics of delivery; requirements on government capacity; and usage characteristics (Gericke et al., 2005).

Table 1: Intervention complexity framework (Gericke et al., 2005)

The framework assisted Noordam et al. (2015) determine the technical complexity of implementing two mHealth interventions and concluded that each domain affected and posed significant challenges for programs operating at scale - for example, one of the interventions was mainly implicated by the delivery characteristics and challenges. These were identified as the lack of human resources and infrastructure requirements such as unreliable network services (Noordam et al., 2015). Moreover, this framework has previously been used to assess the complexity of a range of other health interventions, including condom promotion (Gericke et al., 2005), tuberculosis directly observed treatment, short-course (DOTS) programs (Gericke et al., 2005), diet improvement (Snowdon et al., 2010), and food poisoning risk reduction strategies (Wu & Khlangwiset, 2010; Noordam et al., 2015). Its application to appraise mHealth programs has been assessed again in this thesis.

This conceptual framework created by Gericke and colleagues (2005) has been adapted to assess the factors that have influenced mHealth interventions launched at a regional or national level. The first domain ‘intervention characteristics’ includes any materials, equipment and related resources that have been stated to have hindered or facilitated implementation. The ‘delivery characteristics’ included the facilities, human resources or communication infrastructure such as network coverage, that could impede the intervention.

The domain 'government capacity requirements' includes the legislative and regulatory structures, management systems and collaborative action that influence mHealth implementation. In addition, it refers to the key stakeholders that are required for implementation as well as determining how compatible the initiative is with existing government policies and management information systems. Finally, 'usage characteristics' relates to the user experience, it includes usability and acceptability of the mHealth intervention and whether there is pre-existing demand from the users for the intervention (see **Table *2*** for full description of each domain).

Domain and category	**Criteria**
Intervention characteristics	Characteristics include the basic product design features such as all the supplies and equipment required in an intervention (Gericke et al., 2005). Equipment issues could be the need for highly specialised mHealth platforms, mobile devices or infrastructure such as the type or model of the phone. Furthermore, the ease with which these supplies can be acquired can also be assessed in this domain as well as the level of safety of the equipment. Confidentiality of patient data can be an issue when using SMS based systems and personal mobile phones.
Delivery characteristics	Characteristics include the required facilities, human resources, and the level of communication of an intervention (Gericke et al., 2005). Interventions are categorised according to whether they can be delivered through public or private health facilities, outreach services or hospital care. Human resources are analysed according to the level of skill, education and the degree of supervision needed from health professionals to run the mHealth intervention. The aspect of communication covers the extent of information exchange required between different sectors and therefore, an analysis of infrastructure such as mobile network coverage, internet speed and the availability of electricity.
Governmental capacity requirements	Requirements include legislative and regulatory capacity, management systems and dependence on collaborative action (Gericke et al., 2005). Some interventions will require special legislation and regulation – particularly the case for mHealth such as, national mHealth and eHealth policy. The dependence of the success of an intervention on collaborative action between different government sectors, between government and civil society, or between government and external funding agencies, can be an important constraint to scaling up - for example, whether successful partnerships within the government and mobile network providers can be analysed in this domain.

Usage Characteristics	Characteristics include the usability of mobile phones and whether there is a pre-existing demand for the intervention. Ease of usage includes the extent to which consumer information and education or training is needed for the intervention to be implemented effectively (Gericke et al., 2005). A low level of pre-existing demand and willingness of the consumer towards mHealth will require substantial effort to promote the intervention. The need for interventions to be tailored to meet the individual's needs or cultural background can be assessed in this domain as well as those with a low level of mHealth literacy.

Table 2: Intervention complexity framework applied to mHealth

3. Methods

A qualitative systematic review was conducted to synthesise the literature on the scalability of mHealth interventions implemented at large scale and nation-wide. This chapter explains how the review was carried out.

3.1 Literature search strategy and criteria for study selection

Studies were identified by searching in the database MEDLINE using PubMed. The search strategy was based on the terms ‘mHealth’, ‘scaling up’ and ‘large scale’. It included a combination of Medical Subject Headings (MESH), free-text words and specific terms that needed to be included in the Title and/or the Abstract. In addition, articles that were protocols were excluded using the NOT function. The search was limited to articles published in English during the period between 2009-2019. The search strategy used was:

(((Cell phone [MeSH Terms] AND "last 10 years"[PDat])) AND (mHealth AND "last 10 years"[PDat])) AND (((((Scaled up[Title/Abstract]) OR Scaling up[Title/Abstract]) OR National[Title/Abstract]) OR Large scale[Title/Abstract]) AND "last 10 years"[PDat]) NOT protocol

Studies were then screened based on whether their titles and abstracts met the eligibility criteria and if necessary the full text was further screened if the title and abstract did not fully satisfy the inclusion criteria (see section 3.2). In the case that an article did not meet a criterion, it was excluded and the next article screened. Of all the studies fulfilling the inclusion criteria full texts were read and data was extracted according to the four domains of the intervention complexity framework. To avoid selection bias, another external researcher carried out the search strategy and any differences in the selection of papers were discussed and papers selected accordingly. A PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram was used to present the study selection process based on its four phases (identification, screening, eligibility and inclusion) (see **Figure *1***) (Moher, Liberati, Tetzlaff & Altman, 2009).

An additional search was also carried out to determine any other factors that might have influenced the implementation process of large scale mHealth programmes that were not published on PubMed, or to reinforce any evidence that has already been published. As the BHBM programs are well established national mHealth initiatives and existing for several

years now, the additional search was restricted to information on these programs. Searches were confined to the WHO and ITU websites which document results, case studies, reports and handbooks on the BHBM initiatives. To date three annual reports and five program specific handbooks have been published on the WHO and ITU websites. The reports aim to provide governments with information about how mHealth programs can be scaled-up based on the most recent scientific knowledge taken from experts and best practices around the world. The reports provide guidelines that can assist countries implement their own mHealth programs on a national level. The handbooks are program specific and include mTobaccoCessation, mDiabetes, mBreathefreely, mCervicalCancer and mAgeing (WHO, 2015a; WHO, 2016a; WHO, 2017a; WHO, 2017b; WHO, 2018a). They contain the technical and operational content that are needed to run a large scale mHealth program. The eligibility criteria were also applied and when satisfied data was extracted and integrated into the full analysis based on the intervention complexity framework.

3.2 Inclusion/exclusion criteria

The eligibility criteria included studies that were focused only on mHealth and the use of a mobile devices in the healthcare setting. mHealth was defined in accordance with the WHO definition as any medical and public health practice supported by mobile phones, patient monitoring devices, and other wireless devices (WHO, 2011). This was further specified to include any mobile device that had cellular communication capabilities that allowed for wireless interaction and included android phones, smart phones, personal digital assistants and tablets (Indig, Lee, Grunseit, Milat & Bauman, 2018). Only mHealth interventions that had been implemented on a large scale were included. Large scale was defined as any program delivered on a wide geographical scale, including: regional, state, national or international (Indig, Lee, Grunseit, Milat & Bauman, 2018). mHealth interventions included any mHealth initiative that could be classified under the eight types identified by Aranda-Jan, Mohutsiwa-Dibe and Loukanova (2014) who had successfully used them to assess mHealth intervention implementation in Africa. These eight types of interventions included: “patient follow-up and medication adherence”, “staff training, support and motivation”, “staff evaluation, monitoring and guidelines compliance”, “drug supply chain and stock management”, “patient education and awareness”, “disease surveillance and intervention monitoring”, “data collection/transfer and reporting” and “overview of mHealth projects” (Aranda-Jan, Mohutsiwa-Dibe & Loukanova, 2014). Studies that mentioned factors which

inhibited or facilitated the mHealth implementation process were included – this covered any of the features stated in **Table *2***.

All study designs such as randomised control trials, case-control studies, literature reviews and case studies were included, except for project protocols. Studies which were found more than once in the initial search were excluded. Studies that were not published in English were excluded. Studies which focused on telemedicine, other types of eHealth tools, such computers, internet or e-mail were removed because they were not mHealth specific.

3.3 Data collection and analysis

Based on the research questions and the four domains of the Intervention complexity framework (see previous chapter) a thematic approach was carried out to synthesis and analyse the data. Data from the full-text articles were summarized and presented in the results section according to the four domains: intervention characteristics, delivery characteristics, government capacity requirements and usage characteristics. When an implementation characteristic fell into two or more of these domains, the author selected the most appropriate according to ***Table 2*** and classified it as such. Additionally, the findings from the peer-reviewed literature were also presented and simplified into table format (see ***Table 7*** in the appendix).

3.4 Data on methodological quality

The peer-reviewed studies included in this review were of a variety of study designs and a mix of methods. Applying a common quality assessment tool across all the studies was not feasible. In the case of published literature reviews, methodological quality was assessed using the International Narrative Systematic Assessment Tool (INSA). This is a validated instrument which can be used to assess the quality of both systematic and narrative literature reviews (see **Table *3***). The checklist uses a points-based system judged on seven criteria. For each criterion present in the given study a point will be assigned. Studies with over five points is considered ‘good quality’ (La Torre, Backhaus & Mannocci, 2015).

