Diagnostic and clinical decision support systems for antenatal care: is mHealth the future in low-resource settings?
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Background
Especially in low-resource settings, the majority of maternal deaths are due to avoidable conditions or are indirectly caused by pre-existing conditions or those worsened by the physiological effects of pregnancy. Antenatal care (ANC), which is often the first contact of pregnant women with health services is therefore important for prevention, early detection of pregnancy complications, sensitization to danger signs and referral to a higher level facility where needed. Furthermore, it is an opportunity to build trust between service providers and pregnant women, thereby encouraging timely and appropriate utilization of health care services.

However, there are demand side, supply side and systemic barriers to the delivery of quality ANC, which can influence other phases of the maternal care continuum. These include poor access to health services, shortages of health care workers, high workload, weak and inefficient referral linkages, low confidence and trust of health care workers in their skills and knowledge, and low confidence and trust of pregnant women in the health system. Strategies to overcome supply side challenges include task-shifting and decentralisation of service delivery to primary levels. These are expected to increase the skills and confidence of health care workers and bring services closer to women and their communities. Supportive education and counselling during ANC contact and initiatives to improve women’s experience of care are proposed strategies to overcome demand side challenges.

Technological innovation is gaining support for leapfrogging persistent health system barriers to provide quality care in low-resource settings and could help strengthen maternal health services. In maternal care, mobile health (mHealth) technologies have been adopted in education and behaviour change interventions for women, and in health workers’ training. More specifically, point-of-care and decision support technologies can reportedly bridge the know-do gap in health care workers by aiding clinical decision making and task shifting. However, amidst the growing body of evidence, if and how mHealth addresses the pressing challenges of quality antenatal care in low-resource settings is yet to be fully substantiated.

Based on identified barriers for delivery of quality ANC in LMICs and the promise that mHealth holds, this thesis aims to gain insight into the effect of digital innovations on the quality of ANC in low resource settings, and its implications for practice. The thesis has two main objectives:

1. Identify theoretical explanations underlying the promising use of mHealth.
2. Empirically investigate how mHealth influences ANC service delivery and the experience of care.
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.

**Research Questions**

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?*

**Methodology**

Research questions were answered using three streams of inquiry: theoretical, empirical and critical reflection. By synthesizing evidence from existing literature, the theoretical stream broadly explored the domain of knowledge on clinical decision support systems and the effects of mHealth interventions on maternal health workers’ performance. By conducting a realist evaluation of an mHealth prototype in rural Ghana, the empirical stream specifically tested if and how the promise of diagnostic and clinical decision support systems is translated to reality.

The evaluated prototype was Bliss4Midwives (B4M)- an integrated diagnostic and clinical decision support device that enables health care workers conduct non-invasive screening of pre-eclampsia, gestational diabetes and anaemia in pregnant women during ANC. In addition to diagnostic screening and clinical decision support for referral recommendations, the device supported structured counselling and education of pregnant women. B4M devices were piloted in ten health facilities in two Ghanaian regions (Upper East and Northern) for a one-year period. Data was collected using both qualitative (semi-structured interviews, non-participant observation of ANC consultations, focus group discussions) and quantitative (usability questionnaire, descriptive statistical analysis of screening records from the B4M project database) methods. Lastly, the reflection stream applied a critical and holistic lens in interpreting findings from the theoretical and empirical streams, considering their implications for quality ANC services in low-resource settings.
Evidence on the use of mHealth, specifically diagnostic and clinical decision support systems, in low-resource settings.
Clinical decision support systems reported in literature were found to have been used in a range of 11 interventions in sub-Saharan Africa, predominantly focusing on primary health care in rural settings, lower cadre workers and maternal health. With a few exceptions, most interventions are usability or feasibility pilot studies with small sample sizes.

