



Improving Neonatal Health

**In low resource settings using
Mobile health technology**

Hannah Brown Amoakoh

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Improving neonatal health in low resource settings using mobile health technology

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mobile Health technologie
(met een samenvatting in het Nederlands)

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CHAPTER 1

GENERAL INTRODUCTION

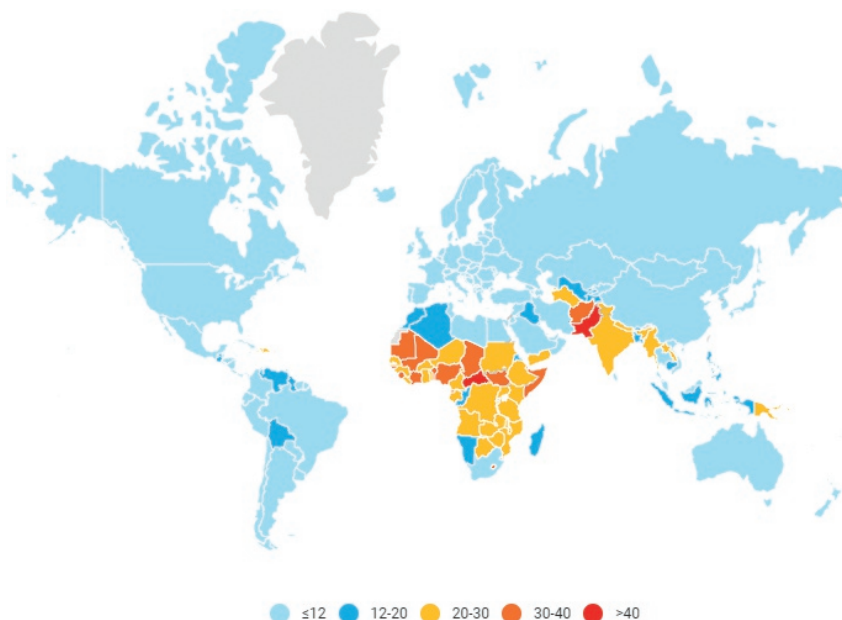
GLOBAL BURDEN OF NEONATAL MORTALITY

Globally, 2.5 million children died in their first month of life (the neonatal period) in 2017 alone, and about 7000 neonates die every day all over the world [1]. Although neonatal mortality declined from 37 per 1,000 live births in 1990 to 18 per 1,000 in 2017, its contribution to childhood mortality is on the ascendancy, accounting for 47% of the 5.4 million childhood deaths in 2017, compared to 40% of the 8 million childhood deaths in 2010 [1–5]. Huge disparities in neonatal mortality exist and persist across regions and countries particularly in sub-Saharan Africa and South Asia where the burden of neonatal mortality is greatest (i.e. 27 per 1,000 live births) [1,6]. Evidence also shows slower rate of decline of neonatal mortality in Africa (18%) compared to other regions of the world where declines of 50% have been attained [3]. Neonates born in sub-Saharan Africa are now nine times more likely to die compared to neonates born in high income countries [1] as compared to a six fold risk of death in 2005 [1,7]. Risk of neonatal morbidity and mortality are prematurity, intra uterine growth restriction, perinatal depression, meconium aspiration syndrome, kernicterus, hypothermia, congenital malformations and neonatal infections [8]. The proportion attributable to each cause varies; preterm birth and malformations largely account for cause of death where neonatal mortality is lower while asphyxia, tetanus, and infections constitute the majority of cause of death where neonatal mortality is higher. Low birth weight though not a direct cause, is associated with the death of many newborn infants.

Concerted global effort to reduce the unacceptably high neonatal death rates is being implemented through the Sustainable Development Goal (SDG) 3.2 which aims to stop preventable newborn deaths by 2030 and also aims for all countries to reduce their neonatal deaths to at least 12 per 1,000 live births [9]. To achieve this SDG goal, priorities for improving newborn health and birth outcomes include finding ways to improve quality of care during labour and birth to reduce intrapartum stillbirths, neonatal mortality and disability; models for strengthening capacity of health professionals in caring for neonates in peripheral hospitals; implementation and scale-up of specific interventions across the continuum of care (preconception, antenatal, intrapartum, immediate postpartum care of both mother and newborn and through the neonatal period) [10]. These priorities must be focused where it counts the most – in low resource settings.

NEONATAL HEALTH IN LOW RESOURCE SETTINGS

Poverty is associated with neonatal mortality and even in low resource settings, urban areas that tend to be often better resourced have lower neonatal mortality rates compared to rural areas [11–14]. Among the urban poor, neonatal mortality is higher compared to rural dwellers [12].

Figure 1: Neonatal mortality rate (deaths per 1,000 live births) in 2017, by country

Source: United Nations Inter-agency Group for Child Mortality Estimation (UN IGME) 2018

Leading clinical causes of neonatal mortality in low resource settings are birth asphyxia, prematurity and infections and these three morbidities altogether account for 90% of newborn deaths in Africa [12]. Neonatal tetanus remains a common cause of neonatal death in settings where lack of hygiene at birth and inadequate cord care are prevalent, as many women are still not immunized against tetanus. The majority of such tetanus infected neonates die between the seventh and tenth day of life [7]. Other risk factors for neonatal mortality in low resource settings include high or low maternal age, multiple gestation, high birth order, low birth weight, close birth spacing, unfavourable health seeking behaviour of mothers, delayed breastfeeding or the absence of breastfeeding [12,14,15]. The complex interaction of these risk factors with economic, financial, social, cultural, political and clinical factors [16] in the absence of adequate quality healthcare service before, during and after birth culminates in the high neonatal mortality observed in low resource settings.

MHEALTH AND ITS POTENTIAL APPLICABILITY IN NEONATAL HEALTHCARE IN LOW RESOURCE SETTINGS

Low- and middle-income countries (LMICs) struggle with health system challenges such as shortage of health workers and insufficient funding of national health systems with a resulting

low capacity to meet the health needs of its population [17,18]. In the light of these challenges, the use of information and communication technology (ICT) in the form of mobile phones (mHealth) presents one of the potential solutions to maximize the impact and efficiency of health systems in low resource settings [19]. With increasing penetration of mobile phone use even in remote areas in LMICs [19] and general acceptability of mHealth interventions by health workers and the community, many mHealth solutions are being implemented with the aim to improve health outcomes in low resource settings [20,21]. Documentation of mHealth interventions suggest that they can reduce the delays in getting pregnant women help, programme cost and improve correct management of patients when used as a decision making tool [19–22]. In the face of shortage of health workers and inadequate national budgets for the provision of health care in LMICs, there is an urgent need to provide neonatal health interventions that work in the context of low resource settings where the burden of neonatal mortality is greatest [10,23,24]; and in this regard, mHealth appears to be a viable option.

NEONATAL HEALTH IN GHANA AND IN THE EASTERN REGION OF GHANA

Ghana is a lower middle-income country with a population of about 28 million people. Her gross national income per capita in 2016 was estimated at \$1,390.00 (US dollars) [25] and her per capita health expenditure in 2015 was \$79.59 (US dollars) [26]. Like many LMICs, Ghana faces constraints with her health workforce. Her estimated number of doctors and nurses/midwives per 1,000 people in 2010 was 0.096 and 0.926 respectively [25]. Neonatal mortality is 25 per 1,000 live births in Ghana [27]. Clinical causes of the observed high neonatal mortality identified in Ghana include non-adherence of health workers to clinical guidelines [28,29]. Training and access to these guidelines for providers is inadequate [30].

The Eastern Region is the fourth most populous region in Ghana. About 2.5 million people reside in her twenty-one (21) administrative districts and 40% of her inhabitants live in four of her administrative districts. The region had about 250 health facilities including hospitals, health centres and Community-based Health Planning Services (CHPS) compounds that provide healthcare services to its residents at the time of conducting this study. Neonatal mortality in the region is 30 per 1,000 live births [13] making it the fourth highest ranking region with regards to neonatal mortality. Leading causes of institutional neonatal mortality in the region include prematurity, birth asphyxia and infections [31]. Like the rest of the country, there are multiple efforts being made by both government and non-governmental agencies to reduce neonatal mortality in the region.

THESIS OBJECTIVE

Overall objective

The overall goal of this thesis was to generate evidence to support improvement in neonatal health outcomes in a low resource setting. This goal was achieved by implementing and evaluating how and why a multifaceted mHealth clinical decision-making support system was used (or not) and, the impact of the intervention on neonatal health in Ghana. The intervention provided easy access to neonatal health protocols to frontline health workers in district level health facilities in Ghana. Under this overall goal, there were two (2) specific objectives; the second objective having three (3) sub-objectives.

PART 1

Specific objective 1

- 1. To evaluate the effect of a multi-faceted mHealth clinical decision-making support intervention on neonatal mortality

PART 2

Specific objective 2 (with 3 sub-objectives)

- 2. To explore and analyse possible explanatory mechanisms for the observed effects of the mHealth clinical decision-making support intervention on neonatal mortality by:
 - 2.1 Assessing utilization of the unstructured supplementary service data component of the mHealth intervention
 - 2.2 Assessing adherence to neonatal protocols before and during implementation of the mHealth intervention
 - 2.3 Describing how and why the mHealth clinical decision-making support intervention was used (or not)

SUMMARY OF METHODS IN RELATION TO STUDY QUESTION AND OBJECTIVES

A holistic approach to the evaluation of the mHealth clinical decision-making support intervention was performed by adopting mixed quantitative and qualitative methods to answer the questions ‘what was the impact of the intervention on neonatal mortality’ and ‘how and why was the intervention used to produce its observed effect’. Table 1 summarizes the methods used to answer each of the study questions or objectives.

