PART 1

Setting the stage: the promise of mHealth

There is likely to be little impact on lives saved or improved without substantial investment in improving the quality of ANC services provided in LMICs.
~ World Health Organization, 2016

CHAPTERS

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Introduction
Part 1 - Setting the stage: the promise of mHealth

Socially, ethically and clinically, pregnant women represent a vulnerable group and up to 75% of maternal deaths are due to preventable or manageable conditions [1–3]. Over 90% of maternal deaths occur in low- and middle-income countries (LMICs) [4]. The main issues underlying maternal mortality in many LMICs are direct obstetric causes such as haemorrhage, sepsis and obstructed labour, poor access and low quality of care (QoC), which result in low demand for maternal health services [5]. An increasingly important proportion of maternal mortality in LMICs is due to indirect or non-obstetric causes attributed to pre-existing conditions or conditions triggered or worsened by the physiologic effects of pregnancy. These include HIV-related complications, anaemia and malaria. In 2015, an estimated 303,000 women died from pregnancy-related causes, most of these representing a disproportionate burden on poor and rural women [4].

Aiming to address high maternal mortality ratio (MMR) in LMICs, world leaders launched the millennium development goals (MDGs) in the year 2000. Various strategies including skilled birth attendance, 4+ antenatal care visits and contraceptive use, were promoted, resulting in a 44% reduction of MMR globally. Further action has been spurred under the third Sustainable Development Goal (SDG) on health and wellbeing, which aims to end preventable maternal deaths and reduce global MMR to less than 70 per 100,000 live births by 2030 [6].

Antenatal care (ANC) is an important part of the maternal care continuum from prenatal to postnatal care, because it is the gateway to maternal health services. It is often the first contact of pregnant women with health services and holds important significance for overall maternal well-being. ANC offers an opportunity for prevention and early detection of pregnancy complications, with referral where needed. It is also a key entry point for continuity of maternity care within the health system, as well as integration of other medical, social and supportive services [7]. The goal of ANC is to build trust between service providers and pregnant women, hereby encouraging the demand and appropriate utilization of health care. Evidence shows that quality ANC has direct and indirect impacts on reducing maternal and perinatal morbidity and mortality and can therefore contribute to realising the aims of the third SDG on maternal health [8]. But which strategies could be leveraged to improve the quality of antenatal care in low-resource settings?

1.1 Quality of Antenatal care

In order to gain insight on strategies to improve ANC, it is important to first understand the components of quality ANC. The Institute of Medicine (IOM) defines quality care as that which is “… safe, effective, patient-centred, timely, efficient and equitable and encompasses three key components of quality: clinical (safe and effective), interpersonal (patient-centred) and contextual (timely, efficient and equitable).”
These are translated in the five broad components of ANC [8, 9]:

i) Education and counselling on pregnancy care, nutrition, birth preparedness and complication readiness, the importance of skilled birth attendance, early post-natal care, breast feeding and family planning;

ii) Screening, early detection and management of pre-eclampsia, anaemia, gestational diabetes, infections such as syphilis, HIV and Hepatitis B, other complications, as well as the administration of tetanus toxoid, folates, iron, and intermittent preventive treatment of malaria during pregnancy (IPTp);

iii) Maternal and foetal assessment and monitoring;

iv) Timely management of identified pregnancy-related complications at the point-of-care or at referral levels where indicated;

v) Provision of other social assistance where available.

ANC coverage in many LMICs has improved since the introduction of the four-visits model in the 1990s [10]. In 2016, the World Health Organization released new recommendations for an optimized ANC package, promoting eight active contacts between pregnant women and providers. The aim is:

“To provide pregnant women with respectful, individualized, person-centred care at every contact, with implementation of effective clinical practices (interventions and tests), and provision of relevant and timely information, and psychosocial and emotional support, by practitioners with good clinical and interpersonal skills within a well functioning health system”. [8]

Essentially, the supply side (i.e. health facilities and health care workers) and demand side (i.e. pregnant women) of ANC interact within the broader milieu of the health system to influence the outcome and experience of pregnancy. Evidence shows that community and individual perceptions of quality maternal care influences health service utilization and the decision to seek care or comply with recommendations [8, 11]. Furthermore, the content and process of ANC not only influences pregnancy outcomes, the experience of pregnancy and demand for services, but could also impact subsequent health seeking and health management behaviours on an individual and ultimately family level. These have led to concerns about the disposition of pregnant women to trust and engage with the health system and emphasises the need for increased focus on the quality of ANC. If services are characterised by good technical and inter-personal quality, and occur within a properly structured and functional service delivery pathway, ANC is an opportunity to build trust between service providers and pregnant women, hereby encouraging their demand and appropriate utilization of care [8].
1.2 Barriers to the provision of quality antenatal care

Despite recommendations on optimising the service delivery package, there has been no commensurate improvement in the quality and content of ANC. Secondary data analysis from ten LMIC countries found that not more than half of women with first trimester ANC registrations who reported at least four ANC visits, received up to six care elements of routine ANC [12]. These were blood pressure measurement, testing urine and blood samples, tetanus toxoid vaccination, iron supplementation and receiving information on birth preparedness and complication readiness. Echoing the conclusions of other authors, Benova et al. noted significant gaps in the content and quality of ANC service provision, which can influence other phases of the maternal care continuum [12, 13]. These findings expose challenges on both supply and demand sides, which impact access and delivery of quality ANC.