Item	**Score**
Background of the study clearly explained / state of the art	0/1
Objective is clear and stated	0/1

Description/Motivation of selection of studies	0/1
Description of the characteristics of the included studies is clear in the paper	0/1
Presentation of results (paragraphs, tables, synthesising of data)	0/1
Conclusion is clear	0/1
The author(s) declare(s) that there is or not conflict of interest regarding the publication of the article	0/1

Table 3: Criteria for assessing scientific quality of narrative reviews (INSA) International Narrative Systematic Assessment tool (La Torre, Backhaus & Mannocci, 2015).

Randomised trials were assessed using Jadad score, this is commonly used instrument to assess the validity and reliability of control trials (see **Table *4***). It assesses studies based on seven items and the presence of three key methodological features: randomization, masking or blinding, and accountability of all patients, including withdrawals. If the items are present, one point is given and high scores relate to high methodological quality (Berger & Alperson, 2009).

Item	**Score**
Was the study described as randomized	0/1
Was the method used to generate the sequence of randomization described and appropriate (e.g., table of random numbers, computer-generated)?	0/1
Was the study described as double blind?	0/1
Was the method of double blinding described and appropriate (e.g., identical placebo, active placebo)?	0/1
Was there a description of withdrawals and dropouts?	0/1
Deduct one point if the method used to generate the sequence of randomization was described and it was inappropriate (e.g., patients were allocated alternately, or according to date of birth, hospital number).	0/−1
Deduct one point if the study was described as double blind but the method of blinding was inappropriate (e.g., comparison of tablet vs. injection with no double dummy).	0/−1

Table 4: Criteria for assessing scientific quality of randomised control trials using the Jadad scale (Berger & Alperson, 2009).

The quality assessment of the remaining studies was evaluated using an informal approach according to the number and different types of biases that occur in research, identified by Pannucci and Wilkins (2010) and Smith and Noble (2014). Examples of these type of biases

included selection, publication, data collection, performance and analysis bias and how they implicated the internal and external validity of studies was also evaluated. **Table *7*** in the appendix presents the major sources of potential biases for each study. This enables the reader, health professional and mHealth implementer to evaluate and scrutinise the study findings, before using them in practice or policy making decisions (Smith & Noble, 2014).

4. Results

This chapter is divided into two main parts. The first sub-section provides a description of the type of studies found in the initial search using PubMed. The second, includes four sub-sections which present and summarise the peer-reviewed literature on mHealth implementation on a large scale, as well as the published literature from the BHBM annual reports and handbooks. These sections are structured according to the four domains of the Intervention complexity framework and they highlight the main factors that need to be considered by implementers when scaling up mHealth initiatives.

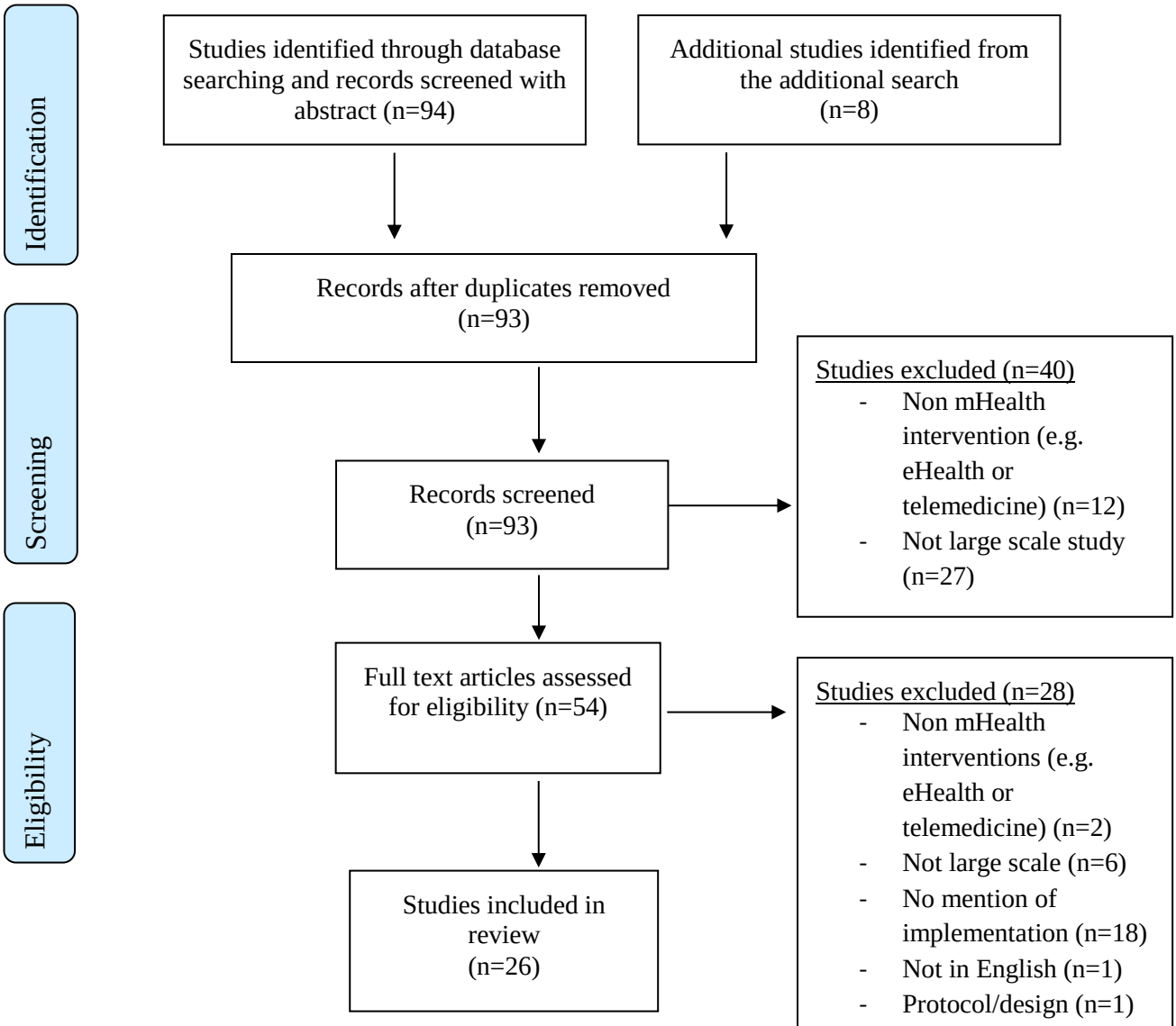

Figure 1: Study selection process based on PRISMA steps

4.1 Types of literature found

From the initial search strategy, 94 articles were found. After reading through all the titles and abstracts and applying the inclusion criteria 40 articles were excluded (See **Figure *1***). The full texts of the remaining articles were read: 28 were excluded and 26 chosen for full analysis and inclusion for the study. The main reasons for excluding articles were because they were not based on large scale (regional or national) programs, they did not refer to any aspects of implementation or because they were not mHealth specific, instead based on eHealth or telemedicine. Of the 26 articles that were included most were conducted in the year 2016 (see **Figure *2***), most came from Africa (9/26) followed by North America (8/26) (see **Figure 3**) most were programs based on patient education and health awareness (7/26) (see **Figure 4**) and most were literature reviews (10/26) or qualitative studies (5/26) (see **Table *7*** in the appendix). After applying the intervention complexity framework, most of the articles covered implementation issues on usage characteristics (10/26), followed by delivery characteristics (6/26) and then intervention characteristics (5/26) and governmental capacity requirements (5/26) (see **Figure 5**).