Table 1: Summary of methodology used to answer thesis objectives

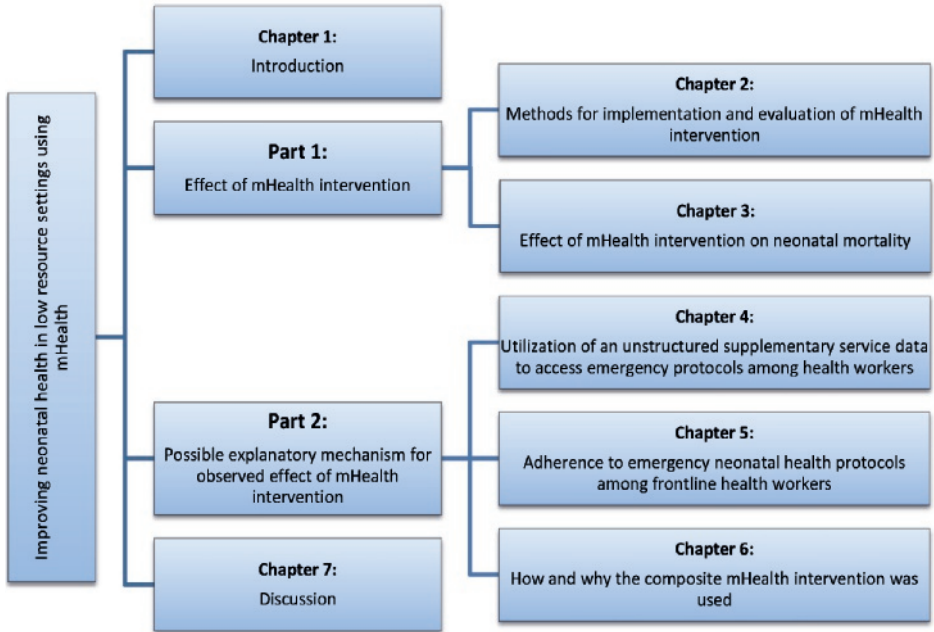
No.	Study Question	Objective	Methodology
1.0	Does the clinical decision-making support intervention (CDMSI) improve neonatal health outcomes	To evaluate the effect of the CDMSI intervention on neonatal mortality	Cluster Randomized Controlled trial
2.1	How was the unstructured supplementary service data (USSD) component of the intervention utilized	To assess the utilization of the USSD component of the intervention	Analysis of USSD utilization data
2.2	How well do frontline health workers adhere to neonatal protocols	To assess adherence to neonatal protocols	Analysis of in-patient neonatal clinical records
2.3	How and why were the different components of the intervention utilized (or not)	To describe how and why the intervention was used (or not)	'Single case study with embedded sub-units of analysis

'This methodology repeats the same 'experiment' in different contexts (sub-units) to answer one specific research question; Each of the 8 intervention clusters was considered as a sub-unit of analysis

THESIS OUTLINE

Detailed description of the cluster randomized controlled trial methodology used to evaluate the clinical decision-making support system will be discussed in chapter 2 of this thesis. In chapter 3, the observed effect of the mHealth clinical decision-making support intervention on neonatal mortality is discussed. The details of utilization of the unstructured supplementary service data component of the mHealth clinical decision-making support intervention that made available emergency protocols on request of frontline health workers is discussed in chapter 4, while chapter 5 provides an understanding of how health workers adhered to these emergency protocols or not. Chapter 6 sheds insights as to how and why the mHealth clinical decision-making support intervention was used by frontline health workers during the implementation of the intervention. Chapter 7 is the discussion of the findings and their implications.

Figure 2: Thesis outline



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PART I

**Evaluation of the effect of an mHealth clinical
decision-making support intervention on
neonatal mortality**



CHAPTER 2

The effect of a clinical decision making mHealth support system on maternal and neonatal mortality and morbidity in Ghana: study protocol for a cluster randomized controlled trial

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ABSTRACT

Background

Mobile health (mHealth) presents one of the potential solutions to maximize health worker impact and efficiency in an effort to reach the Sustainable Development Goals 3.1 & 3.2 particularly in sub-Saharan African countries. Poor quality clinical decision-making is known to be associated with poor pregnancy and birth outcomes. This study aims to assess the effect of a clinical decision making support system (CDMSS) directed at frontline healthcare providers on neonatal and maternal health outcomes.

Methods/Design

A cluster randomized controlled trial will be conducted in sixteen eligible districts (clusters) in the Eastern Region of Ghana to assess the effect of an mHealth CDMSS for maternal and neonatal healthcare services on maternal and neonatal outcomes. The CDMSS intervention consists of an Unstructured Supplementary Service Data (USSD)-based text messaging of standard emergency obstetric and neonatal protocols to providers on their request. The primary outcome of the intervention is the incidence of institutional neonatal mortality. Outcomes will be assessed through an analysis of data on maternal and neonatal morbidity and mortality extracted from the District Health Information Management System-2 (DHIMS-2) and health facility-based records. The quality of maternal and neonatal healthcare will be assessed in two purposively selected clusters from each study arm.

Discussion

In this trial the effect of a mobile CDMSS on institutional maternal and neonatal health outcomes will be evaluated to generate evidence based recommendations for the use of mobile CDMSS in Ghana and other West African countries.

Trial Registration

Clinicaltrials.gov **NCT02468310**. Registered on September 7, 2015; Pan African Clinical Trials Registry **PACTR20151200109073**. Registered on December 9, 2015 retrospectively from trial start date.

Keywords

Maternal; neonatal; clinical decision making; Mobile health (mHealth); text messaging; Ghana

BACKGROUND

The era of the Millennium Development Goals (MDGs) has shown that with appropriate strategies and political will, millions of lives can be improved and saved worldwide [1, 2]. Maternal deaths were halved and under-5 mortality rate (U5MR) declined by more than half over the 25 years of the MDGs [1]. Despite this success, maternal, neonatal and child healthcare remains a prominent public health concern, particularly in sub-Saharan Africa and Southern Asia where most countries did not attain MDG 4 & 5 [2–5]. About 13.6 million women are estimated to have died globally from maternal causes between 1990-2015 [2]. An estimated 303,000 of these deaths occurred in 2015; 99% of them occurred in low- and middle-income countries (LMIC), and 66% in sub-Saharan Africa (SSA). Neonatal deaths also accounted for forty percent (40%) of the 8 million childhood deaths in 2010 [6–8]. Ninety-eight percent of these neonatal deaths occurred in LMIC. Though there is evidence of accelerating decline in maternal and U5MR in all regions of the world [2, 3, 9, 10] the rate of decline is uneven among countries [2, 11]. Inequalities still exist in birth outcomes for mothers and their babies globally; the lifetime risk of a woman dying from maternal causes in SSA is 1 in 36 as compared to a lifetime risk of 1 in 4,900 in high income countries (HIC) [2]; neonates born in SSA are 6 times more likely to die compared to neonates born in HIC [12]. With regards to the decline of U5MR, particularly in the early neonatal period only minor declines have been achieved [9, 11]. It is projected that the global composition of U5MR will continue to shift towards a younger age structure, and that if decreases in child mortality does not focus on neonatal deaths, neonatal deaths will account for about 44.9% of under-5 mortality by 2030 [3].

Maternal and neonatal deaths are caused by a complex interaction of economic, financial, social, cultural and clinical factors [13]. Clinical factors are related to access and quality of antenatal care, skilled attendance at delivery, emergency obstetric care services and post-natal care for neonates. Gaps identified in the quality of care given to pregnant women and their newborns include poor quality of clinical decision making by health providers. Besides knowledge acquired during education in professional training institutions, health providers are known to rely on past experiences, tacit knowledge and intuition, referred to as “mind-lines,” [14, 15] in making clinical decisions for their patients. Different categories of frontline providers deliver maternal and neonatal services within and across various health facilities, as such their experiences, intuitiveness and ability to learn from colleagues may vary as shown in differences in risk-taking preferences and attitude towards risk which can lead to significant variations in the way decisions regarding patient care are made [16]. Reliance on these “mind-lines” may not be based on empirical evidence, and may affect the quality of care rendered to clients. These “mind-lines” therefore cannot be depended upon for sustained quality of care, which is needed to reduce maternal and neonatal morbidity and mortality.

The use of information and communication technology (ICT) in the form of mobile phones commonly referred to as mHealth provides potentially important tools to maximize health worker impact and efficiency [17, 18] and improve service utilization [19] as global efforts to improve maternal, neonatal and child healthcare intensifies through the Sustainable Development Goals (SDGs) 3.1 & 3.2 already underway [20]. Generally, mHealth interventions are well received by health workers and the community [21], however, data is limited as to their effectiveness on patient outcomes, efficiency of health systems or their use by health workers [17, 19, 21–24]. Major areas of application of mHealth interventions has been in the area of tools and communication to support health workers, adherence to treatment regime and data collection [21, 23]. Positive evidence for the applicability of mHealth solutions suggest mobile phones can contribute in reducing the various phases of delay in getting pregnant women help, reducing programme cost and improving correct management of patients when used as a decision making tool [17, 21, 22, 25]. As mobile phone penetration is high even in remote areas in SSA [17] their use by health workers to deliver health care is feasible irrespective of prior education or training in its use [21, 24].

Ghana, a sub-Saharan African country, is one of the 26 countries whose U5MR contributed to 80% of the world's childhood mortality in 2013 [3]. Neonatal mortality rate is 29 deaths per 1,000 live births with higher mortality rates being reported in rural areas of the country [26–28]. Ghana's maternal mortality is presently estimated at 319 per 100,000 live births [29]. Clinical causes of persistently high maternal and neonatal mortality identified in Ghana include non-adherence of health workers to clinical guidelines [30, 31]. Though the prevalence of antenatal clinic (ANC) attendance among pregnant women is high in Ghana, skilled attendance at birth is not optimal (about 74%) [27, 32]. Notable barriers to accessing skilled attendance at birth in Ghana include cost, distance, availability of health facilities and attitude of nurses towards pregnant women [32, 33]. The importance of the quality of care (QOC) given to pregnant women and their newborns for those who opt for skilled attendance at delivery can therefore not be understated.

To help reduce maternal and neonatal mortality in Ghana, we designed an mHealth intervention - a clinical decision making support system (CDMSS) facilitating easy access to maternal and neonatal guidelines for routine and emergency obstetric, antenatal and neonatal care for frontline providers of maternal and neonatal care in Ghana. Our main study objective is to assess the effect of the CDMSS on the incidence of health facility-based neonatal and maternal mortality.