Supply Side Challenges
For effective delivery of quality ANC, health facilities need to have sufficient numbers of supported health workers with the required mix of skills and knowledge and the necessary resources to act [13]. Shortages of skilled health workers and high workload in health facilities especially in remote areas, is a systemic challenge in many LMICs. This is compounded by low technical capabilities of staff, which have not been fully addressed through pre-service or in-service training [14]. Secondly, front-line workers are not always equipped with resources to conduct routine tests and to make referral or management decisions where needed. Especially in lower cadre workers (i.e. trained community health nurses and nursing assistants), this could manifest as low trust and confidence in their ability to make the right decisions. But these are not the only constraints. Even if higher cadre staff such as professional midwives who are believed to possess the required knowledge and skills for decision making are present, staff often feel overwhelmed by a heavy workload or are demotivated by poor working conditions. This increases the risk of skipping recommended ANC components such as education and counselling or overlooking crucial indications for management or referral action [15].

Strategies to mitigate workforce and skill-mix challenges in LMIC and minimize workload due to a high volume of patients, include task-shifting of some service delivery tasks from higher cadres such as midwives and associate clinicians to lower cadre workers including community health workers (CHWs) and auxiliary nurses [16, 17]. Nonetheless, there are concerns about sub-optimal performance of lower cadre workers, the informal nature of their roles within the health system, poor supervision and their collective effect on quality of care [16, 18]. The gap between what HCWs have been trained to do and their capability, referred to as the know-do-gap, has contributed to questions on how health workers’ motivation and performance can be ensured, and if task-shifting strategies are implemented in ways that compromise the quality of care.
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Service delivery gaps at the facility level, weak and inefficient referral linkages within the health system, and scarce resources are additional supply side barriers affecting access to quality ANC. Lack of or delayed diagnostic screening during ANC has implications for early identification of manageable conditions that could put both mother and child at risk [19]. In remote areas, laboratories may be unavailable or ill equipped such that pregnant women cannot receive the full complement of routine ANC screening at the point-of-care (POC). For example, the standard diagnostic criteria for hyperglycaemia in pregnancy based on plasma glucose is not readily accessible in rural areas [8]. Women are therefore subject to unnecessary diagnostic referral and may have to travel long distances- a barrier to accessing the optimal package of maternal health services [20]. This referral inefficiency has a cumulative effect in overburdening and congesting higher levels of care. Weak referral linkages are also reflected in incomplete health information data, low assurance that health workers know when and how to activate the referral system, and the lack of resources to ensure that women can be promptly accompanied to the next level of care.

Both task-shifting and decentralisation of service delivery to the primary level are recognised strategies to increase the skills and confidence of health workers and bring quality maternal services closer to women and their communities [17]. In addition to strengthening service delivery and referral linkages, health workers are better able to provide quality ANC when they are motivated and feel valued [13].

Demand Side Challenges

Pregnant women need to make early and regular contact with health providers through prompt registration and follow-up ANC contact during pregnancy. However, many women, especially the rural poor, encounter barriers to access ANC at the community and health facility levels. This challenge results from limitations of distance and lack of finances. This is compounded by improper management of conditions at facility-level and poor communication and relationships between women and care providers, which undermine women’s experience of care and their perception of its quality [11, 21].

Dissatisfaction and low trust with available services further impacts the community level by demotivating mothers’ decision to seek ANC care at health facilities and decreasing the utilization and demand for ANC [8, 21]. Weak referral linkages are not only an issue with the supply side, but are also reflected on the demand side when pregnant women fail to comply with referral instructions. Reasons for this are not far-fetched and include low trust in health workers and the health system, financial and socio-cultural barriers, as well as wide distances between referral points [14, 22]. Although these concerns have been acknowledged over two decades ago, they still prevail. Strategies to overcome demand side challenges include social accountability initiatives, promotion of supportive education and counselling during repeated ANC contact, and community models of ANC provision [13].
1.3 Bridging the quality gap in antenatal care: the promise of mHealth

Technological innovation is driving economic, social and health system changes in low-resource settings and could strengthen maternal health services [23, 24]. It is used to support the provision and management of health care and is widely referred to as mHealth [25]. mHealth has rapidly gained attention as an innovative way of improving health care access, reducing service delivery inefficiencies, supporting the acquisition of knowledge and skills and influencing demand for and quality of health services in LMICs [25, 26]. In Ghana, Gambia and Uganda for example, mHealth was found to increase referrals to healthcare facilities when used for emergency medical support [27–30]. It has also been adopted for remote patient monitoring, health information systems, data collection and administrative decision making [31, 32].

Use of mHealth for maternal health care has been documented in education and behaviour change interventions for women, as well as in training health workers [30, 33]. Specifically, point-of-care and decision support technologies have been reported to bridge the know-do gap in health workers by aiding clinical decision making and task shifting [34–36]. By improving the process of care and empowering front-line workers with additional tools and skills, mHealth promises to improve QoC and bring care closer to communities [33, 35, 37–39]. Findings from a Nigerian study showed significant improvements in health education and counselling as well as the technical components of ANC using a mobile decision support application [40]. In rural Tanzania, although no causal relationship was proven, mHealth was reported to improve the satisfaction of health workers, with potential to not only enhance their skills and knowledge, but ultimately the quality of maternal care [41]. Reviews of literature have also documented its use for supporting referral linkages, point-of-care services, health promotion, and health-seeking behaviour for maternal and child health [30, 42].