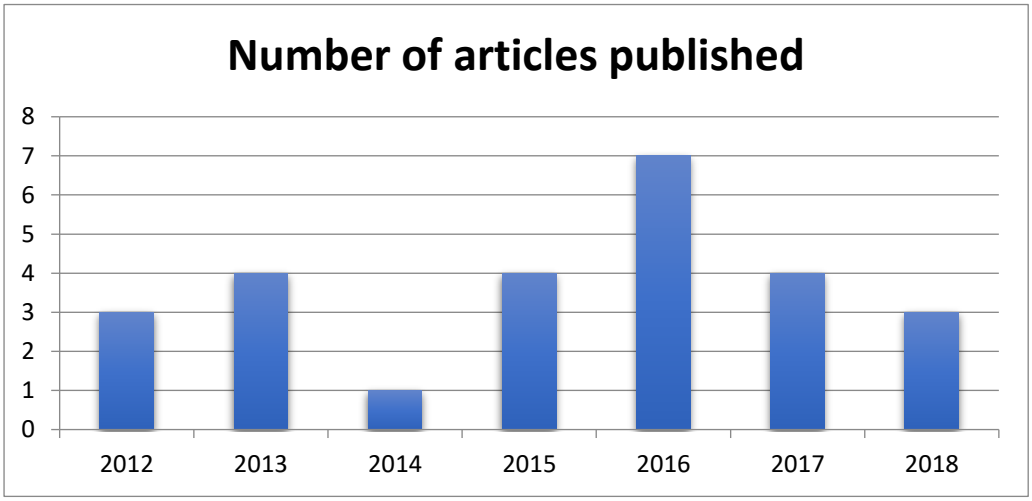

Figure 2: Number of published articles on mHealth per year

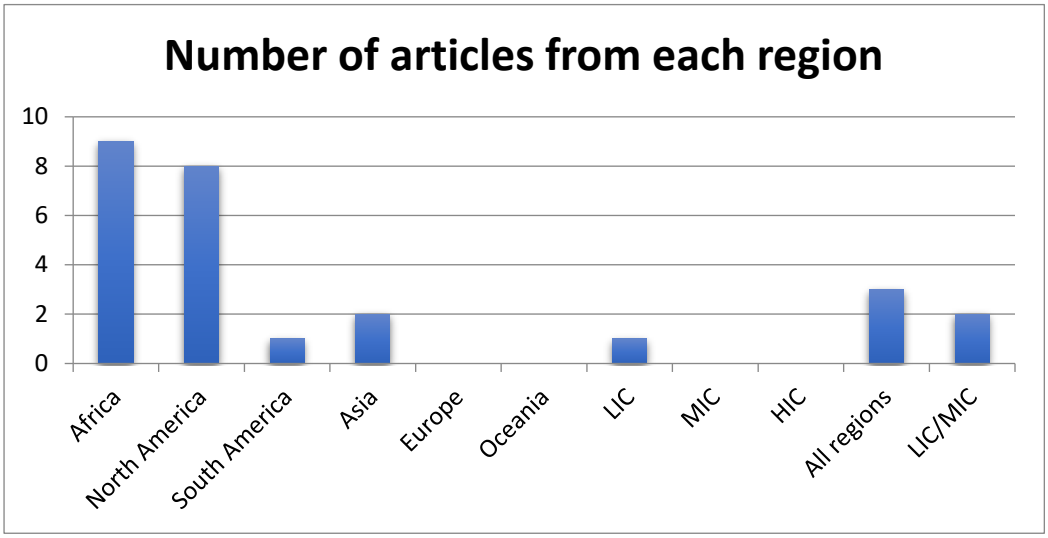

Figure 3: Number of included articles published per global region

LIC = Low-income countries; MIC = Middle-income countries;

HIC = High-income countries

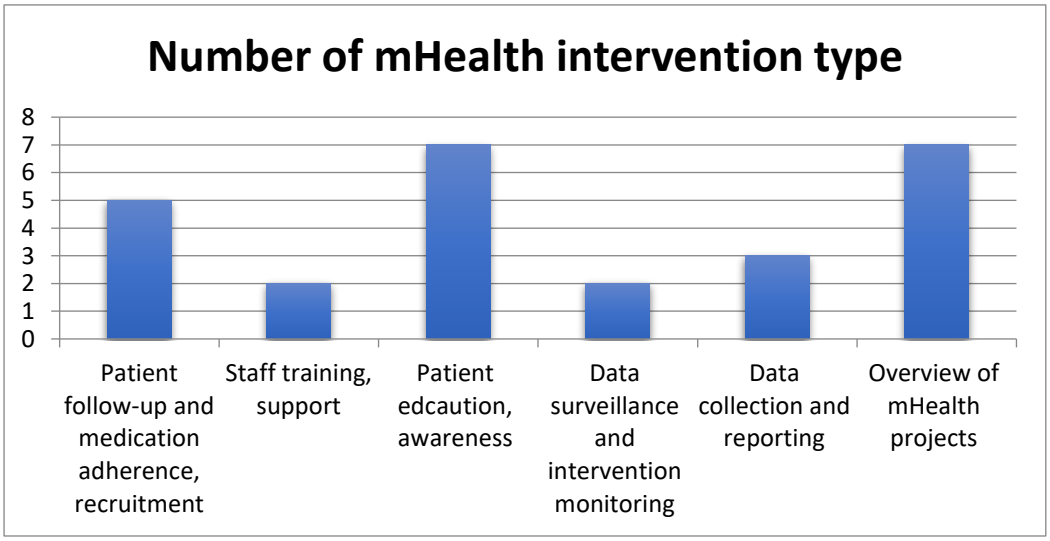

Figure 4: Number of mHealth interventions per type

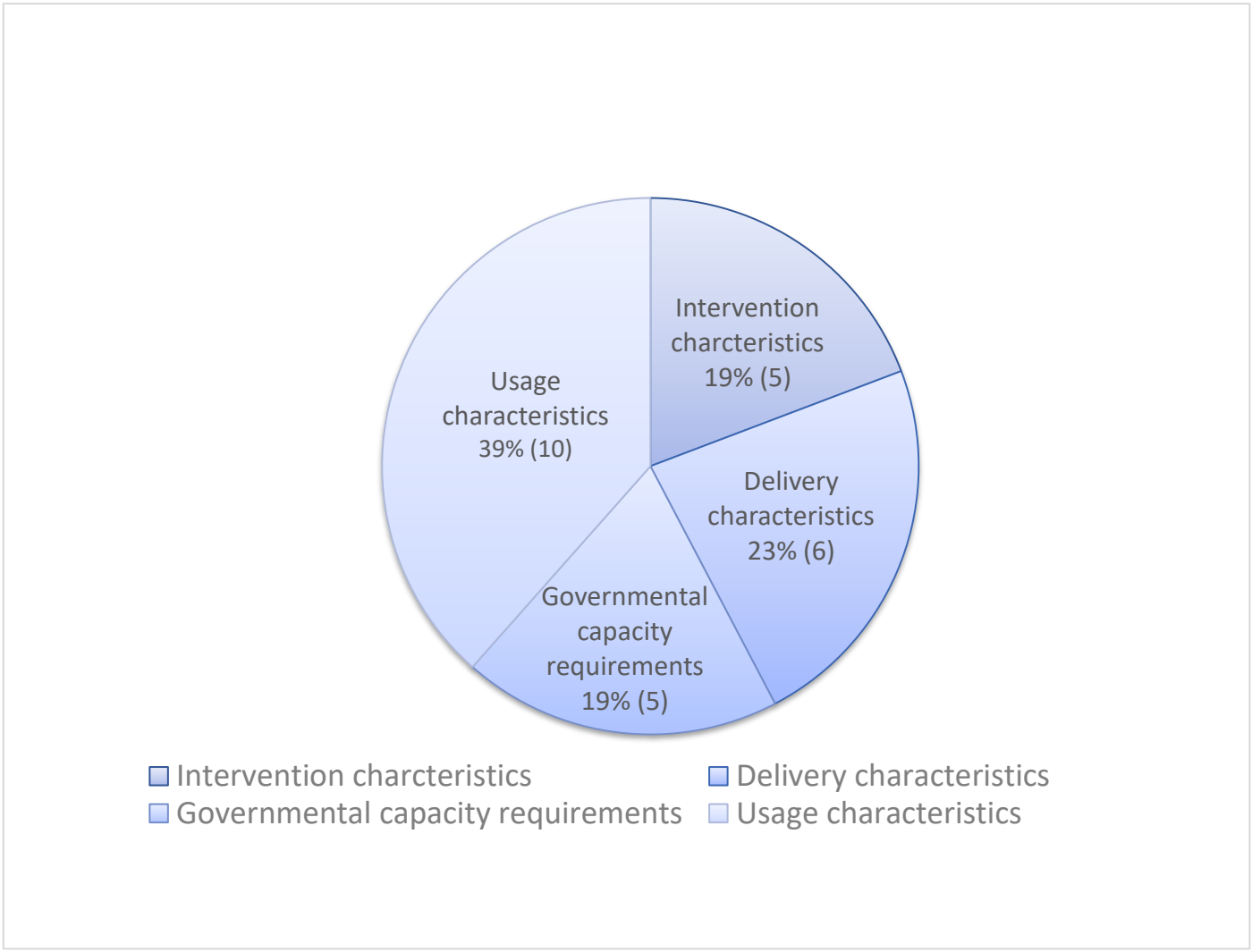

Figure 5: Percentage of included articles per domain

4.2 Usage characteristics

Usage characteristics include all the factors that affect the user and their experience of mHealth. Implementation issues in this domain were cited the most and this section elaborates on them. Mtema et al. (2016) evaluated the user acceptability of a mobile based inter-sectoral surveillance system for rabies monitoring in Tanzania. The system is used by health and veterinary workers to report animal bites and record the number of human and animal vaccines being administered from a population of 10 million inhabitants. The authors found that user experience should be prioritised over technical advances. Health and veterinary workers preferred to use a system that was simple and allowed them to use their own phone. Most users had simple android mobile phones so it was essential that the interoperable surveillance platform was compatible for all models of phones. Ownership of

the mobile phone was a fundamental aspect of sustainability as it incentivised use, reduced the risk of phones being lost and reduced costs for the program (Mtema et al., 2016).