METHODS

Study design

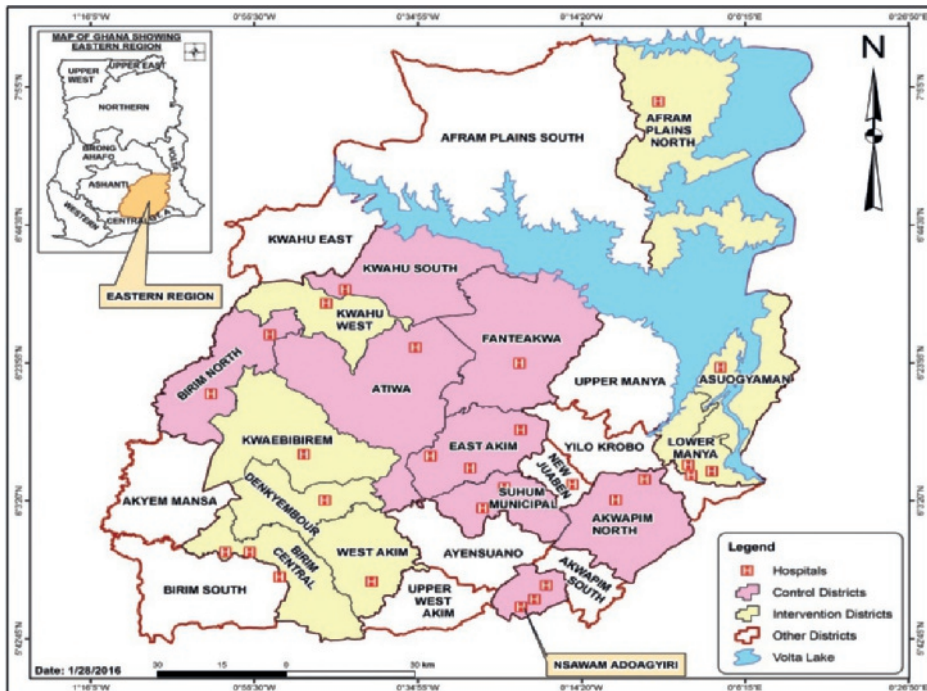
A cluster randomized controlled trial (CRCT) to evaluate the effect of a mobile clinical decision making support system on maternal and neonatal mortality and morbidity will be conducted in 16 districts in the Eastern Region of Ghana. This study will comprise 3 components: i) A baseline study to assess the characteristics of the health facilities and outcome measures of interest in study sites ii) Implementation of a CDMSS for 18 months. iii) A sub-study to assess the quality of care of maternal and neonatal care services at baseline and at the end of the study.

Study site

The study will be conducted in the Eastern Region of Ghana. The Eastern region (ER) is the sixth largest region in terms of land area in Ghana (Figure 1). With an estimated mid-year population of approximately 2.5 million which is 10.7% of the total national population [34], the ER is the third most populous region in Ghana. The region consists of twenty-one (21) administrative districts with Koforidua in the New Juaben district as its regional capital. The ER is predominately rural in nature with pockets of urban areas in mainly the district capitals. About 40% of its inhabitants reside in 4 out of its 21 administrative districts. The most populous districts are Afram Plains Kwahu North district, West Akim district, Kwaebibirem and New Juaben district in descending order. Agricultural (mainly fish and crop farming) and mining activities are the main stay of economic activities of the region. The estimated growth rate of the ER is 2.0% [35].

Each district comprises a number of sub-districts that form the administrative health sub-districts for the region. There are a total of 250 health facilities including 31 hospitals in the region that serve the health needs of the region's populace [35]. Like other parts of the country, the main categories of health care facilities in the ER are - Community-based Health Planning and Services compounds (CHPS), Health centres (HC), Maternity homes and hospitals. At the primary health care level, the CHPS, HC and maternity homes provide services including maternal and neonatal health services to the various communities and refer cases to the hospitals. The regional neonatal mortality rate (NMR) was 29 per 1,000 live births in 2008 [28]. From 2004 to 2014 the NMR of the ER was estimated as 30 per 1,000 live births showing little change over the period [36]. Presently, the ER ranks fourth in terms of high NMR in Ghana [27]. The pregnancy related mortality ratio was also 594 per 100,000 live births in 2007 [37]. The ER was selected for this study for two reasons: its high neonatal and maternal mortality rates and because the intervention could not be implemented in the Greater Accra region where it had been designed and piloted [38].

Figure 1: Map of districts in the Eastern region of Ghana.



The districts were defined as cluster units. Sixteen districts fulfilled our inclusion/exclusion criteria. The regional capital New Juaben Municipal was excluded from the sampling to avoid selection bias as its regional hospital serves as the highest referral point in the region.

Cluster selection criteria

The inclusion criteria for cluster selection for this study include the following: i) District is located in the Eastern Region ii) The district has expected deliveries of $\geq 1,100$ / year for the year 2014 iii) The District Health Management Team and the District Hospital Management Team agree to participate in the study iv) Health facilities within the district conducted at least one (1) delivery in the year 2014. The exclusion criteria for our study are: i) District is located outside the Eastern region ii) The district has expected deliveries of $< 1,100$ / year for the year 2014 iii) The District Health Management Team and the Hospital Management Team do not agree to participate in the study iv) Health facilities within the districts have not conducted at least one (1) delivery during the year 2014.

The year 2014 was selected as the baseline year as the most current data pertaining to deliveries (births) at the time of commencement of the study was for that year. A delivery (births) was a criterion for recruitment as most obstetric and neonatal complications occur around childbirth. Intervention during this period is crucial for survival and health [39].

Sample size estimation

This study is a superiority trial and has been designed and powered for neonatal mortality to contribute evidence for improved neonatal healthcare considering the predicted global upward trend in neonatal deaths [3] compared to maternal deaths. Two formulae were applied; the first formula was applied to estimate the required sample size in a randomized controlled trial with binary outcome while the second formula was applied to inflate the estimated sample size for a CRCT. Neonatal mortality is the primary outcome, and is currently at approximately 30/1,000 live births in the Eastern Region, Ghana. Evidence from previous studies including systematic reviews focusing on neonatal care interventions have shown a 23% to 51% reduction in neonatal mortality in settings including low- and middle-income countries [40–45]. Our intervention will also address neonatal and maternal healthcare, hence we estimate an effect size of 30% on neonatal mortality with the use of this intervention. Intra-cluster correlation coefficient (ICC) for neonatal mortality in Ghana has been estimated at 0.0007256 [46]. To detect a 30% decline in neonatal mortality at a power of 80%, a significance level of 0.05 (two-tailed test), with a fixed number of 8 clusters in each arm of the study, approximately 1065 patients in each of the 16 clusters will be needed.

$$m = \frac{n(1-\rho)}{(k-n\rho)}$$

Where m = number of patients per cluster, k = no of clusters in each arms of the study, ρ = ICC and n = is the number of patients needed to detect this effect in a Randomized Controlled Trial (RCT).

$$n = \theta \frac{\pi_1(1-\pi_1) + \pi_0(1-\pi_0)}{(\pi_1 - \pi_0)^2}$$

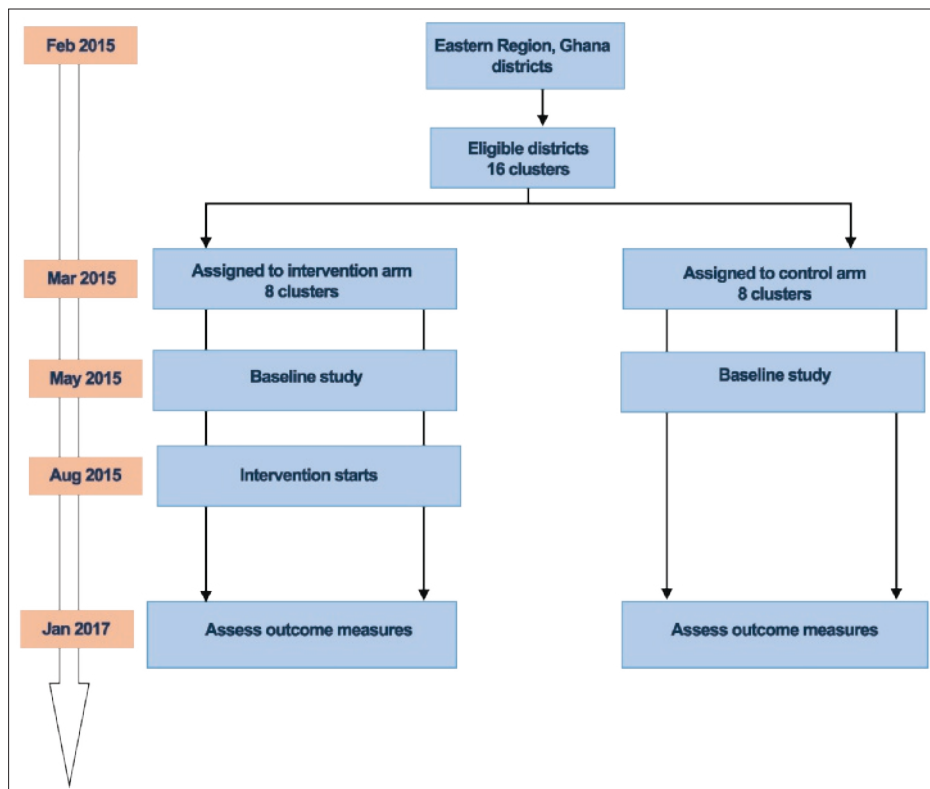
Where π_1 = is the expected proportion of the neonatal mortality in the intervention group after RCT, π_0 = is the expected proportion of the neonatal mortality in the reference group after RCT and θ is the variance of the two proportions at a power of 80% and significance level of 0.05.

Randomization

The study comprises two study arms - one intervention and one control arm. A cluster unit was defined as a district in this study. Twenty-one districts were therefore eligible to be part of the study. Overall seventeen (17) clusters fulfilled the inclusion and exclusion criteria, however the regional capital was excluded from the selection process to avoid selection bias as its regional hospital is the highest referral point in the region. Sixteen clusters were therefore randomized as shown in the trial flow chart (Figure 2). Cluster randomization was preferred over individual randomization to avoid contamination both at the health professional and client levels, which may occur as a result of social interaction. Randomization was performed by an independent data analyst in order to achieve comparability and avoid selection bias. Randomization was

carried out using STATA version 11.0 statistical software. Due to the nature of this intervention, masking was not feasible.

Figure 2: Trial flow chart showing cluster selection, assignment and timelines of CRCT.



Clusters that fulfilled the inclusion and exclusion criteria were randomized into 8 control and 8 intervention clusters. The CRCT started in August 2015 and ends in January 2017.

Sampling of clusters for quality of care study

One well-resourced and one poorly-resourced cluster will be purposively selected from each study arm. The selection criteria will be based on the number and mix of health facilities in the district and the midwife to number of deliveries (per annum) ratio in a district. While purposive selection of these study districts does not allow generalizability of findings, application of these qualitative methods provides insight into the how and why the intervention worked or not.

The Intervention

The intervention is a clinical decision making support system consisting of an Unstructured Supplementary Service Data (USSD)-based text messaging of standard emergency obstetric

and neonatal protocols to providers on their request, based on the results of a formative study previously conducted in the Greater Accra region [38]. As a reference guideline the national Safe Motherhood protocol (SMP) [37], an elaborate tool, that provides detailed state-of-the-art guidelines for maternal and newborn care, ranging from prenatal care, through antenatal, delivery, postpartum, and newborn care was chosen. A committee of medical experts designed concise and precise protocols with respect to word limits using the USSD system and short protocols using USSD templates have been generated. Access to the USSD platform will be limited to a closed user group (intervention group) who will be provided with subscriber identity module (SIM) cards and cell phones by the research team to avoid contamination. To support the use of the USSD-based text messaging system by health care providers, health care providers in the intervention districts will receive monthly reminders via short messaging service (SMS) on the applicability of the text messaging system for clinical decision making.