Diagnostic and clinical decision support systems
Although there are diverse ways in which mHealth can play a role in maternal care, diagnostic and clinical decision support technologies are of special interest in low-resource settings. This is because of their value in facilitating service delivery at the POC, while enabling the devolution of responsibilities to lower cadre staff and improving health workers’ performance [36, 43, 44]. Access to diagnostic systems can eliminate barriers of distance and reduce waiting times and unnecessary referrals by expanding service delivery capacity at peripheral levels. While their value is recognized, the use of diagnostic technologies in low-resource settings is also being debated along the lines of cost-effectiveness, accuracy and clinical impact [39, 44, 45].

Clinical decision support systems (CDSS) address poor adherence by health workers to evidence-based guidelines and support their clinical decision
making capacities [46]. Using programmed algorithms and artificial intelligence they provide evidence-based recommendations in the form of action and referral alerts, guided education and counseling prompts, and risk identification following screening [46]. Because these technologies are designed to be intuitive or automated, the expectation is that they can be used without the need for extensive technological or clinical training. However, findings from existing research show that involved actors need to actively negotiate technologies as a mediator of the care process and that systemic and contextual challenges such as resource shortages and geographical inaccessibility are not easily overcome [47–49].

1.4 Focus of the thesis

Although use of mHealth is fast gaining popularity and support for leapfrogging persistent health system barriers to provide quality care in low-resource settings, there are still many questions about what works and if so, how it works. In LMICs especially, the domain is still nascent and there is weak evidence about its impact, efficacy and cost-effectiveness [50]. Majority of evaluations on mHealth have been conducted in high-income countries where mHealth is not only more advanced, it has progressed faster to systemic integration and scale [51, 52]. The evidence to validate their effectiveness and applicability in low-resource settings is still developing [53]. Legitimate concerns border on if and how the promise of mHealth translates into reality for health workers and beneficiaries of care in these unique contexts.

Some authors have called for a cautious approach to the magical promise of digital innovations. Gado, for one, warns against the fallacy that development can be leap-frogged, citing contextual challenges, social inequities, and the limitations of how much magic mHealth can deliver [54]. Similarly, Pai et al. call for greater attention to the context of the systems under which technology can thrive in order to avoid expecting too much from too little [55]. Nonetheless, by triggering ripple effects that contribute to the quality of service delivery, there are indications that mHealth holds true promise for improving the process of care [55]. Recommendations for making this a reality include designing and evaluating programs that account for complexity, are driven by theoretical evidence and can adapt to the multiplicity of actors and pathways that connect innovation input to existing contexts and eventually lead to better outcomes and impact [55, 56].

Despite the breadth of literature supporting scale-up of digital innovations and ambitions to accelerate attainment of the SDG3 targets, if and how mHealth addresses the pressing challenges of quality antenatal care in low-resource settings is yet to be fully substantiated. Identified supply and demand side barriers to quality ANC and indications that diagnostic and clinical decision support devices can bridge the quality gap in low-resource settings therefore prompts the question:
Part 1 - Setting the stage: the promise of mHealth

What is the influence of mHealth, specifically diagnostic and clinical decision support systems, on the quality of ANC and what are the implications for future ANC strategies?

The term ‘mHealth’ is used broadly in reference to digital innovations in health care including but not limited to diagnostic and clinical decision support systems, while the term ‘diagnostic and clinical decision support systems’ specifically refers to this sub-group of digital innovations.

The aim of this thesis therefore is to gain insight on the effect of digital innovations on the quality of ANC in low-resource settings, and its implications for practice. Objectives are two-fold:

a. Identify theoretical explanations underlying the promising use of mHealth.

b. Empirically investigate how diagnostic and clinical decision support systems influence antenatal care.

Findings are important for revealing the theoretical underpinnings of mHealth use, and to inform mHealth implementation research, its uptake by health system actors and its translation to practice for the delivery of quality antenatal care in low-resource settings.
Research Framework and Questions
2.1 Research framework

Quality of care is a complex and multi-dimensional construct and there is no specific framework for the quality of ANC. However, because ANC is a key component of maternal care, frameworks used to conceptualise the quality of maternal care in general can be applied.

Framework for the quality of maternal and newborn health

QoC frameworks can be broadly classified into perspective, characteristic or system models [57]. Perspective models focus on the various actors involved in the delivery of care (patients, health workers and health managers), characteristic models are framed around the elements and features of care, while system models conceptualise quality care as a product of the structure and process of health care delivery [57]. System models are holistic in that they also account for the actors and features of care. A system model was therefore chosen to inform the conceptualisation of the quality of ANC in this thesis.

In line with a systems approach, the World Health Organisation (WHO) developed a framework for the quality of maternal and newborn care that conceptualises the structure, process and outcome of care [58]. The structure of health care refers to attributes of the setting in which it occurs; that is the contextual characteristics of the health system. This includes material resources, human resources and organizational structure. The process of care describes the transactions that comprise delivery and receipt of care. It includes the health seeking behaviours of women, compliance to care, and actions of health workers in providing care [57]. The outcome of quality maternal care includes coverage of best practices and health outcomes (Figure 1). The framework consists of eight process domains split between the supply or provision of care by health workers and the demand, utilization and experience of maternal care by pregnant women.

Summarily, the WHO framework takes into account the overall role of the health system specifically at health facility level, whilst not failing to acknowledge the importance and effect of the competence and experience of health workers and women. All elements of the framework can therefore be targeted to guide the improvement and assessment of quality maternal care [58].