Age was a useful predicator for program dissatisfaction when individuals were given a phone to use (not their own) for the program. Many older users believed that it was too time-consuming and difficult to learn all the functions of the new mobile phone and were resistant to the program because of that reason. Continuous training, on hand-support and feedback from technical personnel enhanced the user experience and contributed to the sustainability of the current program (Mtema et al., 2016).

Zurovac et al. (2013) studied the ownership and use of mobile phones among health workers, adult patient and parents of sick children in Kenya. Individuals who used their own mobile phones were more likely to engage in the mHealth program. They found that socioeconomic factors play an important role on the ownership of phones. Those who were male, more educated, literate and living in urban areas were significantly more likely to own a phone. Younger people were found to be less likely to own their own mobile phone. However those who did were more likely to be engaged and adhere to the SMS messages (Zurovac et al., 2013).

User willingness was also found to be an important determinant for the success of the large-scale SMS intervention (Zurovac et al., 2013). Christofferson et al. (2015) investigated the engagement patterns among users of a smoking cessation SMS program called 'SmokefreeVet'. They found that individuals who were highly engaged from the beginning of the program (had a high pre-existing demand for the service) were less likely to opt-out and complete the program than those individuals who were less engaged at the beginning of the program. Other reasons why individuals withdrew from the program were not fully explored (Christofferson et al., 2015).

Six articles concluded that the user experience should be at the forefront of any implementer's decision when delivering a behavioural change program through text messaging services (Horvath et al., 2017; Dale, Dobson, Whittaker & Maddison, 2013; Leavitt et al., 2017; Hagoel, Neter, Stein & Rennert, 2016; Cameron et al., 2017; Arora et al., 2016). Tailoring messages to the individual and providing them with individualised feedback on their health progress was found to be a crucial feature for engaging users (Horvath et al.,

2017). The number of SMS being sent to participants each week affected the success of cardiovascular disease interventions. Sending a text every three days was found to be the optimal frequency (Dale, Dobson, Whittaker & Maddison, 2013). Leavitt et al. (2017) examined how effective text messages were at recruiting participants signing up to a national health program. They found that on average it takes two text messages to enrol a participant. In addition, messages worded with an emotional appeal had a better recruitment rate than non-emotional appealing texts. Moreover, Hagoel, Neter, Stein & Rennert (2016) showed that text messages which were worded persuasively and in an interrogative manner had more success at getting people to go for a cancer screening, than those that were not (Hagoel, Neter, Stein & Rennert, 2016).

Cameron et al. (2017) explored how text messages could be culturally and linguistically adapted for all its English and Spanish speaking users in healthyYouTXT program. It is a regional level in the United States (US) and encourages individuals to make healthier food choices. The authors found that cultural adaptations made to messages were highly relevant for users; for example, constructing messages that related to one's family (familismo in Spanish) was a successful way to engage the Hispanic population. The written language was equally important - the lack of accents, symbols and tildes made the program less credible for Spanish users. The style of the language also influenced the individuals' perception of messages. Younger people preferred their SMS to be worded informally; they believed it made a program more personable. In contrast, older people preferred their messages to be addressed formally as this was perceived as more respectful and helped to legitimatise the educational information provided. Moreover, Arora et al. (2016) had similar findings in their study on the evolution of mHealth among the Hispanic population in the US. Successful mHealth programs required messages to be tailored and respectful to their cultural norms. The Spanish population in both the studies mainly came from Mexico, whether these findings can be generalised to rest of the Spanish speaking community needs further exploration.

The BHBM annual report in 2014 also documented the importance of tailoring text messages to the individuals. The mDiabetes program in Senegal makes use of the SMS-messaging in three ways: increasing awareness of diabetes, training community health workers and providing remote consultation and support for people with diabetes. The results after the first year indicated that it was important to tailor messages to the individual, provide information that is simple and easy to understand and when possible (handheld device allowing it)

incorporate voice messages to target illiterate users. (WHO, 2014a). The mDiabetes handbook stated that a significant challenge for mHealth programs is determining how the programs can influence the user's motivations and capabilities to adopt mHealth. Creative and novel solutions are needed to keep users across a nation engaged. Understanding and following models of behavioural change theory can guide in how to do this (WHO, 2016a).

A final usage characteristic found in the literature was the perceived lack of data protection in mHealth (Richard & Ancker, 2015). Results from a nationwide survey in the US showed that consumers believed that mHealth can improve healthcare quality, and sharing data between healthcare professionals is easier and timelier. However, a large majority were found to be very concerned over the security and privacy of their data as well as it being lost or leaked. Reasons why the individuals had these perspectives were not investigated, but the results did find that those who were poorly educated on mHealth and did not fully understand mechanisms such as block chain, were more likely to be concerned about mHealth. Addressing this issue is critical to gaining public trust and support for using mHealth (Richard & Ancker, 2015).

4.3 Delivery characteristics

This section covers the delivery characteristics that influence mHealth program implementation. It relates to the integration of mHealth in existing health systems and the environment it will operate in. Medhanyie et al. (2015) interviewed health workers in Ethiopia whom upload patient data onto online electronic patient health records (EHR) using their mobile phones. Healthcare workers found the program to be time consuming and led to more work as they were also instructed to fill out paper versions. The high turnover of staff also made the program more challenging as many health workers were not familiar with the EHR and this led to incomplete online records. Workers found that using their phones disrupted their workflow and productivity as it caused an additional distraction and many used their phones for unintended purposes. This in turn increased the cost of running the programs as some workers used more minutes than stipulated. Moreover, Littman–Quinn et al. (2013) found that in Botswana, high staff turnover threatened the functioning of mHealth programs. New users often have negative perceptions towards programs because of their belief that it disrupts workflow. The lack of local technological or maintenance support personnel hampers the success of large scale mHealth (Littman–Quinn et al., 2013).

Saunders et al. (2018) studied the use of mobile phones for TB treatment adherence in Peru. They highlighted that the issue of data protection posed the greatest risk to mHealth programs. They found that the program's messages were not always accessed by the intended user but someone else. This was likely because many family members shared mobile phones or some individuals had more than one phone (Saunders et al., 2018). A systematic review of mHealth in maternal care found that users sharing phones implicated interventions negatively, as in the case of receiving SMS it was not guaranteed that the targeted patient received the message (Colaci, Chaudhri & Vasan, 2016). In addition, poor network coverage, issues of theft or damage and faults to phones disrupted the success of mHealth interventions (Saunders et al., 2018). Poor network reception or lack of network coverage was a very common implementation barrier for mHealth projects (Agarwal, Perry, Long & Labrique, 2015). Additionally, lack of electricity to charge phones or small battery lives of phones caused many problems for many workers using mHealth. This finding is consistent throughout the literature, in both high and low quality studies (Ngabo et al., 2012) (Colaci, Chaudhri & Vasan, 2016).

The BHBM annual report in 2016, highlighted the importance of implementers taking an ecosystems perspective. This perspective ascertains that all programs are vulnerable to change depending on the environment they are implemented in. mHealth programs need to be flexible in their design, because the political landscape can always change as well as the advancing technology. The environment should be continuously monitored so programs can be responsive and adopt the benefits of new innovations in content or delivery and helping them to remain relevant to the communities they support (WHO, 2016b).

Additionally, the handbooks mBreatheFreely and mAgeing provided information on operation management, content development, technological considerations, promotion & recruitment and monitoring & evaluating. The handbooks recognise that the context and environment in which they are delivering it in is highly important. Contextual information includes knowledge on the target group, state of mobile communication, cultural, contextual, geographical, incentives, stakeholders, promotional and dissemination activities and consistent with users' capabilities, priority health problems, and their motivations and preferences (WHO, 2017a; WHO, 2018a).

4.4 Intervention characteristics

Intervention characteristics are factors which predominantly involve the mobile phone and its functionalities. Christopoulos et al. (2017) conducted a literature review on all text messaging services that aim to improve HIV care for patients in US. The programs which offered participants a fixed allotment of minutes experienced tremendous obstacles; users often ran out of minutes or data which meant they could no longer receive messages. Billing issues were also a problem for programs with budgets - participants were found to make expensive overseas calls or buy games, which were reimbursed within the mHealth program to maintain patient engagement. Programs which offered unlimited data and minute plans seemed to overcome this problem. The type of phone also appeared to influence program engagement rates. Programs which offered participants a mobile phone in exchange for taking part in it found that android smart phones were more likely to be used than the simpler mobile phones offered (Christopoulos et al., 2017). Gibbs et al. (2017) found that the apps on sexually transmitted infections (STI) information had varying degree of accurate information content. Apps did not document where their information came from so the validity and credibility of the program to provide effective information was not clear.