Text messaging based on the USSD system was chosen as a low-cost, easily-accessible and instant way of requesting needed information during routine and emergency situations by the healthcare provider to enhance clinical decision making. To access the USSD platform, healthcare workers send a text to a specified short code and this assists in the quick share of the needed information. Access to the USSD platform is free and unlimited. The USSD platform is linked to the general electronic data platform of a telecommunication company whose policy and practice assures 99.99% availability of the general electronic data platform. However availability of phone reception to assess the network may differ according to location of health facilities.

Monitoring

Uptake of the intervention will be monitored by the frequency of intervention usage using data about requests made to the USSD collected by the telecommunication company providing technical support for the USSD. All health facilities in the intervention arm will be visited periodically to assess the functionality of the intervention on-site. Research assistants (in this case district health information officers have been recruited) will be trained to supervise data collection activities in the non-hospital facilities in all clusters and to provide updates concerning challenges providers may face with the use of the USSD platform to the research team. The supervisory role of the district health information officers includes ensuring that documentation from the non-hospital facilities is complete and collation of completed data collection forms for submission to the project team. The district health information officers will not make any changes to what is recorded on the completed forms. Thus they will not assess morbidity or mortality causation.

Data collection

Data about district and facility characteristics in both arms of the study using a structured questionnaire will be collected. These include human and logistical resources, ANC attendance, number of deliveries, obstetric and neonatal admissions, primary and secondary outcomes at the baseline and at the end of the study.

The impact of the intervention will be evaluated by extraction of data of outcome measures of interest from the district health information management system-2 (DHIMS-2) database which has been shown to provide reliable estimates of measures [47, 48]. This study will assess the effect of a CDMSS on the commonest causes of neonatal and maternal morbidity and mortality in Ghana. Protocols for diagnosis of these conditions are standardized by the Ghana Health Service across the different categories of health facilities hence diagnosis across facility type are similar. We assume that healthcare workers make accurate diagnosis of these common sources of morbidity most of which diagnosis can be made using physical examination and rapid diagnostic tests. The diagnoses these healthcare workers across the different categories of health facilities make forms the basis of data entered in the DHIMS-2. Details of all the outcome measures the CRCT seeks to extract from the DHIMS-2, however, covers only hospital data. The non-hospital health facilities report only aggregate data through their district health directorate into the DHIMS-2. Details of outcome measures of interest to the CRCT will therefore be collected at the facility level for non-hospital facilities participating in the trial. The diagnosis will be based on what is recorded in the DHIMS-2, or what is recorded in the facility health record books by the healthcare providers as these diagnoses are expected to follow the standard case definitions for Ghana. Availability of network connectivity in health facilities will be measured during the post-intervention evaluation using a Likert scale administered to the healthcare providers.

The quality of care of neonatal and maternal healthcare services will be assessed by measuring health provider adherence to the standard emergency protocols at baseline and at the end of the study. Provider adherence to these protocols for common neonatal and maternal conditions will be assessed using a checklist based on the SMP in use in Ghana. Qualitative assessment (focus group discussions and key informant interviews among healthcare workers) as to how the intervention was used and why it produced the effects observed will be conducted in the 2 intervention districts where the quality of care study will be conducted.

All data will be collected in an anonymous format. Double entry of data collected will be done and data will be handled in accordance with good clinical practice. Figure 3 summarizes the schedule of enrollment and time-points for assessments for this study.

Statistical analysis

Data analysis and reporting will be in line with the CONSORT statement guidelines [49]. In this study, randomization was done at the district level and not at the health facility level. All health facilities within a district therefore form a cluster. Clusters may differ slightly in their characteristics as can be seen in the higher number of non-hospital health facilities in the control arm. We will conduct descriptive analysis of both intervention and reference groups at baseline to explore potential differences in study baseline characteristics of clusters and participants in both study arms. To assess the risk of imbalance in baseline characteristics among the clusters, we will use the c-statistic of the propensity score model of the study. The c-statistic of the propensity score model of the study is considered an appropriate tool to detect baseline imbalance in CRCTs where sample size is large and when a large number of covariates are measured [50]. Any observed imbalance in the baseline characteristics of clusters will be adjusted for in the statistical analysis.

The effect of the CDMSS on primary and secondary outcomes will be analyzed based on principle of intention to treat to minimize over-estimation of the effect of the intervention. Logistic regression will be applied to investigate the effect of CDMSS on all outcome measures considering a potential clustering effect of the CRCT design and adjusting for potential confounders. Results will be reported as relative risks with corresponding 95% confidence intervals. A two-tailed statistical significant level of 0.05 will be used. Among clusters in the intervention arm, descriptive analysis of the availability of network connectivity in health facilities will be done and any significant difference in network availability will be adjusted for using logistic regression. STATA software package [51] and MLwiN software version 2.1 [52] will be employed to handle the analysis.

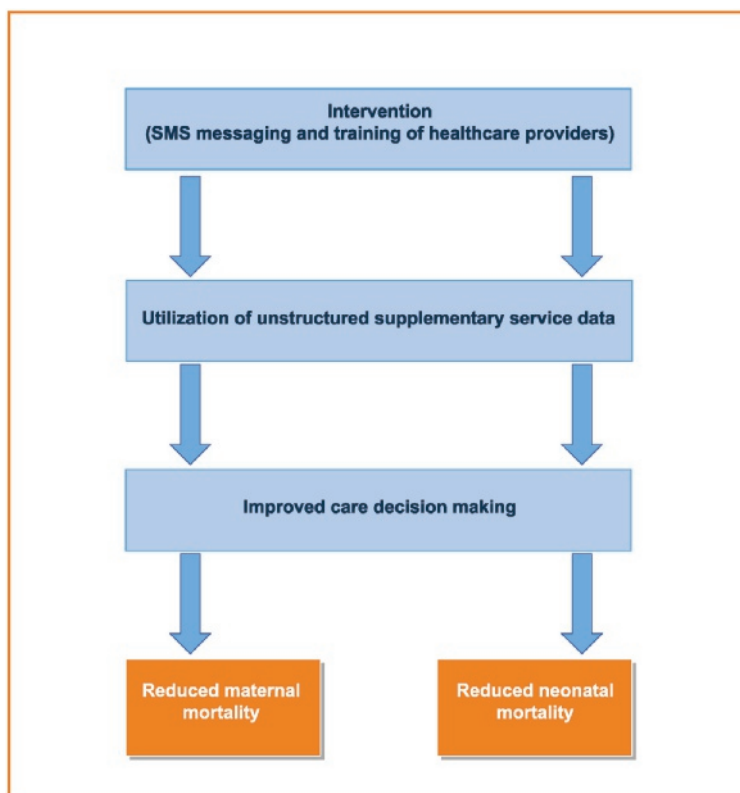
Descriptive analysis of the adherence of healthcare providers to standard maternal and neonatal protocols shall be done by cluster. Logistic regression will be applied to investigate the association between health provider adherence to protocols and the incidence of maternal and neonatal mortality. Responses from focus group discussions and key informant interviews will be manually transcribed, analysed and grouped into various themes emphasizing the key convergent and divergent views that explain how and why the healthcare providers adhered or did not adhere to intervention protocols.

Expected outcome

This intervention is expected to improve clinical decision making which will lead to a decline in maternal and neonatal deaths (Figure 4). Neonatal and maternal mortality rates based on the number of live births, neonatal deaths including perinatal deaths and the number of maternal

deaths in each cluster as well as in each arm will be estimated. These rates estimated will be compared to the rates before the intervention.

Figure 4: Conceptual framework for evaluating the effect of a CDMSS on maternal and neonatal mortality and morbidity in Ghana (2016).



The intervention includes training of frontline health workers to utilize the unstructured supplementary service data. The impact of the intervention will be assessed by measuring maternal and neonatal deaths.

Recruitment and consent of participants

The intervention has been designed for use by frontline providers of maternal and neonatal healthcare services to support users in making clinical decisions regarding their clients. The impact of the intervention will be measured by extracting data about maternal and neonatal participants who seek care from frontline workers working in health facilities participating in this study (Table 2). Maternal and neonatal participants will be indirectly recruited into this study. Consent to participate in the study was therefore sought from the heads of the District Health Management Team, the Hospital Management Team and heads of non-hospital health facilities in the randomized clusters. Prior consultation was held with the Eastern Regional Health

directorates team before commencing the research. Written informed consent was sought from all heads of participating district health directorates and health facilities prior to the enrolment of the health facilities into the study. Processes to assure privacy, confidentiality and free choice to withdraw from this study during the conduct of the trial were explained in the consent form. Signatures were collected as evidence of consent.

Table 2: Number of health facilities participating in the CRCT

'District	Arm	Hospital*	Health centres	CHPS	Maternity home
District 1	Intervention	1	1	7	0
District 2	Control	2	6	10	1
District 3	Intervention	1	7	3	0
District 4	Control	1	5	4	1
District 5	Intervention	3	2	9	1
District 6	Control	1	6	7	0
District 7	Intervention	1	3	3	0
District 8	Control	3	4	6	2
District 9	Control	1	3	5	1
District 10	Intervention	3	2	0	1
District 11	Intervention	1	3	2	0
District 12	Intervention	1	8	1	1
District 13	Control	1	7	5	1
District 14	Control	3	6	1	0
District 15	Control	2	4	3	0
District 16	Intervention	1	3	3	1

[†]Districts have been renamed 1 to 16 for anonymity; *Hospitals include private hospitals in clusters; CHPS, Community-based Health Planning and Services

Benefits and risk

This intervention is not invasive. Participants are at minimal risk for being part of the study. The provider's standard of health care delivery is being assessed and thus they may feel a little uncomfortable. The researchers will bear this in mind and ensure this is as minimal as possible by assuring providers of anonymity and confidentiality. This study will enable health care professionals enhance service delivery through access to CDMSS in the case of randomization into the intervention group. Potential benefit to the provider is enhanced service delivery, while to the client; the benefit is indirect and long term. This is because the intervention aims at quality improvement of maternal and neonatal health service delivery.

DISCUSSION

We have described the protocol for a cluster randomized controlled trial to evaluate the effect of an mHealth clinical decision making support system compared to routine care on maternal and neonatal mortality and morbidity in a context of high maternal and neonatal mortality using the SPIRIT checklist [53]. A CRCT is preferred in this kind of intervention to minimize contamination within clusters and optimize scalability of the intervention in real life context. This CRCT is being implemented with the support of the regional and local health managers who supervise the work of the frontline health workers. The implementation process of this trial will be well documented. If successful, this CRCT will provide evidence for the use of an mHealth-based CDMSS to reduce maternal and neonatal mortality facilitating the attainment of the SDGs. Lessons learnt from this CRCT can inform recommendations to design and upscale mHealth interventions within the Ghana Health Service system as a whole and in other LMIC particularly in West Africa. This CRCT will also provide the opportunity to get to know how frontline health workers will use an mHealth intervention to support their clinical decision-making. Data gathered from the requests made to the USSD platform will provide insight into the information needs of frontline health workers of maternal and neonatal health care services contributing to recommendations for training programmes for frontline health workers.