Framework for mHealth and the quality of antenatal care

Inspired by the WHO framework, the quality of ANC is operationalised in this thesis at the structure, process and outcome levels. In the previous sections, mHealth has been positioned as a promising bridge between the supply and demand sides of ANC process. However, the WHO framework does not accommodate the possible effect of digital technologies in the process of care. mHealth can influence the provision of ANC by interacting with actors within the health system context. By serving as an innovation bridge between health workers and pregnant women, it is expected to influence the outcome of care. In addition to the supply (health workers) and demand (pregnant women)
components of ANC delivery, mHealth is therefore introduced in an adapted framework, as the third component of the process of quality ANC (Figure 2).

Figure 1 - WHO framework for the quality of maternal and newborn health care

Figure 2 - Research Framework

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Part 1 - Setting the stage: the promise of mHealth

The structure of care was conceptualised as attributes of the setting in which it occurs. These contextual attributes are acknowledged to operate within the health facility, as well as in the broader health system structure. Overall, quality ANC is a function of the process of care, interlinking provision of care by health workers and the experience of pregnant women, with mHealth as an innovation bridge mediating the process (Figure 2).

Perspectives of the main ANC actors involved in the provision of care and the experience of it are therefore considered in this thesis. The specific interest on the supply side is the performance of providers to deliver ANC services. Performance is the ability of health care workers to provide quality ANC, defined by their availability, productivity, competence and responsiveness [59]. It concerns the ability of workers to demonstrate sufficient knowledge and technical skills for delivering ANC in accordance with standard evidence-based guidelines. This includes early detection and management of complications or risks through screening and assessment, adequate education and counselling, and activating referral to a higher level of care when necessary. On the demand end, the focus is on the experiences of pregnant women with respect to their interpersonal relationship and communication with providers of care and how this influences their demand and utilization of ANC services. Due to insufficient evidence of causality between mHealth and health outcomes, as well as the risk of weak surrogate endpoints, the outcome level is addressed only at the level of proximal or immediate outcomes [55].

2.2 Research questions

Research questions were formulated with the research framework in mind, and in line with the promise that mHealth, specifically diagnostic and clinical decision support systems may influence the quality of ANC in low-resource settings by overcoming identified barriers. The first and second columns in Table 1 present the ANC barriers earlier described in section 1.2, alongside the features of mHealth that hold promise for addressing these barriers. The third column identifies anticipated outcomes from leveraging mHealth for ANC. For example, access to health care is a barrier to quality ANC and point-of-care diagnostic and screening devices could increase the utilization and demand for ANC services as well as improve access to ANC services.

The main research question addressed by this thesis is:

*How does mHealth, specifically diagnostic and clinical decision support systems, influence the quality of antenatal care in low-resource settings and what are the implications for future ANC strategies?*
Three sub-questions were further posed:

1. *What is the evidence on the use of mHealth, specifically diagnostic and clinical decision support systems, in low-resource settings?*

2. *How does mHealth, specifically diagnostic and clinical decision support systems, influence the performance of maternal health workers in low-resource settings?*

3. *How do pregnant women experience mHealth, specifically diagnostic and clinical decision support systems for ANC, in low-resource settings?*

Answers to these sub-questions lay the foundation for considering the implications of mHealth for future ANC strategies in low-resource settings. The implications of findings related to each of the three sub-questions are therefore first addressed in the respective thesis chapters followed by extensive reflections in the concluding chapter.

**Table 1 - Promise of mHealth for quality antenatal care**

<table>
<thead>
<tr>
<th>Barrier to Quality ANC</th>
<th>Promise of mHealth</th>
<th>Anticipated outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to health care</td>
<td>Point-of-care diagnostic and screening devices</td>
<td>Utilization and demand for ANC increases</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improved access to ANC services</td>
</tr>
<tr>
<td>Workforce shortages and high workload</td>
<td>Clinical decision support systems</td>
<td>Enhanced decision making skills of health workers</td>
</tr>
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<td></td>
<td></td>
<td>Supports task-shifting</td>
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<tr>
<td>Weak and inefficient referral linkages</td>
<td>Generates referral recommendations based on diagnostic and clinical data</td>
<td>Decreased number of unnecessary referrals</td>
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<td></td>
<td></td>
<td>Women trust and comply with referral recommendations</td>
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<tr>
<td></td>
<td></td>
<td>Early detection and timely management for women with high-risk pregnancies</td>
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<tr>
<td>Low confidence and trust of health workers in their skills and knowledge</td>
<td>Clinical decision support systems</td>
<td>Enhanced decision making skills of health workers, which boosts confidence</td>
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<tr>
<td>Low confidence and trust of pregnant women in the health system</td>
<td>Supports structured education and counselling</td>
<td>Improved interpersonal relationship and communication between women and health workers</td>
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<tr>
<td></td>
<td>Point-of-care diagnostic and screening devices</td>
<td>Increased utilization and demand for ANC</td>
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<td>Women trust and comply with referral recommendations</td>
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Research Design
3.1 Research methodology

Three streams of inquiry were pursued in order to answer the research questions. A theoretical stream broadly explored the underpinnings of mHealth interventions by synthesising evidence from existing literature. Using a case-study design, the empirical stream specifically tested and further explored how the potential of diagnostic and clinical decision support systems is translated to reality. Thirdly, the reflection stream took a critical and holistic lens in interpreting findings and considering their implications.

In the following sections the three streams of inquiry are detailed alongside approaches applied to addressing research sub-questions 1-3.

3.1.1 Streams of inquiry

3.1.1a Theoretical stream: evidence synthesis

The identification of theoretical explanations underlying the promising use of mHealth, i.e. the first thesis objective, required examining existing evidence. Evidence synthesis is a form of secondary data analysis and up to 14 different types have been identified for use in health research [60]. Two of these were employed in this thesis.