Style et al. (2017) found that when community health workers used mobile phones to collect patient data electronically, it was the size of the mobile phones' internal memory capacity (IMC) that posed the greatest technological challenge for implementers. Phones with limited IMC and central processing unit speed were unable to collect enough data. The short battery life of mobile phones was also an issue particularly when the phone was used for social use not for collecting patient data. Malfunctions of the phones frequently occurred and the lack of fast network coverage made updating phones burdensome. Furthermore, users were never fully sure whether their uploaded forms had been saved and many made unnecessary duplicates (Style et al., 2017). Aranda-Jan, Mohutsiwa-Dibe and Loukanova (2014) found that successful mHealth is highly reliant of technical characteristics when implementing mobile projects in Africa. Low-cost, ease of use, reliable network coverage and having access to technical provision or expert knowledge were commonly cited factors for successful implementation (Aranda-Jan, Mohutsiwa-Dibe & Loukanova, 2014).

Callaway et al. (2012) investigated the role that mobile phones play during the Haitian Earth quake in 2010. They tested an interoperable patient tracking platform that on-the-ground medical providers could use to upload patient medical data on vulnerable populations such as

unaccompanied minors, pregnant women, traumatic orthopaedic injuries and specified infectious diseases. They found that the mHealth platform was beneficial and feasible to use in large disaster settings but required considerable effort. The system must be able to operate without internet connection and enable volunteer staff to use their own mobile phone to help minimize program costs and improve accessibility. It must also be able to manage the large volumes of ‘‘non- affiliated’’ and international volunteers in disaster settings. Given the transient nature of volunteer activity and types of work, data protection and security were a technical concern and the solutions included tiered access, passwords and permission requests to the platform (Callaway et al., 2012).

4.5 Governmental capacity requirements

The domain of governmental capacity requirements involves the role of the government in large scale mHealth programs. It was the least addressed domain in the peer review literature but the most addressed in the BHBM documents (see **Table *5*** for details). The goal of the BHBM reports and handbooks is to inform and share knowledge of mHealth with national governments, therefore this result in not unexpected. The handbooks are very comprehensive program specific guides which inform governments on every detail that needs to be considered before implementing national mHealth programs.

The peer reviewed literature acknowledged that the actions by governments alone are insufficient to address mHealth challenges. Cooperation from every sector is needed in the efforts to find sustainable and effective solutions (Leon, Schneider & Devious, 2012). Leon, Schneider and Devious (2012) reviewed the benefits and challenges of various mHealth community-based services in South Africa. They found that for successful mHealth implementation a highly supportive and financially committed government is needed. A national eHealth strategy was suggested as a possible approach for gaining government support and commitment. A literature review conducted by Tomlinson, Rotheram-Borus, Swartz and Tsai (2013) concluded that to achieve appropriate mHealth scale-up, concerted cooperation by governments, funders and private enterprises was needed to set sufficient standards for the safe use of mHealth for everyone to comply with.

Blauvelt et al. (2018) investigated how a regional based health and nutrition hotline in Malawi could be scaled-up to cover the nation. They found that it was only feasible to

upscale a community based mHealth program when all relevant stakeholders are involved, including the government, in the implementation process. It requires strong leadership and a long-term vision endorsed by all the stakeholders. The authors interviewed government officials who were involved in the program and many stated that collaboration was critical for the required expertise to implement a national mHealth programme. The success of the hotline was partly due to the partnership with one of Malawi's mobile network providers. This was an essential implementation feature; providers can offer technical assistance and offer lower operating costs for the program (Blauvelt et al., 2018).

Kalländer et al. (2013) found that collaboration with mobile operators is necessary for the technical support they can provide to mHealth program coordinators. The challenge therefore is how to get the health ministers and officials at the same table as mobile service providers, doctors, technologists, and financiers. To develop meaningful collaboration, implementers must appreciate all the different stakeholders' incentive structures; and they need to persuade and motivate stakeholders to come together around one common goal: successful mHealth implementation (Kalländer et al., 2013).

The BHBM annual report in 2014 provided insights into the mTobaccoCessation in Costa Rica. The program sends text messages to encourage and educate individuals on how they could give up smoking. The program was initially tested locally and then implemented nationally. It is run by the ministry of health and science and the ministry of telecommunication. The program has been able to maintain sustainability as the Costa Rican government has decided to finance the program through increasing the tax on tobacco. This is a win-win solution as it not only has it raises the price of tobacco above inflation, but also it makes it more expensive for consumers and reduces consumer demand. This has a helped finance a program that supports people to quit smoking (WHO, 2014a).

The BHBM report in 2015 showed that with government promotion the mDiabetes program in Senegal could utilise the messaging program for a secondary purpose, raising awareness about Ebola. During the epidemic in West Africa, the government of Senegal used the mDiabetes infrastructure to send SMS-messages to educate and inform people about their Ebola risk. The 2015 report also demonstrated that including mHealth programs into national policy plans was a vehicle for ensuring long term government commitment and sustainability.

The mCervicalCancer program in Zambia achieved government commitment by being part of the national cancer policy and its strategic plan 2021 (WHO, 2015b).

The BHBM report in 2016 described the implementation process of the mDiabetes program in Egypt and India. The ministry of health in Senegal was found to be an instrumental actor for both the countries during the implementation process because they were able to advise them on their own experience of running mDiabetes nationally. The ability to exchange practical knowledge through bilateral collaborations was shown to be successful for this program. The report also highlighted the need for other sectors outside of healthcare to play a part in achieving mHealth's goals of improving the whole populations' health. Multiple sectors must come together around a common goal. mCervicalCancer Zambia provided an example of this which involved participation from the WHO, the African development bank, ministries of health and technology, the national telecom regulator, academia, civil society and select private sector companies. The report documented the challenge of incentivising all the partners but stated the importance of having a partnership perspective. This is because each sector offers their own level of expertise leading to a greater chance of implementation success (WHO, 2016b).

Anticipated lessons learnt from the BHBM	Not anticipated lessons learnt from BHBM
Begin by implementing a basic SMS program which works. The simplicity will be more acceptable and enable a stronger case for adding other programs to it in the future (*usage characteristics).*	National governments' demand for mHealth has exceeded expectations *(governmental capacity).*
Political commitment is needed from government ministries to ensure that the programs are entrenched into the national agendas (*governmental capacity*).	Nations are willing to share mHealth content and experiences across borders. In mDiabetes for example, bilateral meetings have happened between Senegal and Egypt to share SMS content and program management recommendations *(governmental capacity).*
mHealth services must be integrated into a country's broader strategy and action plan for the	mHealth platforms can be used for alternative purposes than they were designed for. Senegal

health condition it is addressing *(governmental capacity).*	showed this by using their mDiabetes platform to share messages on Ebola in 2014 (*delivery characteristics).*
User feedback on SMS content and format is imperative for the messages to be engaging and understood and absorbed (*usage characteristics*).	There are several ways to ensure sustainability, and these are often proposed by countries themselves, such as Costa Rica using funds from tobacco taxes (*governmental capacity).*
User engagement is a challenge and services need to consider how to creatively keep users engaged *(usage characteristics).*	Mobile operators are very willing to support programs. The benefits for them are less about the short-term profit and more on longer- term skills upgrading as a service provider (*governmental capacity).*
Robust monitoring and evaluation is essential for building an evidence base as well as for further program development and improvement *(intervention characteristics).*	Strong national promotion campaigns for a mHealth service are fundamental. National promotion campaigns were key for Costa Rica increasing the registration numbers (*governmental capacity).*
The willingness for partnerships with global or national entities varies significantly between countries. The government will always make the final decisions on which partners they will work with *(government capacity).*	SMS may limit participation for certain people. One way by India was to enable people to register into their mHealth program by giving a missed call to the short code. This has led to Interactive Voice Response (IVR) being considered for inclusion *(intervention characteristics),*

Table 5: The most valuable lessons from BHBM initiatives (WHO, 2016a)

5. Discussion

mHealth is an evolving field which runs the risk of not realising its full potential due to the abundance of small scale implementations and the lack of large scale ones (mHealth alliance, 2010). This literature review presents a comprehensive overview of information on scaling up mHealth programs and is intended for implementers seeking to deliver mHealth to larger populations (see ***Table 6:*** *Recommendation box for mHealth implementers*). It has examined and synthesised the current mHealth literature on regional and national mHealth initiatives and applied the Intervention complexity framework to identify key characteristics that influence mHealth implementation.

5.1 Principal finding

Usage characteristics were found to pose the greatest challenge to large scale mHealth projects. mHealth implementation should pay attention to the technical issues of end-user acceptability and usability. The individual's perspective, whether it is the patient or the healthcare worker, should be at the forefront of any implementation process. The most common mode of delivering large scale mHealth is the use of SMS-based services and this finding is consistent with existing literature (Tomlinson, Rotheram-Borus, Swartz & Tsai, 2013). User feedback on the content and format of text messages is imperative for the messages to be engaging, understood and absorbed (WHO, 2016b).