Though this study will provide much needed evidence to bridge the knowledge gap about the effect of an mHealth intervention on maternal and neonatal health outcomes, the study has some limitations. Firstly, we assume that once the USSD platform is assessed, the information retrieved will be used for action; this may not always be the case. We expect that the assessment of the quality of care of maternal and neonatal healthcare services in the 4 purposively selected clusters will address this limitation to a large extent. Secondly, there is generally a limitation with regard to network availability, electricity and well-functioning phones in Ghana particularly in the rural areas; this may affect the ability of healthcare providers in some remote areas to use the intervention. Thirdly, this study will not assess neonatal or maternal mortality at the community level. The attributable risk of death for neonates born at home compared to those born in health facilities in SSA is estimated to be 21% [54]. The DHIMS-2 database from which data for evaluation of the CRCT will be extracted is a web-based platform built on District Health Information System 2 (DHIMS-2) open source software. DHIMS-2 serves as data recording, collection, collation and analysis tool that host the entire national health data of Ghana. Data entry into the DHIMS-2 is done using primary data collection tools and standard registers designed for various health services and programmes. The DHIMS-2 does not capture community level health outcomes. The contribution of out-of-facility deaths to maternal and neonatal mortality is therefore not captured in the DHIMS-2. The CDMSS has also been implemented as an institutional based support system to be used by health facilities that

contribute data to the DHIMS-2. Thus community level data (contribution of the out-of-health facility deliveries to neonatal and maternal deaths) will not be assessed in this study. However, given that 74% of deliveries in Ghana occur in a health facility with a skilled attendant [27], we expect our sample to include majority of maternal and neonatal clients as clients who self-select to deliver at health facilities are usually followed up in the communities by the health workers. These clients are likely to seek healthcare services from these facilities. Lastly, there may be concurrent maternal and neonatal healthcare interventions running at the time of the trial. These interventions could influence the results of our study although they are likely to be independent from the randomization. However, the study team will document all concurrent maternal and neonatal health services occurring in the study sites and carefully interpret our results based on this real life context.

TRIAL STATUS

The trial was registered at clinicaltrials.gov on September 7, 2015 (trial identifier number **NCT02468310**) and the Pan African Clinical Trials Registry on December 9, 2015 (trial identification number **PACTR20151200109073**). Registration at the Pan African Clinical Trials Registry was done retrospectively after the trial commenced. The recruitment for the trial commenced on August 10, 2015 and is expected to be completed by the end of January, 2017. During the initial 6 months of the CRCT, there were over 2, 500 requests made to the USSD platform. These requests were made from 94% of health facilities participating in the CRCT.

DECLARATIONS

Ethical Approval and Consent to participate

Ethical approval for this study was obtained from the Ghana Health Service Ethics Review Committee (Reference: GHS-ERC: 10/09/14). Consent to participate in this study was also obtained from the heads of district health management teams and from the heads of the various health facilities in the randomized clusters. The study is designed in accordance with the guidelines of Good Clinical Practice (GCP) and the Declaration of Helsinki on ethical principles for conducting research.

Consent for publication

Not applicable.

Availability of supporting data

Approval to store data generated through this CRCT in a repository is still pending. Data from the CRCT is therefore currently not available at a specified repository.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

HBA, KKG and EA prepared the first draft of the manuscript. IAA, DEG, KKG, EA, MC and GAK initiated the study and provided critical comments on the review of the manuscript. CS provided critical comments on the final manuscript. All authors contributed to the design of the trial and have read and approved the final manuscript.

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CHAPTER 3

The effect of an mHealth clinical decision-making support system on neonatal mortality in a low resource setting: a cluster-randomized controlled trial

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ABSTRACT

Background

MHealth interventions promise to bridge gaps in clinical care but documentation of their effectiveness is limited. We evaluated the utilization and effect of an mHealth clinical decision-making support intervention that aimed to improve neonatal mortality in Ghana by providing access to emergency neonatal protocols for frontline health workers.

Methods

In the Eastern Region of Ghana, sixteen districts were randomized into two study arms (8 intervention and 8 control clusters) in a cluster-randomized controlled trial. Institutional neonatal mortality data were extracted from the District Health Information System-2 during an 18-month intervention period. We performed an intention-to-treat analysis and estimated the effect of the intervention on institutional neonatal mortality (primary outcome measure) using grouped binomial logistic regression with a random intercept per cluster. This trial is registered at ClinicalTrials.gov (*NCT02468310*) and Pan African Clinical Trials Registry (*PACTR20151200109073*).

Findings

There were 65,831 institutional deliveries and 348 institutional neonatal deaths during the study period. Overall, 47.3% of deliveries and 56.9% of neonatal deaths occurred in the intervention arm. During the intervention period, neonatal deaths increased from 4.5 to 6.4 deaths and, from 3.9 to 4.3 deaths per 1,000 deliveries in the intervention arm and control arm respectively. The odds of neonatal death was 2.09 (95% CI (1.00;4.38); $p=0.051$) times higher in the intervention arm compared to the control arm (adjusted odds ratio). The correlation between the number of protocol requests and the number of deliveries per intervention cluster was 0.71 ($p=0.05$).

Interpretation

The higher risk of institutional neonatal death observed in intervention clusters may be due to problems with birth and death registration, unmeasured and unadjusted confounding, and unintended use of the intervention. The findings underpin the need for careful and rigorous evaluation of mHealth intervention implementation and effects.

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Keywords: neonatal mortality, Ghana, mHealth, low and middle income countries

BACKGROUND

Neonatal mortality remains undesirably high in many low- and middle-income countries (LMICs) despite recent improvements in neonatal health outcomes.^{1,2} In 2010, ninety-eight percent of the 3.2 million neonatal deaths, occurred in LMICs and,^{3,4} the majority of these deaths occurred in sub-Saharan Africa (SSA). Significant causes of neonatal morbidity and mortality in LMICs include birth asphyxia, infections and prematurity.³ Although interventions against these and other causes of neonatal mortality exist (e.g., early initiation of breast feeding, hygienic care of the cord and kangaroo-mother care for preterm infants, immediate drying and provision of warmth for newborns, vitamin A supplementation, and intramuscular vitamin K injection),^{5–9} these interventions do not reach those who need them the most.¹⁰ Higher neonatal mortality rates have been projected if interventions are not put in place to stop neonatal deaths.¹¹ There is therefore an urgent need to focus attention on neonatal interventions in LMICs.

Mobile health (mHealth) interventions hold promise of bridging the gap in improving access to neonatal healthcare services,^{12,13} and improved health outcomes in LMICs. There have been many documentations of pilot mHealth studies in LMICs.^{14–16} Although these mHealth interventions are well received by health workers and the community,¹⁷ evidence of their effectiveness on patient outcomes, efficiency of health systems or their use by health workers is limited.^{17–19} A shift of mHealth interventions from small pilot studies to larger studies that utilize more robust techniques to assess health outcomes is required to bridge the knowledge gap regarding their effectiveness. One of such large mHealth intervention studies was recently conducted by the Accelerate Project in Ghana.²⁰

Ghana is a lower-middle-income country with high neonatal mortality rates of 25 deaths per 1,000 live births.²¹ Higher mortality rates are reported in rural areas of the country.^{22,23} Clinical causes of persistently high neonatal mortality in Ghana include non-adherence of health workers to clinical guidelines.^{24,25} Training and access to these guidelines for providers is inadequate.²⁶ Clinical decision-making support systems that facilitate easy access to maternal and neonatal guidelines for healthcare providers could improve the quality of maternal and neonatal care in Ghana.^{27,28} To improve access to neonatal health guidelines for health providers, the Accelerate Project designed and implemented an mHealth intervention whose components were based on suggestions for clinical decision-making support gathered in a previous formative study.²⁶ The intervention aimed to provide quick and easy access to emergency maternal and neonatal health protocols to frontline health workers on the request of the health workers. This mHealth intervention was implemented in a cluster-randomized controlled trial in the Eastern Region of Ghana.

Description of the intervention

The mHealth clinical decision-making support intervention (mCDMSI) consisted of 4 components - phone calls (voice), text messaging (SMS), access to the internet (data) and access to an unstructured supplementary service data (USSD) that provided protocols for management of obstetric and neonatal emergencies in response to selection from a short code drop down menu. Unstructured supplementary service data is a communications protocol that allows two-way exchange of data between phone users and information linked to the pre-designed short codes stored on a remote computer of a telecommunications company. This makes USSD more interactive than text messaging. Each response message linked to a short code is limited to a length of 150 to 182 alpha numeric characters. The messages in this intervention were created by a team of frontline health workers, family physicians, obstetricians and paediatricians in the Greater Accra Region, drawing on the Ghana's Safe Motherhood protocols.²⁹ All four components of the intervention were part of a single composite intervention delivered on a non-smart mobile phone (table 1). Access to the USSD was considered to be the main intervention component. Health workers were expected to use the phones primarily to access neonatal and maternal health emergency protocols via the USSD and obtain additional support from colleagues and the internet via the other intervention components. Each project mobile phone had a unique Subscriber Identification Module (SIM) card. All the SIM cards were networked in a Closed User Group (CUG) that allowed free and unlimited access to the USSD. Access to the intervention was however limited to the project SIM cards to avoid contamination.

Study objectives

In the CRCT whose findings are reported here, we evaluated the utilization and effect of the mCDMSI on institutional neonatal mortality in the Eastern Region of Ghana.

METHODS

Study design

A two-arm cluster-randomized controlled trial (CRCT) to evaluate the effect of mCDMSI on neonatal mortality was implemented in 16 districts in the Eastern Region of Ghana.²⁰ Each of the 16 districts formed one cluster in this study. The intervention period lasted for 18 months.