First, a scoping review was conducted to partly address research sub-question one. By collating evidence from a broad topic area, scoping reviews are useful for assessing the necessity for other types of more detailed synthesis [61]. In this case, a review of evidence on the use of point-of-care (POC) clinical decision making devices in sub-Saharan Africa was conducted. Second, findings from the scoping review formed the basis of conducting a realist review to build theoretical explanations on how mHealth influences the performance of maternal health workers in LMICs. Rooted in the ontological perspective of scientific realism, realist reviews use theoretical reasoning to investigate complex questions [62, 63]. In order to identify explanatory patterns from existing studies during the review, the context of mHealth interventions was linked to the actors involved, the mechanisms triggered in these actors and the resultant outcomes. By questioning the ‘how’ of mHealth, part of research sub-question two was hereby addressed. Unlike the first two research sub-questions, answers to research sub-question three did not involve a stand-alone literature review because elements of the experiences of pregnant women were already partly captured in the scoping review.

Importantly, the theoretical stream synthesised evidence beyond the boundaries of the thesis questions in order to support generalizability of findings. It explored evidence from multiple LMICs, on different types of mHealth and from interventions that focused not only on ANC, but also on other aspects in the continuum of maternal care such as delivery and post-natal care. Evidence from literature was further supported by primary data collection under the empirical stream.
3.1.1b The empirical stream: evaluation of a diagnostic and clinical decision support device

Using a case study design, the empirical stream involved the evaluation of an identified diagnostic and clinical decision support device for antenatal care in one LMIC. The decision to adopt a case study design was informed by the need for in-depth contextual analysis and in order to make comparisons within and between contexts [64]. The three main elements presented in the research framework were explored in the selected case; mHealth as an innovation bridge between the provision and experience of care; health workers performance in delivering ANC, and the experiences of pregnant women on the demand side of the care process. In doing so and by complementing findings under the theoretical stream, research sub-questions 1-3 became completely addressed.

Summarily, the empirical stream met the requirements for study objective two. That is, to investigate how diagnostic and clinical decision support systems influence ANC.

Data specific to each sub-question were collected using appropriate methods described below. First, the study context and the research case are briefly introduced.

The Ghanaian Context

In Ghana, the Maternal Mortality Ratio in 2015 was reported at 319 per 100,000 live births with a large range of uncertainty (from 216 to 458) [65]. The main direct causes for this included haemorrhage (39%), hypertensive disorders (35%) and unsafe abortions (7%), while indirect causes (26%) comprised severe anaemia, diabetes and malaria [66].

Despite policy and practice measures, a complex of factors continue to slow down progress in maternal health and there are concerns about its quality [66]. Assessment of ANC quality in 12 rural health facilities from one of ten administrative regions- the Upper Eastern region, found that facilities scored reasonably high (0.84) on quality of routine ANC using an observation checklist. When disaggregated, however, scores related to the technical aspects of care such as counselling and laboratory examination, were below expectations (<0.45), where the minimum and maximum attainable scores were 0 and 1 [37]. Similar to studies in other LMICs, urinalysis for glucose and protein was rarely carried out, but blood pressure examinations received maximum scores [12, 37]. These findings were explained as largely due to poor adherence to clinical practice guidelines. An additional explanation is lack of screening tools or lack of knowledge on how to conduct tests and interpret results for appropriate action. Frontline maternal health workers have also cited poor referral chains and low staffing as some of the factors influencing their decision making capabilities [14].

Peripheral health facilities in Ghana known as Community Health Planning

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1 In part two of the thesis, the study context and research case are discussed in detail.
Part 1 - Setting the stage: the promise of mHealth

Services (CHPS) represent up to 60% of all health facilities. Constituted as part of a strategy to deliver maternal and child care closer to communities and improve woman-provider relationships, resource and staffing constraints limit the possibility of screening tests to be conducted in pregnant women at these points of care [67, 68]. These constraints necessitate diagnostic referral to secondary or tertiary level facilities, which has cost and time implications for pregnant women and demotivates their compliance to referral recommendations. In addition, poor feedback between health facilities ultimately affects patient monitoring and accurate record keeping. Other health system challenges include poor staff attitudes and motivation, which influence the performance of HCWs.

Case Study: The Bliss4Midwives Intervention
In response to the identified challenges with delivering quality ANC particularly in rural areas (see Chapter 2, Table 1), a group of seven organizations came together as a public-private partnership to propose an mHealth-driven solution. This consortium comprised local and international partners from Ghana and the Netherlands². The result was the design and deployment of a prototype device tagged ‘Bliss4Midwives’ (B4M).

B4M is an integrated diagnostic and clinical decision support device that enables health workers to conduct non-invasive screening of pre-eclampsia, gestational diabetes and anaemia in pregnant women. By facilitating POC screening for pre-eclampsia, gestational diabetes and anaemia, the device was expected to ensure early detection and prompt action, facilitate woman-friendly consultation and decrease unnecessary ANC referrals. B4M is composed of diagnostic and supportive components described and illustrated below (Figure 1).

Diagnostic components include:

- Non-invasive Pronto-7® Rainbow Pulse Co-Oximetry™ device, Masimo Corporation, Irvine, California, USA for arterial oxygen haemoglobin, pulse rate and total haemoglobin concentration.

- Suntech Medical® Advantage™ OEM non-invasive blood pressure (OEM-NIBP).