Text messages that are simple, concise and tailored to the individual were found to be the most successful way to engage users (Horvath et al., 2017). The wording, style of language (Hagoel, Neter, Stein & Rennert, 2016), number of SMS sent per week (Dale, Dobson, Whittaker & Madison, 2013) as well as making messages culturally and age appropriate (Cameron et al., 2017) are also important factors. Implementers must adapt programs to meet the needs of their target users but this poses great technological challenge for national population-wide programs. Further research must establish how to accommodate a wider range of contexts, cultures and those with poor digital literacy to better understand and mitigate any potential negative impacts on gender, equity and rights (WHO, 2019).

Another key finding is that users prefer to use their own mobile phones. Mtema et al. (2016) found that when health workers used their own mobile phones for collecting patient data they were more willing and committed to the program. Mobile ownership incentivises use as

individuals feel more comfortable using their own phone. Furthermore, this reduces the chance of damage to the phone and the overall cost of the program as there is no need to provide phones or training (Mtema et al., 2016). However, use by individuals of their own phones for mHealth is not without drawbacks; for example, not all models of phones will be compatible with the mhealth program's software and infrastructure (Style et al., 2017).

5.2 mHealth barriers and gaps in research

Health workers' adoption of mHealth is shaped by their own pre-existing experiences, knowledge and digital literacy. Health workers who struggle to use mobile phones, will question their usefulness as they may not fully understand the information generated by the technology. They might also become anxious and worry about making errors when using their mobile phones for providing health care. In some instances, poor digital literacy threatens job security (WHO, 2019). Patients might also regard health workers' use of mobile phones as unprofessional because of the association with recreation. On the other hand, some patients like be contacted via their mobile phones. Targeted communication can increase access for some groups of individuals and reach people who speak minority languages by providing access to health workers who speak their language. But some individuals still prefer face-to-face contact and worry that their confidential health information might be more easily shared with others without their consent. This is a worry particularly for those who have a stigmatising disease (WHO, 2019).

Addressing the human factor in mHealth implementation is critical to adoption of mHealth because people make medical decisions based on their previous knowledge and experience. User feedback on SMS content and format is vital for the program messages to be understood, absorbed and followed. Yet implementers must assess how well mHealth will integrate into a health system and the delivery characteristics that come with that. The feasibility of mHealth for some health workers, particularly in rural or remote areas, remains fragmented as they experience logistical challenges. These include poor network connectivity and access to electricity to charge their mobile phones (Agarwal, Perry, Long & Labrique, 2015; Ngabo et al., 2012; Colaci, Chaudhri & Vasan, 2016). Rather than delivering health services more efficiently, mobile phones can instead cause delays and frustration. Health workers often report usability issues and poor integration with other digital systems.

Therefore, it is necessary that institutional support, technical supervision and local advisors are available to ensure smooth integration into existing systems (WHO, 2019).

Many of the studies found in this review were taken from emerging market countries and none were found within Europe. This is an unusual finding given that the European region is the most active in implementing mHealth. However, many mHealth interventions in Europe have been launched on a small scale through pilot testing (Kay, Santos & Takane, 2011) and this might explain why the European region is under-represented in this review. Another reason is that European regulatory bodies, reimbursement authorities and national and international political bodies often find it difficult to react quickly, or consistently, to the rapidly changing arena of digital health technology given their commitment to data protection and safety (Cowie et al., 2016). In contrast to Europe, mobile phone network coverage in Africa is more ubiquitous than paved roads and electricity, investment in scaling up mHealth is less cautious and has rapidly expanded (Colaci, Chaudhri & Vasan, 2016). This is mainly driven by the desire of governments, international agencies and the private sector to harness initiatives that provide measurable, long-term impact on the delivery of health programmes and that address the geographical barriers related to access of care (Labrique et al., 2018). The increased push from the private industry to lead the scale-up mHealth in developing countries is due in part to the lack of regulatory constraints and the perceived growth in market share that mHealth can offer (Tomlinson, Rotheram-Borus, Swartz & Tsai, 2013). Nonetheless, whether these findings from developing countries found in this paper can be universally applied and transferred to the European setting is not certain, and this will be the next step for future research to explore.

Finally, an ecosystem perspective should be applied by implementers. This means taking into consideration all the environmental aspects including infrastructure, hardware, digital applications, workforce capacity, leadership, regulatory and policy frameworks, standards and interoperability and socio-cultural considerations – as articulated in the BHBM handbook. The maturity of the ecosystem should be assessed to determine whether the mHealth intervention will integrate successfully within it. Future research needs to provide evidence on how this can be done so that countries do not waste resources and capital investing in mHealth services that are not suitable for their setting (WHO, 2019).

Recommendation Box	
Usage characteristics	➢ Individuals should be able to use their own phones ➢ Training, support and feedback from support personnel should always be available to users ➢ SMS interventions must have messages that are tailored to the individual, taking account of age and cultural background. ➢ Promotional activities and education on data protection and how to store and share information safely, is critical for public trust. ➢ Individuals that do not have a pre-determined need/desire or willingness towards the program are less likely to engage in it.
Delivery characteristics	➢ Ensuring that there is sufficient network coverage ➢ Providing health workers with phones that have a long battery life or providing portable phone chargers. ➢ Integrating mHealth into health systems needs to be carefully considered ➢ Ensuring users have safety passwords or permission requests to access the mHealth system
Governmental capacity requirements	➢ mHealth programs need to be firmly integrated into national policy to ensure government commitment and sustainability ➢ Cooperation is needed between all stakeholders ➢ Operators can lower cost for programs and provide technical support for projects ➢ A common goal and purpose is shared amongst all stakeholders
Intervention characteristics	➢ Quality of the phone is important ➢ Phones that are used to collect data must have large internal memory capacity

- mHealth programs must be simple to use and operate
- Technical experts on hand
- Content of apps need to be accurate, reliable and valid

Table 6: Recommendation box for mHealth implementers

5.3 Limitations

This review included a comprehensive and thorough thematic analysis based on the available literature. It was carried out systematically and the four domains from the Intervention complexity framework were easily applied to enable the relevant mHealth implementation information to be highlighted. Despite this approach, there were some limitations present in this study.

Firstly, given that 94 articles were found in the initial search and eight documents in the additional search, these results seem far too limited to encompass all the available information on scaling up mHealth programs. This has the potential for publication bias, which could have been avoided by a deeper systematic approach involving searching in other databases, manually searching through retrieved reference lists, contacting experts, searching in trial registries, conference proceedings and other sources for grey literature as they contain a vast amount of rich experience on mHealth project implementation (Aranda-Jan et al., 2014). Studies that were included were publications written in English, restricting findings of projects published in other languages.

The next limitation relates to the studies that were included in this review. All study designs were included as it was decided that the evidence generated through the variety of methods is of interest to a range of audiences (e.g. research teams, funders, policy makers and practitioner advocates) and provides broader results than one study design does alone. Qualitative case studies and opinion pieces were included, which were found to be of low quality, unreliable, context-specific and highly subjective to the author. Given the nature of the research problem and questions being asked, case studies were included, and they were found to provide rich and useful insights based on real-life situations that should not be dismissed (Reis, 2009). Additionally, some of the high quality systematic literature reviews were found to report on a mix of small scale and large scale mHealth implementation

information. Given that this review is about large scale interventions only, these results have the potential to suffer information bias. However, there is a lack of literature on this topic and so findings from small scale studies are still useful to the overall debate and such findings were treated cautiously rather than avoided altogether. Moreover, most of the articles included were results from surveys or interviews on the users' acceptability and usability of mHealth. Therefore, it is not surprising that the most common characteristic influencing mHealth implementation was found to be usage characteristics. Nevertheless, these findings were based on the best available literature at the time and future studies will be able to avoid these biases once the field develops further.

The use of the Intervention complexity framework enabled the themes that lie across studies to be found and analysed successfully. The application of the framework however, has the potential for selection bias as it only includes four domains which have many overlapping features when applied to mHealth. Deciding which domain an implementation issue falls under best, is not clear; some issues might fall into two or more domains. For example, the number of text messages sent to a patient per week, might fall into both intervention characteristic and usage characteristic. Moreover, the framework does not include the economic and cost effectiveness considerations that are needed to run large-scale initiatives. Addressing cost-effectiveness is essential to mHealth implementation and sustainability as some mHealth projects may be based on very expensive technology that might not be scalable for that reason. Development agencies, telecommunications companies, and governments require intensive cost evaluation and research for better informed investment decisions. Without a financial domain, this framework causes confusion and lacks complete relevancy in this field.

5.4 Conclusion

Mobile phones are universal, functional and their structural properties - namely low start-up costs, communication capabilities, and flexible payment plans - make them an attractive tool for healthcare intervention (mHealth alliance, 2010). As the mobile technology becomes more sophisticated, so does its potential to play a leading role in transforming healthcare. The field is still emerging and more evidence is needed before mHealth projects can be expanded to whole populations. Scaling up mHealth initiatives is technically complicated and faces many barriers. Whilst acknowledging the innovative role mHealth can play in strengthening

health systems, it is important to evaluate their effectiveness so that they are delivered with the intended quality and without causing disruption and financial hardship to people accessing them (WHO, 2019). There are currently more mobile subscriptions on the planet than there are people (International Telecommunication Union, 2019). Satisfying the user and tailoring programs to them and their needs are fundamental to maintaining user engagement and commitment to mHealth. In conclusion, to reach its full potential mHealth must engage and incentivise all stakeholders involved, as well as the end-users.