Health workers conducted 1,323 partial or full antenatal screening with B4M on 940 women, resulting in clinical decision support for 835 (88.8%) B4M beneficiaries. Descriptive analysis of the B4M case study showed that the device was used in facilities with and without existing diagnostic alternatives. However, screening compliance (i.e. regular use of the device), completeness (i.e. conducting all tests per visit) and consistency of use (i.e. at every ANC visit per woman) was generally low. Extremes of adoption behaviour in health facilities (ranging from 1.5 to 9 months) and a wavelike usage pattern of peaks and dips over the ten-months period revealed that the enthusiasm of health workers for the benefits of B4M did not lead to sustained engagement over time. Individual, systemic, and technology-related factors were found to influence the potential of clinical decision support systems to improve quality of care in low-resource settings. However, clinical decision-making is only one aspect of the continuum of care. Success of mHealth was also found to be hampered by other deficiencies in the health system such as weak referral linkages and inability for workers to act on referral recommendations. To be sustained and integrated into routine use, initial and refresher training of users, technical and supervisory support, trust in decision recommendations and enabling factors in the health system were identified as necessary conditions.

Influence of mHealth, specifically diagnostic and clinical decision support systems, on the performance of maternal health workers in low-resource settings.
The key scholarly contribution from the theoretical stream is that the magical promise of mHealth for maternal health workers performance in low and middle-income countries is yet to be optimized because evidence is concentrated on the adoption and utilization phases. We found health facilities with moderate and low B4M usage, but none with high usage behaviour. Usage variation was explained by the extent to which suppressive or supportive mechanisms were triggered in the context of the seven health facilities from the case study. Nevertheless, I-C-A-M-O (Intervention-Context-Actors-Mechanism-Outcome) configurations were identified for three pre-performance outcomes i.e. adoption, utilization and competence. Mechanisms supporting adoption (O) were usability (M) and empowerment (M); third party recognition (M) made users feel supported and motivated to utilize (O) mHealth; while empowerment (M) was the main explanatory mechanism for improved competence (O) of maternal health workers (A) using mHealth. These mechanisms played out at multiple inter-related actor levels including at program, health facility and beneficiary levels, ultimately guiding how health care workers responded to the intervention.
Summary

By supporting partial decentralized screening and pregnancy education and counselling, the potential of diagnostic and clinical decision support devices such as B4M to improve some elements of the process of quality ANC was established under the empirical stream. However, these did not necessarily lead to timely detection and effective referral of women with high-risk pregnancies as most women were screened in the 2nd or 3rd pregnancy trimester and referral compliance could not be traced. Through skills gained and the ability to provide routine services at the point-of-care, B4M supported HCWs to deliver quality antenatal care and boosted their confidence. Contrarily, reliance of workers on B4M as an expert decision-maker had negative consequences on the quality of care. This occurred when the experience and training of health workers (mind-line) was not in agreement with the referral recommendation from B4M (e-line), and users deferred to the e-line despite conflicting clinical signs.

Pregnant women’s experiences of mHealth, specifically diagnostic and clinical decision support systems for ANC, in low-resource settings.
Beneficiaries valued B4M for saving money and time by eliminating the need for diagnostic referral in about 700 of 940 women, with higher perception of time efficiency in larger facilities where the laboratory turn-around time was longer. We were unable to ascertain if B4M users accepted and acted on the decision recommendations but reflections suggested that either health care workers were not communicating referral recommendations or women were not acting on them. The B4M case study showed that despite mixed initial reactions of fear and curiosity by pregnant woman, by enabling structured education and counselling during ANC and improving access to services at the peripheral level, B4M enhanced the interpersonal process of care and improved women’s experience of ANC. Woman-centred engagement was, however, not established; observations showed that pregnant women’s engagement with mHealth in study sites was not yet at the level that fosters shared decision-making. Compared to their educated counterparts, poor women with low literacy were usually passive participants in the care process.