- Urisys 1100® Urine Analyzer, Roche Diagnostics, which automatically reads protein and glucose levels in urine through Chemstrip®.

These components meet requirements of the Food and Drug Administration or European Standard of Electronic Engineering and conform to standards for developing medical prototypes- ISO 13485 [67].

² Ghanaian partners: Association of Church Development Projects (ACDEP) and Presbyterian Health Services-North (PHS-N); Netherlands partners: Cordaid, Relitech, TNO Organization for Applied Scientific Research, Simavi and Enviu.
1- Portable water and heat resistant dustproof case; 2- Automated blood pressure cuff; 3- Urinary glucose and protein Chemistrips; 4- Urisys 1100® Urine Analyzer; 5- Pron-to-7® Rainbow Pulse CO-Oximetry™ device; 6- Android tablet with decision support algorithms; 7- Traffic-signaling alert system; 8- Unique QR code for easy tracking and recall of patient records; 9- AC adapter for charging the device.

Figure 1 - Diagnostic and supportive components of B4M

Supportive components of B4M served to integrate diagnostic data, archive and facilitate easy storage and retrieval of women’s records, and guide health workers in education and counselling. They include:

- An android tablet that paired with diagnostic components via Bluetooth was pre-programmed with decision support algorithms according to Ghana Health Service guidelines. The decision support component used a traffic-light system to indicate level of risk or referral urgency while prompting patient counselling, management or referral.

- Pregnant women were linked to the system on the first B4M screening visit via Quick Response (QR) codes affixed to their health record booklets.

Summarily, the B4M device has three main functions: diagnostic screening; clinical decision support and the provision of referral recommendations; counselling and education. A project database collated individual-level records on all conducted screenings. Based on its technical composition and functions, the B4M device is representative of diagnostic and clinical decision support devices as a sub-group of digital innovations, making it a suitable case study for addressing the research questions.
In 2016, the B4M prototype devices were piloted without pre-testing in 10 health facilities in two Ghanaian regions (Upper East and Northern regions) for a one-year period (Figure 2).

Figure 2 - Boundary map of Northern and Upper East regions of Ghana showing B4M project locations. Locations with referral facilities are identified by purple ovals.

Selection of intervention facilities was done in consultation with local program managers and district administrators. It was largely guided by high ANC-load per facility and remote distance from referral hospital. To ensure that more women could benefit from the device, B4M was permanently stationed in some health facilities, while in others, one device was rotated between two facilities. The program logic and how this innovation was expected to bridge gaps in quality ANC was based on a number of underlying assumptions:

i) POC screening for anaemia, gestational diabetes and pre-eclampsia would increase demand for and utilisation of ANC services and improve access to services at the peripheral level.

ii) By prompting education and counselling during ANC, B4M would enhance the interpersonal process of care and improve women’s experience of ANC.

iii) When health workers receive diagnostic and clinical decision support from B4M, unnecessary referral is decreased and women requiring referral to the next level of care are more likely to comply with referral instructions because they trust the decision.
iv) By saving time and money for diagnostic referral, enhancing the decision making skills of health workers and improving the efficiency of the referral process, B4M improves the quality of ANC.

Empirical stream: methodology and methods
Three methodological approaches were applied in the empirical stream to evaluate B4M: quantitative method, realist evaluation and qualitative method (Figure 3). The study area and population of the empirical stream is complementary to and prescribed by the scope of the B4M pilot.

Figure 3 - Empirical stream

a. Realist evaluation
The positivist approach to implementation research together with lack of sufficient insights on theoretical underpinnings on the role of mHealth in public health outcomes has been critiqued [69]. Traditional methods of inquiry assess program effectiveness or technological fit, but are viewed as inadequate to justify policies on mHealth use due the complex nature of the domain [70]. Known as black-box approaches, they tend to ignore the context of intervention and the role of agency, which may explain varying results across different levels of care and why one size does not always fit all. The domain of mHealth is transdisciplinary in nature because recognition of the social and institutional systems in which they are introduced requires wider reliance on non-experimental tools and methods that are tailored to fit the context and scope of the intervention [71]. Production of knowledge on mHealth therefore has to be iterative, responsive and adaptable to social complexities [56]. For this reason, evaluation of the B4M intervention has
to go beyond establishing simply whether the program works, to assessing the specific components that work, why they work and how exactly they work [72].

Realist evaluation, a method of theory-driven inquiry was proposed by Pawson and Tilley in 1997 and is recognized in health policy and systems research as a useful methodology for evaluating complex interventions [73, 74]. It considers the context, mechanisms and outcomes of an intervention to answer the questions: what works?; for whom?; in what respect?; to what extents?; in what contexts? and how? [73]. While traditional evaluation questions focus on ‘what?’ RE focuses on ‘how?’ In line with the principles of scientific realism, realist methodology understands that interventions or programs are modified by or are modifiers of the complex social reality in which they are embedded [73]. According to Pawson and Tilley, programs or interventions can be viewed as theories, which are embedded in the open social systems in which they operate. To understand programs, one has to recognize that outcomes are a result of mechanisms acting in context. This is typically presented in series of statements that have a C-M-O configuration. That is, in context C, mechanism M generates outcome O. The context is understood to be the setting in which the change occurs and includes social interrelationships, organizational norms and values. That is, factors which establish the conditions relevant to the operation of the program mechanism [73].