Conflicts of interest

The research has been conducted in collaboration with Maastricht University at the location of the partner-organization, empirica Kommunikations und Technologieforschung GmbH in Bonn, Germany. Nevertheless, the research was carried out independently and does not necessarily represent the views of the University or empirica. The study has not been financially supported or funded. No conflict of interest to declare.

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Appendix

Study	Study design	mHealth intervention	Aim of study	Implementation/study outcome	Quality	Major source of potential bias
Harnessing the Question-behaviour effect to enhance colorectal cancer screening in an mHealth Experiment **(Hagoel, Neter, Stein et Rennert, 2016)**	Randomised control trial	Encourage patients to go to their colorectal cancer screening	To assess whether population screening uptake could be increased when text messages were in an interrogative grammatical form than not.	Text messaging services should be worded in a simple, concise and interrogative manner to enhance screening uptake (usage characteristic).	Low	The method of randomisation was not described which has potential for selection bias. The study was not described as double blinded and has potential for performance bias. Description of withdrawal and drop outs was not clear and has potential for attrition bias *Jadad score: 1 = Low quality study
Recruiting Pregnant smokers from text4baby for randomised controlled trial of quit4baby **(Leavitt et al., 2017)**	Randomised control trial	Patient recruitment	To test the feasibility and effectiveness of recruiting pregnant smokers using text messages into a smoking cessation trial.	Text messaging services should be worded to have emotional appeal to enhance recruitment (usage characteristics).	Low	The method of randomisation was not mentioned and it is not clear whether the study was double blinded or not. Furthermore, the sample was not representative of the general population as the participants had been involved in a previous mHealth program which might suggest they are more willing to be recruited by text messages than other women. *Jadad score: 2 = Low quality study
Mobile phone interventions for TB should ensure access to mobile phones to enhance equity – prospective observational cohort study in	Prospective cohort study	Mobile phone education and awareness.	To assess mobile phone access among patients with tuberculosis, focusing on vulnerable patients and those who later had adverse treatment outcomes.	Poor network coverage, problems with theft, damage, faults of the phones as well as people having more than one phone was an issue (delivery characteristics).	Moderate	Results were under reported as not all data was collected e.g. data on the changes in mobile phone access over the course of the patient's illness. There were notable events (such as Peru's increased economic growth) that might have threatened the internal validity of the study's outcomes.

Peruvian shantytowns **(Saunders et al., 2018)**						
Engagement and abstinence among users of a smoking cessation text message program for veterans **(Christofferson et al., 2016)**	Prospective cohort study	Text messages that encourage users to quit smoking, patient follow-up.	To evaluate the use and effectiveness of the SmokefreeVet program for users enrolled between 2013-2014.	Individuals that had a pre-determined demand for the mHealth intervention were more likely to benefits from it. Implementers need to consider behavioural change theories to increase user adoption (usage characteristics).	Moderate	The data collected from the users was self-reported, which has the potential for response bias. The study contains point prevalence abstinence outcomes over five weeks, this not sufficient to evaluate smoking intervention given that it is chronic and relapsing condition. No user data was collected on reasons for withdrawal of the intervention, therefore the accuracy of assumptions is unknown.
Health workers' experiences, barriers, preferences and motivating factors in using mHealth forms in Ethiopia **(Medhanyie et al., 2015).**	Cross sectional study (questionnaire)	Mobile phones used to access electronic maternal health care forms for data exchange.	To assess health workers' experiences, barriers, preferences, and motivating factors in using mobile health forms to collect maternal health data on smart phones.	mHealth interventions integrating into existing health systems is a vast challenge; increased work load as data is collected both manually and electronically, high turnover of staff requiring constant training on the mHealth program and high level of worker resistance to new technology. Problems with accidently deleting electronic forms, password setting and username settings were common (delivery characteristics)	Low	The sample size was small threatening the reliability and validity of the results. Only two investigators carried out the data collection and analysis process which might have the potential for information and reporting bias.
Public perspectives of mobile phones' effects on healthcare quality and medical data security and privacy: a two-	Cross sectional study (questionnaire)	Mobile phones used for collecting and sharing health data.	The objective was to gauge consumer perceptions on medical data security, privacy and healthcare quality in mHealth	Consumers place high value on privacy and security. Many participants believed that privacy and security would worsen as results of using mobile phones to store and share personal health information. There is a fundamental need to educate the public about how they can safely store and share their data as well as standard bodies to push for more robust	Moderate	Sampling coverage and section bias due to non-response bias are documented limitations. The sampling strategy was random and representative in terms of gender, age and employment but not for education level and mot ethnicity. The survey questions lacked construct validity and the scope of the survey limited the

year nationwide survey **(Richardson & Ancker, 2015)**				mHealth security standards (usage characteristics).		opportunity for researchers to discover the attitudes behind the perspectives.
Describing the evolution of mobile technology usage for Latino patients and comparing findings to national mHealth estimates **(Arora et al., 2016)**	Cross sectional study (questionnaire)	Education and awareness	To assess the Hispanic populations', use of mobile technology and compare findings with national mHealth estimates.	Text messaging services need to be tailored to the individual's culture and massages need to be culturally appropriate (usage characteristics)	Moderate	The self-reported data on mobile phone use is subject to recall bias. The sampled population was taken at a single site (Los Angeles) which may differ from the Hispanic population in other places, limiting the external validity of findings.
Ownership and use of mobile phones among health workers, caregivers of sick children and adult patients in Kenya: cross-sectional national survey **(Zurovac et al., 2013)**	Cross sectional study (questionnaire)	Overview of mHealth	To determine the coverage data on mobile phone ownership and SMS use among health workers and patients are needed.	User-willingness is crucial to whether the mHealth program will be accepted and used by individuals (usage characteristics).	Moderate	Exclusion of urban facilities in non-malaria areas in the capital may have underestimated ownership and use of mobile phones among the patients. In the absence of assessment of individual patients' socioeconomic status, the use of proxy measures for determination of urbanization and poverty status may have introduced some misclassification. Finally, courtesy bias in responses cannot be ruled out for assessment of willingness to receive SMS interventions.
Sustainable Cost Models for mHealth at Scale: Modelling Program Data	Cost-modelling analysis	Education on family planning	To explore strategies for mHealth program sustainability and develop cost-recovery models for program implementers using	The Government must act as a key partner in negotiating reduced costs for programs and users. They can also play a crucial role in promoting and marketing the program nationally (governmental capacity requirements)	Moderate	Data was only collected during one year of the program so outcomes were unable to capture program variability and trends over a longer period. The most critical of these limitations is the assumption that users will pay for health communication messages via

from m4RH Tanzania **(Mangone et al., 2015)**			2014 operational program data from Mobile for Reproductive Health (m4RH), a national text-message (SMS) based health communication service in Tanzania.			SMS. While paying to send text messages is standard practice in Tanzania, charging users to receive content may limit program use:
Cultural and linguistic Adaptation of a healthy diet text message intervention for Hispanic adults **(Cameron et al., 2017)**	Mixed methods study	Patient education on healthy diets	To evaluate the acceptability among the Hispanic population on the linguistically and culturally adapted text messages in the HealthyYouTXT program.	Text messages need to be tailored to the individuals predisposing characteristics such as age to successful engage users (usage characteristics).	Low	The Hispanic population were mainly of Mexican origins and generalisability of findings for other Hispanic populations warrants further study. There was potential for selection bias as the sample was not representative of the population; fewer men taking part in the study than women.
Applying a framework for assessing the health system challenges to scaling up mHealth in South Africa **(Leon, Schneider & Devious, 2012)**	Mixed methods study	Overview of mHealth	To assess the health system challenges to scaling up mHealth in South Africa.	Successful implementation of national mHealth programs includes the high prevalence of supportive governments financially and politically with a committed eHealth strategy (governmental capacity requirements.	Moderate	The main limitation is the interviews and case study examples of organisations using mHealth describes positive appraisal of mHealth and does not consider those who may have had a less positive experience.
Implementation of seek, test, treat, retain interventions using mobile	Literature review	Medication adherence and education	To describe the lessons learnt from using mobile phones and text messaging to support HIV	Allocated number of minutes was found to hamper the program functioning as often it was not enough for participants – unlimited amounts of minutes/data	Moderate	Limited number of studies used, which included small scale studies. Description and motivation of the selection of studies was not clear as well as a thorough background and clear objective stated.