Table 1: Components of the intervention

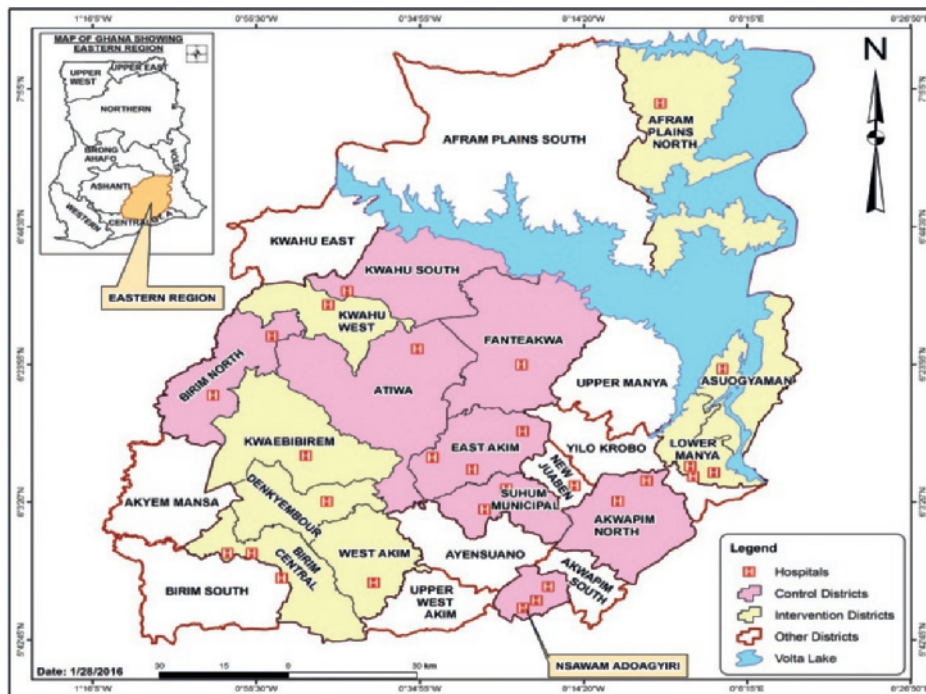
Intervention component	Description
Cell phones	Distribution of the non-smart mobile phones by the research team to health facilities in the intervention clusters (districts) either as a shared-use phone or as individual-use phone. Each midwife was provided an individual-use phone and each health facility had a shared-use phone
Closed User Group (CUG)	A network of SIM cards with unlimited access to make free phone calls to other SIM cards within the network. All intervention users constituted membership of the CUG
Text messaging	Sending of up to 100 free SMS per month to SIM cards in as well as outside the CUG
Data bundle	System that provides up to 25megabytes of free data per month to the project SIM cards
Monthly credit top-up	[‡] An automated system from the telecommunication company that topped up 2.50 cedis (0.70 US dollars) worth of Vodafone credit on project SIM cards each month. This top up credit could be used at the discretion of the health worker for making calls, texting or browsing the internet beyond the limits set for text messaging and data bundle aforementioned
Reminders	Monthly reminders sent to the intervention users reminding them of the availability of the USSD protocols
Training	Health workers were trained on how to use the intervention firstly at a group gathering in each intervention district capital before the start of the cluster randomized controlled trial and then at least once during monitoring visits in their individual health facilities during intervention implementation
Unstructured Supplementary Service Data (USSD)	A communications protocol that allows a two-way exchange of data between a phone user and pre-programed information linked to short codes stored on a remote computer of a telecommunication company. This makes it more interactive than text messaging. Each response message linked to a short code is limited to a length of 150 to 182 alpha numeric characters. In the intervention districts it was used for requesting and receiving text-message based standard emergency obstetric and neonatal protocols on the request of a health worker. Access to the USSD was limited to only project SIM cards (CUG members). For CUG members access to the USSD was free and with no limits to the number of times the USSD could be accessed

[‡]Exchange rate of 1 US dollar= 3.56 cedis is based on the Bank of Ghana exchange rate at start of the intervention in August 2015

Study site

The study site was the Eastern Region of Ghana, the third most populous region in Ghana (Figure 1).³⁰ The region is divided into twenty-one (21) geographic local administrative units called districts. At the start of intervention implementation, there were a total of 250 health facilities i.e. Community-based Health Planning and Services compounds (CHPS) and maternity homes, Health centres (HCs), and hospitals in the Eastern Region. At the primary health care level, the CHPS, HCs and maternity homes provide services including neonatal healthcare services to the various communities and refer cases to the hospitals. The Eastern Region ranks fourth in terms of high neonatal mortality rate (NMR) in Ghana.³¹ The NMR for the region in 2014 was 30 per 1,000 live births.³¹

Figure 1: Clusters participating in randomized controlled trial to evaluate the effect of an mHealth clinical decision-making intervention on neonatal mortality in Ghana.



Cluster selection criteria

The inclusion criteria for cluster selection for the CRCT included the following: i) District located in the Eastern Region of Ghana ii) Expected deliveries of $\geq 1,100$ / year for the year 2014 for a district iii) Both District Health Management Team and the District Hospital Management Team agree to participate in the study iv) Health facilities within the district should have conducted at least one (1) delivery in the year 2014. The exclusion criteria for our study were: i) District location outside the Eastern Region ii) Expected deliveries of $< 1,100$ /year for the year 2014 for a district iii) The District Health Management Team and the Hospital Management Team disagreeing to participate in the study iv) Health facilities within the districts not conducting at least one (1) delivery during the year 2014.

The year 2014 was selected as the baseline year as the most current data pertaining to deliveries (births) at the time of commencement of the study was for that year. The protocol for this study has been published previously.²⁰ As data analyzed in this study was obtained from Ghana’s national institutional health database, informed consent of patients for this study was not applicable. Consent to utilize data from the national institutional health database and to conduct

this study was obtained from the Regional Health Directorate, Eastern Region, Ghana. The study was approved by the Ghana Health Service Ethics Review Committee (Reference: GHS-ERC: 10/09/14), and was registered at clinicaltrials.gov *NCT02468310* and Pan African Clinical Trials Registry *PACTR20151200109073*.

Randomization and masking

Out of the twenty-one eligible districts in the Eastern Region, seventeen districts fulfilled the inclusion and exclusion criteria for the CRCT. The regional capital was excluded from the selection process to avoid selection bias as its regional hospital is the highest referral point in the region. Sixteen clusters were therefore randomized into 8 intervention and 8 control clusters (figure 2). Cluster-randomization was preferred over individual randomization to avoid contamination both at the health professional and client levels, which may occur as a result of social interaction. A randomization scheme of permuted blocks was used to randomize the 16 districts equally to the two-armed program (control and intervention). The randomization scheme consisted of a sequence of blocks such that each block contained a pre-specified number of treatment assignments in random order. The purpose of this was so that the randomization scheme was balanced at the completion of each block. Randomization was performed by an independent data analyst in order to achieve comparability and avoid selection bias. Within the randomized clusters, all health facilities that conducted deliveries in the year preceding the start of the intervention (2014) were recruited into this study. Due to the nature of this intervention, masking was not feasible.

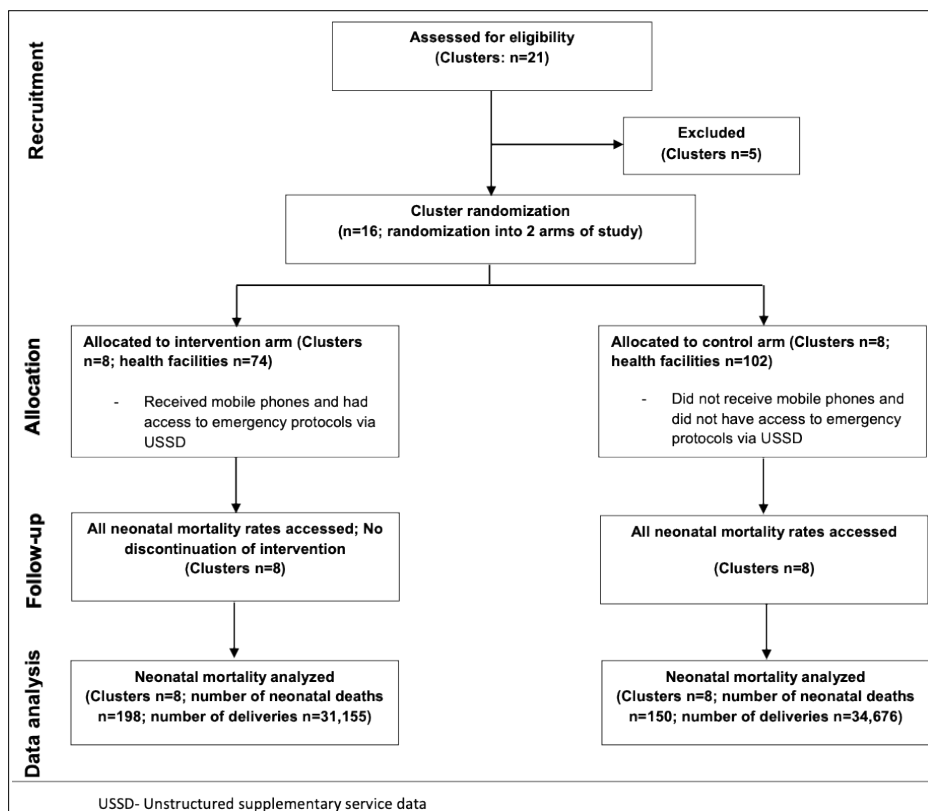
Sample size calculation

This study was designed as a superiority trial with neonatal mortality as the primary outcome. To detect a 30% decline in neonatal mortality at a power of 80%, a significance level of 0.05 (two-tailed test), with a fixed number of 8 clusters in each arm of the study and intra-cluster correlation coefficient for neonatal mortality of 0.0007256,³² approximately 1,065 patients in each of the 16 clusters was needed.²⁰

Recruitment of clusters

Participation in this study was at the cluster level. The impact of the intervention was measured by extracting data about deliveries that occurred in health facilities in the clusters recruited in this study.

Figure 2: Trial flow-chart of cluster randomized controlled trial to assess the effect of an mHealth clinical decision making tool on neonatal mortality in Ghana.



Data collection

Data was extracted from the district health information management system-2 (DHIMS-2) database. The DHIMS-2 is a data recording, collection, collation and analysis tool that hosts the entire national institutional health data of Ghana.²⁰ Data in the DHIMS-2 comes from mainly public health facilities and a few private ones. The DHIMS-2 has been shown to provide reliable estimates of measures in some studies,^{33,34} however, other studies have reported incomplete entries for certain variables in the database.³⁵

In the DHIMS-2, data of clients or patients who seek health services in a health facility is captured either in aggregate per health facility (e.g., hospital 'A' had 20 deliveries), or as individual level data of all patients who were treated in each health facility. Individual level data is however, limited to clients who are seen and treated in hospitals. With regards to this study, data that was available in the DHIMS-2 and captured as aggregate per health facility were the number

of neonatal deaths and the number of deliveries. Detailed information regarding each delivery captured in the DHIMS-2 was limited to hospital deliveries, and further limited to peri-partum maternal data (e.g., age, parity, and duration of pregnancy etc.). Thus, detailed information about babies delivered e.g., Apgar scores, weight and gender could not be obtained from the DHIMS-2. For each delivery that occurred in a hospital, there was no data that linked the detailed maternal delivery information to neonatal deaths that occurred in each health facility. Given these limitations with the DHIMS-2, we extracted data regarding incidence of neonatal mortality and deliveries per health facility and individual records of peri-partum characteristics of women who delivered in hospitals in the study clusters for the 18-month intervention period (August 2015 to January 2017), from the database. Figure 3 illustrates the data structure for this study. Due to technical challenges with data entry and extraction from the DHIMS-2, seven hospitals agreed and captured the individual records of women who delivered in their facilities on excel spreadsheets that were given to the project team for analysis. The data entry in such situations was done by the hospital health information officers responsible for entering that data into the DHIMS-2 and the data was validated by the head of the health information unit in these hospitals. Thus data analysed in this study is a combination of data already captured in the DHIMS-2 at the time of data analysis and, facility level data that may or may not be presently captured in the DHIMS-2. There were 8 private hospitals in total in this study; only one contributed individual level data into the database for analysis.