A program’s mechanism represents implicit processes and tangible or intangible resources that facilitate outcomes. Mechanisms underlie the outcome of programs and its impact within the specific socio-cultural context. These are usually expressed in behavioural changes and reasoning of the users, end beneficiaries and other stakeholders involved in the intervention. An extended approach to presenting realist findings which has been adopted by other authors is an Intervention-Context-Actors-Mechanism-Outcome (I-C-A-M-O) configuration [75]. The ICAMO configuration was deemed more appropriate for use in this thesis because it allowed a further distinction between the features and characteristics of the mHealth Intervention (I), the HCW or actors (A) who use it, and the contextual layers in which the program operates- environmental context (C) and organizational or health system context (C).

In order to supplement the realist review conducted in the theoretical stream and fully address research sub-question two, a realist evaluation (RE) of B4M was carried out. This allowed us identify the causal factors underlying how B4M influences health workers performance. Although realist evaluation is both method and design neutral, mixed methods (qualitative and quantitative) of data collection were employed because the advantages of either method are combined, which enhances the scope and depth of evaluation.

b. Quantitative method
The B4M project database automatically collated individual-level records on all screenings conducted with the device. Information included: device number, B4M visit date, B4M visit number and QR code, mother’s name, parity, expected date of birth, gestational age, actual date of birth and outcome, women’s history,
presenting complaints, diagnostic decisions, HCWs action (i.e. counseling, testing and treatment) and referral recommendations. Descriptive quantitative analysis of usage records, diagnostic results and referral recommendations from B4M, provided empirical evidence for the first research sub-question. An additional quantitative data activity involved the administration of usability questionnaires to HCWs. Questionnaires were developed from standardized tools and contained 12 items for measuring two constructs—perceived usefulness and perceived ease of use of B4M [20, 21]. Respondents selected options from strongly disagree to strongly agree on a five-point Likert scale (Appendix 1).

c. Qualitative method
Qualitative data were collected to address research sub-questions two and three. These included individual semi-structured interviews with various respondent groups involved in the B4M intervention (Table 1). Using a semi-structured checklist and observation guide, non-participant observation of ANC consultations with and without the device in use, was carried out in health facilities. Furthermore, one focus group discussion was carried out with representatives of the B4M consortium, in addition to a theory-validation meeting with B4M users. With the exception of pregnant women respondents, all qualitative data collection was conducted in English. Interview guides for pregnant women were first developed in English language before being translated to the local language. All interviews were audio-recorded and subsequently transcribed before analysis.

3.1.1c The reflection stream: the whole is greater than the sum of its parts
Critical reflection is a process and a method that is aimed to spur learning and was appropriate for addressing the overarching question related to the implications of thesis findings [76]. By critically examining the various knowledge perspectives unveiled through research, critical reflection can be a useful step towards transformative action; making meaningful interpretations of what has been done and learnt [77]. In this case, reflection focused on the design and implementation of diagnostic and clinical decision support systems for ANC in low-resource settings and the disconnection between the promise and reality of mHealth. Furthermore, the reflection positions the researcher within the process of learning as an active participant and influencer of the meanings constructed. Whilst critical reflection has mostly been used for self- and group-reflection, especially in the social sciences and educational fields, in this thesis an applied approach as encouraged by Ash and Clayton was used to “generate learning (articulating questions, confronting bias, examining causality, contrasting theory with practice, pointing to systemic issues), deepen learning (challenging simplistic conclusions, inviting alternative perspectives, asking “why” iteratively), and document learning (producing tangible expressions of new understandings for evaluation)” [78]. In Chapters 4-8 of the thesis, which addresses sub-questions 1-3, critical reflection is employed to discuss the implications of results from individual studies. These lay the foundation for a more detailed analysis that is presented in the concluding thesis chapter.

The research methods employed in this thesis are summarised in Table 1.
## Table 1 - Research methods

<table>
<thead>
<tr>
<th>Research sub-questions</th>
<th>Theoretical stream</th>
<th>Empirical stream</th>
<th>Reflection stream</th>
<th>Data/Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What is the evidence on the use of mHealth, specifically diagnostic and clinical decision support systems in low-resource settings?</td>
<td>Scoping review</td>
<td>Quantitative study: viability of B4M</td>
<td>Critical reflection</td>
<td>Secondary data (evidence synthesis)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Descriptive quantitative analysis of screening records from B4M project database</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Semi-structured interviews (UER-10HCWs, 4HFM, 1LPM, 1DHOIO 1DHD; NR-5HCWs, 2HFM, 1LPM, 1DHOIO)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Non-participant observation of ANC consultations (UER-3HFs; NR-2HFs)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Usability questionnaire (UER-10HCWs; NR-4HCWs)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>HF checklist for ANC capacity (UER-4HFs; NR-2HFs)</td>
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<td></td>
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<td></td>
<td></td>
<td>1 FGD with B4M consortium</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Joint theory validation meeting (16 HCWs from NR and UER)</td>
</tr>
<tr>
<td>3. How do pregnant women experience mHealth, specifically diagnostic and clinical decision support systems for ANC in low-resource settings?</td>
<td>N/A</td>
<td>Qualitative study: pregnant women’s experiences of B4M</td>
<td>Critical reflection</td>
<td>Semi-structured interviews (UER-10HCWs, 20 PW)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Non-participant observation of ANC consultations (UER-3HFs)</td>
</tr>
</tbody>
</table>

ANC- Antenatal care; B4M- Bliss4Midwives; DHD- District Health Director; DHIO- District health information officers; FGD- focus group discussion; HCWs- Health care workers; HFs- Health facilities; HFM- Health facility managers; LPM- local program managers; N/A- Not Applicable; NR- Northern Region; PW- Pregnant women; UER- Upper East Region
3.2 Research validity

Validity, a measure of research credibility in both quantitative and qualitative research, is the extent to which concepts or data are accurately measured and analyzed to draw conclusions [79, 80]. Specific measures were taken throughout the research process to minimize research bias and ensure accurate interpretation and representation of findings.