Framework on mHealth-actor-context interactions for quality antenatal care
The research framework for mHealth and the quality of antenatal care presented in Chapter 2 (Figure 2) and Chapter 3 (Figure 3), positioned mHealth as an innovation bridge between the supply and demand sides of ANC. In Chapter 6 (Figure 3), this concept evolved into a three-stage framework mapping the contextual factors that trigger specific mechanisms connecting mHealth to maternal health worker performance. The framework showed that evidence on mHealth for maternal health workers is concentrated on the adoption and utilization phases, guiding evaluation questions for the B4M case study. It also informed the construction of initial program theories of the intervention i.e. how B4M was expected to lead to anticipated outcomes. In Chapter 7, initial program theories were tested through realist evaluation after which a modified

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framework was presented, shaping our understanding of how and in what way diagnostic and clinical decision support systems could bridge the ANC quality gap. The collective output of these processes resulted in the modification of the initial research framework. The thesis therefore led to a framework depicting how beyond merely serving as an innovation bridge, mHealth influences the process and outcome of quality maternal care by: i) introducing a layer of contextual complexity, ii) interacting with features and resources of the health system and health facility, and iii) triggering mechanisms in various actors (device users, facility supervisors, other health care workers, program implementers and pregnant women), modifying the ways in which services are provided and ultimately leading to its use or non-use.

Eight Critical Reflections

i) To ensure accuracy in decision making, diagnostic and clinical decision support devices should be implemented only if their use is necessary, affordable, results are trustworthy (reliable and valid) and the advantage of conducting screening at the peripheral level cumulatively outweighs other alternatives that require diagnostic referral.

ii) Task-shifting through diagnostic and clinical decision support devices was effective in lower cadre workers for whom it is a powerful motivator. They, however, require regular supervision and support to maintain interprofessional interdependence. Of concern is that by encouraging user autonomy, introduction of diagnostic and clinical decision support devices could disrupt interprofessional collaboration—whereby less experienced workers bypass consulting with more experienced colleagues on clinical care.

iii) Diagnostic and clinical decision support devices cannot substitute effective pre-service and in-service clinical training and service delivery competencies, which strengthen the mind-lines of health care workers.

iv) The promise of mHealth is dependent on the extent to which it is situated within an enabling environment. Device designs should be modified to accommodate contextual nuances. One approach is to promote the design and deployment of locally designed technologies. Furthermore, sociocultural and other limitations to referral compliance and actionability of referral advice must be addressed.

v) The potential of digital innovations for quality care will not be realised if digital literacy gaps in target users are not addressed as part of a structured pre-service curriculum.

vi) In order to establish the effect of mHealth on quality of care, implementation research must go beyond pilot interventions to provide evidence on how mHealth influences health workers’ competence and performance, as well as users experience of care.
vii) Financial and environmental sustainability of mHealth innovations in LMICs are threatened by insufficient funding for implementation research in this domain, and the lack of an exit strategy or protocols for e-waste management.

viii) Multi-stakeholder engagement in the pre-implementation phase is also necessary for sustained mHealth adoption and utilization.

Recommendations for future research
Due to our inability to fully explore identified gaps, it is recommended that future research maps referral linkages for maternal care and identifies how mHealth can be implemented in ways that bridge structural or process gaps in the referral system. Furthermore, the modified research framework serves as a foundation for additional studies that can explore the pathway and mechanisms related to mHealth, health care workers’ competence and improved performance for quality ANC. Learning from this experience, we also recommend additional action research on this topic where the full benefits of realist methodology can be harnessed by applying it in all phases of the research cycle.

Conclusions
Diagnostic and clinical decision support systems influence the quality of antenatal care by boosting the confidence of health care workers for service provision and the trust of pregnant women in health workers, which could impact their future health-seeking behaviour. In addition to contextual bottlenecks and the need for an enabling environment, design and implementation strategies of interventions may limit if and how mHealth will improve maternal health workers’ performance. However, while there is optimism that the promise and potential of mHealth can be realised in low-resource settings, it cannot be expected to leapfrog the broken spine of health systems to deliver quality ANC.