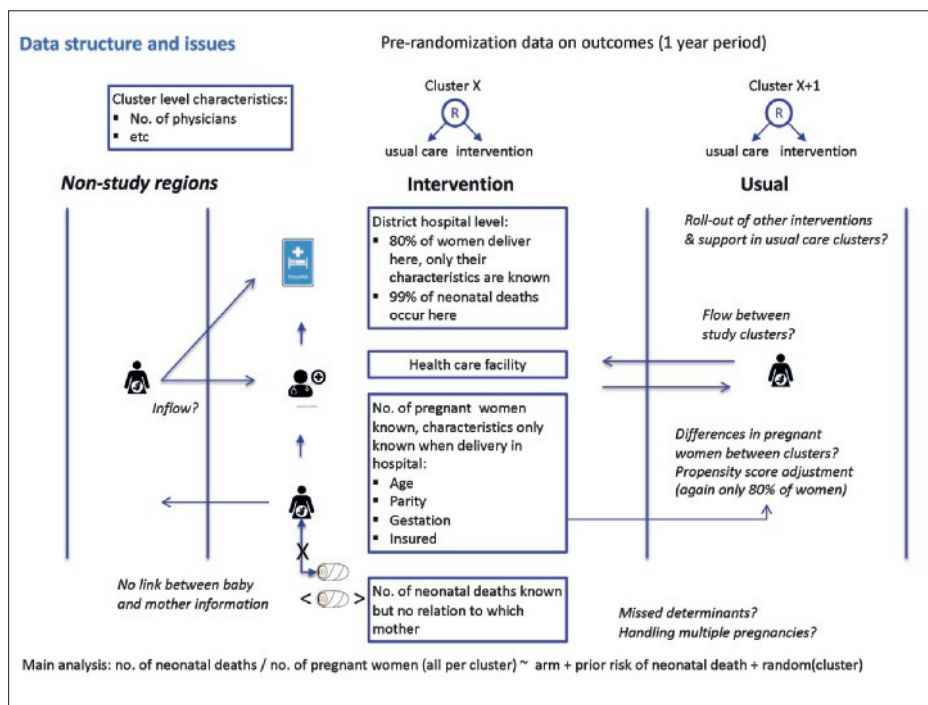
The research team collected baseline data regarding the number of doctors and midwives at post in each health facility and the location of health facilities. We classified health facilities into two groups of remote and non-remote areas based on access. Remote facilities were located either more than 30 min' walk, or more that 15 min motor-bike ride from the main district township, and had poor road access (uneven and untarred roads overcrowded with weeds and shrubs) leading to them.³⁶ Non-remote health facilities were located either within 30 minutes' walk, or 15 min motor-bike ride from the main district township, and had good road access leading to them.

Data concerning the use of the USSD protocols during intervention implementation was extracted from the database of the telecommunication company that provided support for the intervention (Vodafone Ghana).

Four intervention clusters were of interest in this study for 2 reasons; i. they shared boundaries with non-study clusters that did not have hospitals and/or, ii. they recorded high neonatal mortalities. In Ghana, address systems are not well established. To enable us analyse the addresses of women who delivered in hospitals within these clusters, the district health management team (DHMT) in each cluster was tasked to identify addresses within and outside their district from a list of addresses captured as addresses in their district in the DHIMS-2. The

DHMT run the day-to-day health activities within a district, travelling to every corner of their districts; they are therefore a good resource with regard to identification of names of locations within a district that may not be formally documented.

Figure 3: Data sources and structure for cluster randomized controlled trial evaluating the effect of a clinical decision-making intervention in the Eastern Region of Ghana.



Outcome measures

The primary outcome measure estimated in this study was institutional neonatal mortality which included deaths of babies admitted from birth and those (re)admitted from home. Utilization of the mCDMSI for clinical decision-making was estimated as a secondary outcome. For this study neonatal mortality was defined as death of a new-born occurring from birth up to the 28th day of life.³⁷ In Ghana, the expulsion of a product of conception before 28 completed weeks of gestation is considered an abortion. We therefore limited our analysis to pregnancies of gestation 28 completed weeks or more.

Statistical analysis

We performed an intention-to-treat analysis at cluster level. We assessed the peri-partum characteristics of the women who delivered in hospitals during the intervention period to identify

possible imbalance in characteristics of these women and their pregnancies in the study arms. We limited our analysis of peri-partum characteristics of women delivering in health facilities to pregnancies of women in the reproductive age group of 15 to 44 years³⁸ as the excluded ages formed <1% of available data. Potential sources of imbalance in the study arms i.e., age, parity, duration of pregnancy were summarized and expressed as means or medians, while insurance status and education level of women were expressed as numbers and percentages (table 3). Differences in distributions of these potential confounders between the intervention and control arms were assessed using t-tests or Wilcoxon rank-sum tests and chi-square tests where appropriate. We calculated the proportion of remotely located health facilities, the number of deliveries per midwife and, number of deliveries per doctor per cluster to assess cluster level imbalance in the study arms.

We defined our denominator for neonatal mortality rate as ‘number of deliveries’ as we could only obtain information regarding peri-partum conditions of pregnancies that resulted in deliveries from the DHIMS-2. We estimated neonatal mortality as the number of neonatal deaths per the number of deliveries occurring in each cluster. We estimated the neonatal mortality per cluster during the one year proceeding the intervention period (prior risk of neonatal mortality) and analysed the trend in neonatal mortality in the clusters during the intervention period. We estimated the effect of the intervention using a grouped binomial logistic regression with a random intercept per cluster specifying the Laplacian approximation to correct for the clustered design and estimated the intra-cluster correlation. We adjusted for the prior risk of neonatal mortality per cluster in analysis. The effect of the intervention compared with the control group was expressed with odds ratios (with 95% CI and p-values), which, given the low risk of the outcome, may be interpreted as relative risks.

Additional analysis of addresses of women who delivered in hospitals in four intervention clusters (clusters B, C, F and H) was performed to assess the proportion of deliveries within a cluster that were actually deliveries by women who lived within a specified cluster. We further analysed the correlations between the number of USSD requests (maternal and neonatal requests combined) and the number of deliveries per cluster; the number of neonatal USSD requests and the number of neonatal deaths using Spearman correlation as a proxy for the extent to which the intervention was utilized in decision-making.

All analyses were two-tailed with a significance level 0.05, and were performed in Stata version 13.³⁹

FINDINGS

Overall, 176 health facilities participated in this study: 74 of the health facilities were in the intervention arm of the CRCT, the rest (102) were in the control arm. Each cluster had at least one district hospital and a varying mix of health facilities, CHPS and maternity homes. The intervention arm had a higher proportion of remotely located health facilities compared to the control arm. The ratios of the number of deliveries to the number of doctors and midwives were comparable in both study arms at baseline. Table 2 describes the baseline characteristics of each cluster.

There were 65,831 deliveries during the intervention period. Of these deliveries, 31,155 (47.3%) were in intervention clusters and the rest were in the control clusters. The median number of deliveries per cluster in the intervention arm was 3,665 (range 1,580 - 6,319); in the control arm, median number of deliveries was 3,750 (range 2,076 - 10,473). In both study arms, most deliveries occurred in hospitals (intervention arm- 26,303 (84.4%); control arm- 25,780 (74.4%)). During the intervention period, there were 348 neonatal deaths; 198 (56.9%) of these deaths occurred in the intervention arm and 150 (43.1%) occurred in the control arm (ignoring clustering, the crude odds ratio of neonatal death in the intervention arm compared to the control arm was 1.47 (95% CI (1.19;1.82); $p < 0.001$)). Neonatal deaths ranged from 4 to 80 (median=16) in intervention clusters, and 0 to 86 (median=9) in control clusters. All but 1 neonatal death occurred in hospitals; this neonatal death occurred in a HC in a control cluster.

Characteristics of women delivering in hospitals in the study clusters

Due to data availability, detailed information of women who delivered in the study clusters was analysed for 39,803 deliveries (representing 76.4% of hospital deliveries). Of this number, 45.5% were from intervention clusters and 54.6% were from control clusters. The women delivering in the study hospitals were on average aged 27.1 (SD=6.4) and 27.3 (SD=6.3) years in the intervention and control arms respectively ($p < 0.001$). Seventy-five percent (75%) of the women in this study had experienced at least one previous childbirth. Women in the intervention arm delivered at a slightly earlier gestation (median gestation was 37 weeks) while most women in the control arm delivered at 38 weeks ($p < 0.001$) (table 3). Spontaneous vaginal delivery was the main mode of childbirth in both study arms (over 70%), followed by caesarean sections (24.4% and 22.7% in intervention and control arms respectively). The control arm recorded a higher proportion of assisted deliveries (4.8% representing 1,049 deliveries) compared to intervention arm (1.1% representing 194 deliveries ($p < 0.001$)). The proportion of twin deliveries (1.7%) was the same in both study arms. More than twice the number of women delivering in the intervention arm (35.6%) had no form of formal education or had only attained primary education as compared to women in the control arm (13.4%) ($p < 0.001$). Both study arms had the same proportion of

tertiary level educated women (6.4% for both intervention arm and control arm). Nearly all women delivering in the hospitals held a form of health insurance. The proportion of health insured women was however, slightly lower in the intervention arm (97.7%) compared to the control arm (99.3%) ($p < 0.001$).