Measures taken to ensure credibility of findings included data triangulation, validating qualitative responses through feedback meetings and interviews, and training of research assistants in data collection and analysis methods. The questionnaire administered to health workers to measure device usability was developed from standardized validated tools and program managers were invited as experts to assess its applicability within the context. In the theoretical stream, at least three researchers were wholly or partly involved in the selection of eligible studies and the extraction of data, enriching the process of analysis and interpretation through reflexivity [79]. Conducting multiple interviews with different categories of stakeholders under the empirical stream, as well as using different methods to address each research question aided data triangulation and strengthened the validity of findings. The interview guide, information sheets and consent forms for pregnant women were forward-translated to the local languages (Kusaal and Mampruli) while retaining conceptual meaning, and then back-translated by an independent translator to ensure accuracy. Trained local research assistants conducted interviews in the local languages.

The interdisciplinary nature of the research team further enhanced study validity. The fields of expertise represented included maternal health, health policy and research, epidemiology, global/public health, realist methodology, qualitative and quantitative research. All team members had competence working in low-resource settings. By working closely with administrative leaders and B4M project partners during data collection in Ghana, potential problems with field entry and recruitment were minimised. At least two representatives from the project consortium, at least one of whom was a local partner, were involved in data analysis, interpretation and representation of study findings. This ensured that findings were accurate reflections of the contextual realities, hence minimising the researchers’ inherent biases. Finally, a data validation meeting was conducted with HCWs, and fieldwork in the empirical phase concluded with a dissemination meeting with all levels of stakeholders including district officials. During this meeting, preliminary findings were shared and feedback was received with further discussions on actionable findings. In so doing, the risk of misinterpretation was minimized and participants enhanced the richness and truth value of the conclusions drawn [79].
3.3 Ethical considerations

In recognition of the ethical implications of any form of research, institutional approval from the EMGO+ Scientific Committee of the Amsterdam Public Health Institute in the Netherlands (Reference Number: WC2017-026) was received. The empirical component of the thesis was approved by the Navrongo Health Research Centre Institutional Review Board, as an amendment to the already approved research proposal of the B4M intervention (Approval ID: NHRCIRB18).

Using informed consent forms, verbal or written consent for interviews was secured from all individuals who participated in the study. Depending on level of education, consent was confirmed by the signature or appended thumbprints of respondents. Ethical considerations specific to each research question are described in the corresponding thesis chapters. Generally, particular emphasis was placed on cultural sensitivity, do no harm, confidentiality and non-attributability, as well as the benefits and risks of the research to participants.

The Erasmus Mundus Joint Doctorate Fellowship Specific Grant Agreement 2015–1595, funded this doctoral research. The Dutch Ministry of Foreign Affairs’ Life Sciences and Health Development (LS&H4D) grant number LSH14GH16, which financed the Bliss4Midwives proof-of-concept, contributed to activities under the empirical stream. Funding agencies had no role in study design, analysis, or preparation of the peer-reviewed manuscripts.

3.4 Thesis outline

Part two of the thesis is based on articles that have been published in or accepted for publication in international peer-reviewed journals. Articles are organised in a pattern of theoretical and empirical streams that address research sub-questions 1-3 (Table 2). Because chapters 4-8 were written as individual articles, there is some overlap of information with the introductory section (Chapters 1-3). In Chapters 4 and 5, the innovation component of the research inquiry is reported; clinical decision support interventions are reviewed from literature and empirically examined in the Bliss4Midwives intervention. Chapters 6 and 7 report findings on the supply side of ANC delivery where realist methodology (synthesis and evaluation) was used to investigate the role of mHealth, and more specifically diagnostic and clinical decision support systems, on health workers’ performance. Chapter 8 presents findings on the demand side of antenatal care services by looking at pregnant women’s experiences with B4M-mediated ANC, using a qualitative study. The thesis concludes in part three where theoretical contributions and recommendations for mHealth as a future strategy for quality ANC are discussed (Chapter 9). This takes the form of a critical reflection on all preceding chapters.
# Research Design

## Table 2 - Thesis outline

<table>
<thead>
<tr>
<th>Research Question</th>
<th>Thesis Chapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>How does mHealth, specifically diagnostic and clinical decision support systems influence the quality of antenatal care in low-resource settings and what are the implications for future ANC strategies?</td>
<td>4  5  6  7  8  9</td>
</tr>
<tr>
<td>1. What is the evidence on the use of mHealth, specifically diagnostic and clinical decision support systems in low-resource settings?</td>
<td>4  5</td>
</tr>
<tr>
<td>2. How does mHealth, specifically diagnostic and clinical decision support systems influence the performance of maternal health workers in low-resource settings?</td>
<td>5  6  7</td>
</tr>
<tr>
<td>3. How do pregnant women experience mHealth, specifically diagnostic and clinical decision support systems for ANC in low-resource settings?</td>
<td>8  9</td>
</tr>
</tbody>
</table>

*Theoretical stream* - Chapters 4 and 6  
*Empirical stream* - Chapters 5, 7 and 8  
*Reflection stream* - Chapters 4 - 9
Part 1 - Setting the stage: the promise of mHealth

References


Part 1 - Setting the stage: the promise of mHealth


Part 1 - Setting the stage: the promise of mHealth