phones and text messaging to improve engagement in HIV care for vulnerable population in the United States. **(Christopoulos, et al., 2017)**			treatment and retention in care.	packages would overcome this problem (intervention characteristics)		* INSA score: 4 = moderate quality study
Systematic review on what works, what does not work and why of implementation of mobile health (mHealth) projects in Africa **(Aranda-Jan, Mohutsiwa-Dibe & Loukanova, 2014)**	Systematic literature review	Overview of mHealth in Africa	To analyse the experience of mHealth implementation in Africa and identify factors that influence the success and failures of mHealth projects.	Readily available technical experts and supportive personnel was found to be a critical for successful mHealth adoption (intervention characteristics)	High	The review may suffer publication bias as only studies included in English were included, excluded programs in French and Spanish. The review was not entirely systematic as it was only limited to peer-reviewed literature and not the grey literature. * INSA score: 7 = High quality study
Evidence on feasibility and effective use of mHealth strategies by frontline health workers in developing countries SR **(Agarwal, Perry, Long & Labrique, 2015)**	Systematic literature review	Staff support tools	To synthesise the evidence on the feasibility and effectiveness of mobile-based services in healthcare delivery.	Adoption of mHealth programs by health workers depended on their age, level of education, year of experience as well as cultural barriers (delivery characteristics).	High	Most the studies included were based on pilot activities which provide minimal information about the effectiveness mHealth tools by health workers for improving healthcare delivery. Conflict of interests were not found to be mentioned. * INSA score: 6 = High quality study

The effectiveness of mobile-health behaviour change interventions for cardiovascular disease self-management: SR **(Dale, Dobson, Whittaker & Maddison, 2015)**	Systematic literature review	Mobile phones used to educate and support patients in making healthy lifestyle changes and adhere to medication.	To determine the effectiveness of mHealth interventions on behavioural lifestyle changes and medication adherence for cardiovascular disease self-management.	The number of SMS sent per week to the receiver is important to keep the user engaged (usage characteristics).	High	Studies included were limited to the English language therefore the review may suffer publication bias. A meta-analysis was not carried out due to the heterogeneity of the outcome data. * INSA score: 7 = High quality study
Can you recommend any good STI apps? A review of content, accuracy and comprehensiveness of current mobile medical applications for STIs and related genital infections **(Gibbs et al., 2016)**	literature review	Education	To review the content and accuracy of apps for people seeking information on STIs.	Apps do not always document where their information has come from. Many lack validity and legitimacy (intervention characteristics).	High	Authors were only interested in accessible (open) apps rather than those designed for a specific (closed) population and researchers were using their own smart phones so decided to exclude them. Subjective element of assessing apps may be present and leading to selection bias. The motivation for selecting studies and the inclusion criteria that studies needed to adhere to was not thoroughly mentioned. *INSA score: 5 = High quality study
Using technology to assess and intervene with illicit drug using persons at risk for HIV **(Horvath et al., 2017)**	Literature review	Overview of mHealth literature	To assess the literature on mobile phone-based interventions can help drug using persons at HIV risk	It is critical to tailor messages so they are relevant and engaging. Messages that provide users with feedback should use humour rather than shaming language. Apps that give users control over its components, are easy to use, colourful and interactive were found to be engaging factors (usage characteristics).	High	The search strategy was not systematic or extensive. Only one database was used to find data and inclusion criteria of included studies was not stated. The few studies that were included in the review and many had a small sample size or were pilot studies so not were not generalizable for large scale studies. *INSA score: 6 = High quality study

Mobile health (mHealth) approaches and lessons for increased performance and retention of community health workers in low and middle income countries: a review **(Kalländer et al., 2013)**	Systematic literature review	Staff support tools	To identify the promising practices and experiences learned, as well as novel and innovative approaches of how mHealth can support community he alth workers.	Collaborations are more likely when all partners display a strong affinity to the goal. Collaborations cane provide resources, technical support and reduced costs to programs. The challenge is finding the incentives for all stakeholders (governmental capacity requirements).	High	A limited number of mHealth projects were found which specifically targeted community health workers. The sources of the information reviewed were primarily obtained from project websites because few peer-reviewed evaluations were identified, potentially resulting in over reporting of positive results and underreporting of challenges or failures. The methodology lacked a clear inclusion criteria of included studies. * INSA score: 6 = High quality study
mHealth interventions in Low-Income Countries to address maternal health: a systematic review **(Colaci et al., 2016)**	Systematic literature review	Overview of mHealth	to explore the current evidence on the use of mHealth for matern al health interventions in low- and low middle-income countries.	sharing phones disrupt the successfulness of mHealth programs; it is uncertain that targeted user has received the mHealth intervention (delivery characteristics).	High	only papers published in peer-reviewed journals to improve the quality of the review, this may have resulted in the omission of outside reports from non-profit organizations, white or grey literature, or papers published in technology journals. Another limitation is that we only included papers published in English. Increasing the quality of the studies as well as the diversification of programs and research groups would contribute to the generalizability of the findings. * INSA score: 7 = High quality study

Implementation of mHealth applications in Botswana: telemedicine and education on mobile devices in low resource setting **(Littman-Quinn et al, 2013)**	Opinion piece	Overview of mHealth in Botswana	To describe mHealth in Botswana, including describing the challenges and future direction of mHealth in the country.	Negative perception from health workers to adopt mHealth was due to their belief that it increased workload and disrupted workflow (delivery characteristics)	Low	There was no information on how the authors found their data as there was no methodology on a search strategy or inclusion and exclusion criteria described. Findings presented lack validity and reliability and are at risk of information bias; quality and interpretation of the data based on the authors' subjectivity.
Scaling up mHealth: where is the evidence? (**Tomlinson, Rotheram-Borus, Swartz & Tsai., 2013).**	Opinion piece	Overview of mHealth literature	Discusses several points pertinent to developing a robust evidence base for scaling up mHealth interventions. It highlights the problem – current state of evidence, what constitutes evidence, what needs to happen next, research stages and standards for scaling up and extensive recommendations for scaling up	National governments must be involved in national mHealth to ensure programs comply with safety and regulatory standards set by them (governmental capacity requirements).	Low	There was no information on how the authors found their data as there was no methodology on a search strategy or inclusion and exclusion criteria described. Findings presented lack validity and reliability and are at risk of information bias; quality and interpretation of the data based on the authors' subjectivity.
Scaling up a health and nutrition hotline in Malawi: the benefits of multi-	Qualitative case study	Patient education on health and nutrition	To describe a multi-sectoral collaboration that enabled the scale up of a health advice telephone service.	Nationwide coverage on mHealth programs require leadership and long term vision shared with all stakeholder. Close collaborations from the government, mobile operators, private sector stakeholders are vital. Local	Low	Findings of the case study cannot be generalised to wider populations as they are context-specific given the location they were carried out in. Cases studies are at risk of information bias; they are based on the analysis of qualitative (i.e. descriptive) and

sectoral collaboration **(Blauvelt et al., 2018)**				people need to feel ownership over the program for it to be adopted (governmental capacity requirements).		observational data which is subject to the authors' interpretation and subjective opinions. Case reports are also produced retrospectively and may be subject to recall bias or an over-interpretation of findings. (Reis, 2009; Nissen & Wynn, 2014)
Mobile phones as surveillance Tools: Implementing and evaluating a large-scale Intersectoral Surveillance System for rabies in Tanzania **(Mtema, et al., 2016)**	Qualitative case study	Mobile phones as a surveillance tool.	To develop and deploy a mobile phone based surveillance system for healthcare workers to report rabies cases, animal bites and human and animal vaccine use.	User experience is critical for wide scale adoption by users. Users want to use their own phones, have access to continuous training and support feedback from personnel. The age of the user influences user adoption (usage characteristics).	Low	(See same as above)
Experience in running a complex electronic data capture system using mobile phones in large-scale population trial in Southern Nepal **(Style et al., 2017)**	Qualitative case study	Mobile phones as health data surveillance tool.	To share the experiences in the design and implementation of the EDC (electronic data capture) system.	The quality of the phone influences the success of the intervention. Short battery lives and limited internal memory capacity hindered the complexity of data collected (intervention characteristic).	Low	(See same as above)
Disaster mobile health technology: lessons from Haiti **(Callaway et al., 2012)**	Qualitative case study	Data collection and reporting.	To develop, deploy and evaluate an electronic patient medical record and tracking system.	In disaster settings, mHealth interventions need to be simple, require little training, accessible without internet connection and have a high level of data security and tiered access to them (intervention characteristic)	Low	(See same as above)

Designing and implementing an innovative SMS-based alert system (RapidSMS-MCH) to monitor pregnancy and reduce maternal and child deaths in Rwanda **(Ngabo et al., 2012).**	Qualitative case study	Data collection and reporting system.	To describe the design and implementation of a mobile phone-based communication system aiming to monitoring pregnancy.	The lack of electricity in rural areas hampers the ability of health workers to recharge phones and continue using the mhealth program (delivery characteristics).	Low	(See same as above)

Table 7: Summary of peer-reviewed studies (*Jadad score and INSA score)