Effect of the mHealth intervention on neonatal mortality

During the 18-month intervention period, institutional neonatal mortality in the intervention arm increased from 4.5 to 6.4 deaths per 1,000 deliveries and in the control arm from 3.9 to 4.3 deaths per 1,000 deliveries. At cluster level, six intervention clusters and three control clusters recorded higher neonatal mortality during the 18-month intervention period (figure 4). The remaining clusters recorded lower or same incidence of neonatal deaths during the intervention period compared to the pre-intervention period. Intention to treat analysis, accounting for variation in the clusters showed non-significant higher odds of neonatal death in the intervention arm compared to the control arm (odds ratio=2.10 (95% CI (0.77;5.77); $p=0.15$) and the intra-cluster correlation coefficient was 0.22 (95% CI (0.10;0.41)) (table 4). Adjusting for the pre-intervention risk of neonatal mortality in the clusters, the odds of neonatal death was 2.09 times higher (95% CI (1.0;4.38), $p=0.051$) in the intervention arm compared to the control arm.

Analysis of addresses of women delivering in key intervention clusters

Cluster C recorded the highest neonatal mortality in the intervention arm. In this cluster, 98.5% (2,217) of all addresses captured in the DHIMS-2 as being located in district C were identified by the DHMT staff. Of the addresses identified, 49% were within the cluster, 44.5% were from other four intervention clusters and, 6.5% were from control and non-CRCT clusters. In cluster F (district with second highest neonatal deaths in the intervention arm), 91.5% of 4,251 addresses were identified. Of the addresses identified, 73.1% were addresses within the district, 22.2% were addresses in control clusters, 4.1% were addresses in non-CRCT clusters, and <1% were addresses from other intervention clusters. For cluster B, 96.4% (2,994) of the addresses of women who delivered in the district hospital were identified by the DHMT staff. Of the addresses identified, 67.7% were within cluster B, while 29.7% were from neighbouring non-CRCT clusters that did not have hospitals and 2.4% from other intervention clusters. In cluster H, 96% of 1,892 addresses were identified, of which 73.5% were from the cluster H while 23.6% were from non-CRCT clusters, 2.8% were from other intervention clusters, and <1% were addresses in control clusters.

Table 2: Characteristics of study clusters

*Cluster	Number of health facilities			Proportion of remotely located health facilities n (%)	*Number of deliveries per midwife	*Number of deliveries per doctor	Prior risk of neonatal mortality per 1,000 deliveries
	CHPS n (%)	Health Centre n (%)	Hospital n (%)				
Intervention							
A	3 (27.27)	7 (63.64)	1 (9.09)	11 (100.00)	110	350	2.39
B	10 (66.67)	1 (6.67)	4 (26.67)	15 (100.00)	98	459	3.63
C	3 (37.50)	3 (37.50)	2 (25.00)	8 (100.00)	85	*312	18.53
D	2 (33.33)	3 (50.00)	1 (16.67)	6 (100.00)	103	1,035	1.45
E	7 (77.78)	1 (11.11)	1 (11.11)	9 (100.00)	77	1,072	0.93
F	2 (18.18)	8 (72.73)	1 (9.09)	11 (100.00)	103	436	1.53
G	1 (16.67)	2 (33.33)	3 (50.00)	6 (100.00)	74	348	2.88
H	4 (50.00)	3 (37.50)	1 (12.50)	8 (100.00)	93	771	2.60
Total	32 (43.24)	28 (37.84)	14 (18.92)	74 (100.00)	92	534	4.48
Control							
I	11 (57.89)	6 (31.58)	2 (10.53)	19 (100.00)	84	490	0.34
J	5 (45.45)	5 (45.45)	1 (9.09)	11 (100.00)	99	2,186	2.74
K	7 (50.00)	6 (42.86)	1 (7.14)	14 (100.00)	99	690	7.25
L	8 (53.33)	4 (26.67)	3 (20.00)	15 (100.00)	63	370	2.70
M	6 (60.00)	3 (30.00)	1 (10.00)	10 (100.00)	82	825	6.67
N	6 (42.86)	7 (50.00)	1 (7.14)	14 (100.00)	87	676	2.59
O	1 (10.00)	6 (60.00)	3 (30.00)	10 (100.00)	124	436	7.25
P	3 (33.33)	3 (33.33)	3 (33.33)	9 (100.00)	116	539	0.78
Total	47 (46.08)	40 (39.22)	15 (14.71)	102 (100.00)	93	527	3.92

*Clusters have been anonymized A-P

*Data represents the one year preceding the start of the intervention

*Excludes data from one hospital whose hospital management did not provide baseline data during data collection

Table 3: Characteristics of women delivering in hospitals in CRCT clusters during the intervention period

*Cluster	Age of women (years)		Parity of women		Gestation (weeks)		*Total deliveries (N=39,803)		Type of delivery (N=39,803)		
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	n (%)	Spontaneous vaginal delivery n (%)	Caesarean n (%)	*Assisted n (%)		
Intervention (n=18,091)											
A	28.37 (5.89)	1 (0-2)	38.29 (2.25)	1,904 (10.52)	1,239 (65.97)	638 (33.97)	1 (0.05)				
B	27.09 (6.43)	2 (1-2)	37.15 (1.54)	3,116 (17.22)	1,944 (64.09)	1,037 (34.19)	52 (1.71)				
C	27.53 (6.38)	2 (1-3)	38.31 (2.51)	2,305 (12.74)	1,490 (64.75)	796 (34.59)	15 (0.65)				
D	26.70 (6.58)	2 (1-4)	37.62 (1.81)	1,915 (10.59)	1,501 (78.38)	413 (21.57)	1 (0.05)				
E	26.27 (6.57)	2 (0-3)	39.05 (1.98)	824 (4.55)	639 (77.55)	184 (22.33)	1 (0.12)				
F	27.02 (6.33)	1 (0-3)	35.87 (0.72)	4,252 (23.50)	3,599 (85.16)	609 (14.41)	18 (0.43)				
G	26.75 (6.37)	1 (0-2)	38.09 (2.02)	1,854 (10.25)	1,341 (72.33)	407 (21.95)	106 (5.72)				
H	26.50 (6.58)	1 (0-2)	38.48 (2.21)	1,921 (10.62)	1,618 (84.23)	303 (15.77)	0 (0.00)				
*Total	27.09 (6.40)	1 (1-3)	37.39 (2.02)	18,091 (100.00)	13,371 (74.48)	4,387 (24.44)	194 (1.08)				
Control (n=21,712)											
I	27.40 (6.27)	1 (0-2)	36.97 (1.96)	2,186 (10.07)	1,519 (69.49)	454 (20.77)	213 (9.74)				
J	26.46 (6.64)	2 (1-3)	36.58 (1.72)	961 (4.43)	736 (76.91)	187 (19.54)	34 (3.55)				
K	26.44 (6.66)	2 (1-4)	38.99 (2.29)	1,138 (5.24)	875 (77.85)	249 (22.15)	0 (0.00)				
L	26.52 (6.56)	2 (1-3)	36.72 (1.63)	2,556 (11.77)	2,023 (79.18)	512 (20.04)	20 (0.78)				
M	26.63 (7.07)	2 (1-3)	39.09 (2.68)	762 (3.51)	571 (75.43)	181 (23.91)	5 (0.66)				
N	26.98 (6.45)	1 (0-2)	37.09 (2.15)	2,244 (10.34)	1,708 (76.15)	531 (23.67)	4 (0.18)				
O	27.93 (5.96)	1 (0-3)	39.22 (2.11)	9,070 (41.77)	6,101 (67.29)	2,249 (24.80)	717 (7.91)				
P	27.02 (6.35)	1 (0-2)	38.46 (1.86)	2,795 (12.87)	2,181 (78.12)	555 (19.88)	56 (2.01)				
*Total	27.31 (6.30)	1 (0-3)	38.23 (2.30)	21,712 (100.00)	15,714 (72.48)	4,918 (22.68)	1,049 (4.84)				

*Clusters have been anonymized A-P

*Column percentages are presented

*Includes vacuum, forceps and vaginal deliveries with episiotomy

*Total per CRCT arm

Table 3: Continued

Cluster	Number of multiple gestation deliveries (N=38,938)		Education level of women (N=20,918)			Number of women insured (N=37,633)	
	n (%)	n (%)	None n (%)	Primary n (%)	Secondary n (%)	Tertiary n (%)	n (%)
Intervention (n=18,091)							
A	40 (2.10)	129 (6.78)	129 (31.66)	210 (11.04)	1,168 (61.38)	396 (20.81)	1,895 (99.53)
B	41 (1.35)	505 (16.24)	337 (7.94)	1,119 (35.98)	1,390 (44.69)	96 (3.09)	3,075 (98.68)
C	55 (2.67)	0 (0.00)	299 (17.13)	29 (7.61)	281 (73.75)	71 (18.64)	702 (99.86)
D	39 (2.04)	11 (0.57)	1,465 (95.88)	205 (10.71)	1,611 (84.17)	87 (4.55)	1,910 (99.74)
E	20 (2.44)	252 (31.66)	299 (17.13)	129 (16.21)	377 (47.36)	38 (4.77)	668 (83.19)
F	53 (1.25)	337 (7.94)	299 (17.13)	605 (14.25)	3,071 (72.31)	234 (5.51)	4,062 (95.53)
G	25 (1.35)	299 (17.13)	1,465 (95.88)	256 (14.67)	1,109 (63.55)	81 (4.64)	1,849 (99.78)
H	30 (1.56)	1,465 (95.88)	2,998 (19.19)	11 (0.72)	49 (3.21)	3 (0.20)	1,921 (100.00)
Total	303 (1.71)	2,998 (19.19)		2,564 (16.41)	9,056 (57.96)	1,006 (6.44)	16,082 (97.66)
Control (n=21,712)							
I	51 (2.33)	126 (5.78)	190 (25.13)	225 (10.32)	1,618 (74.22)	211 (9.68)	2,176 (99.54)
J	17 (1.77)	648 (67.43)	145 (6.47)	13 (1.35)	266 (27.68)	34 (3.54)	961 (100.00)
K	18 (1.58)	121 (10.64)	74 (0.82)	297 (26.12)	668 (58.75)	51 (4.49)	1,133 (99.56)
L	39 (1.55)	105 (4.64)	185 (6.62)	257 (11.37)	1,758 (7.775)	141 (6.24)	2,526 (98.83)
M	2 (0.78)	190 (25.13)	159 (4.62)	43 (5.69)	500 (66.14)	23 (3.04)	737 (96.72)
N	36 (1.60)	145 (6.47)	185 (6.62)	223 (9.96)	1,595 (71.21)	277 (12.37)	2,231 (99.42)
O	165 (1.82)	74 (0.82)	185 (6.62)	52 (0.57)	8,484 (93.58)	456 (5.03)	9,003 (99.26)
P	28 (1.00)	185 (6.62)	1,594 (7.45)	154 (5.51)	2,288 (81.92)	166 (5.94)	2,784 (99.61)
Total	356 (1.68)	1,594 (7.45)		1,264 (5.91)	17,177 (80.29)	1,359 (6.35)	21,551 (99.26)

^aClusters have been anonymized A-P

^bTotal per CRCT arm

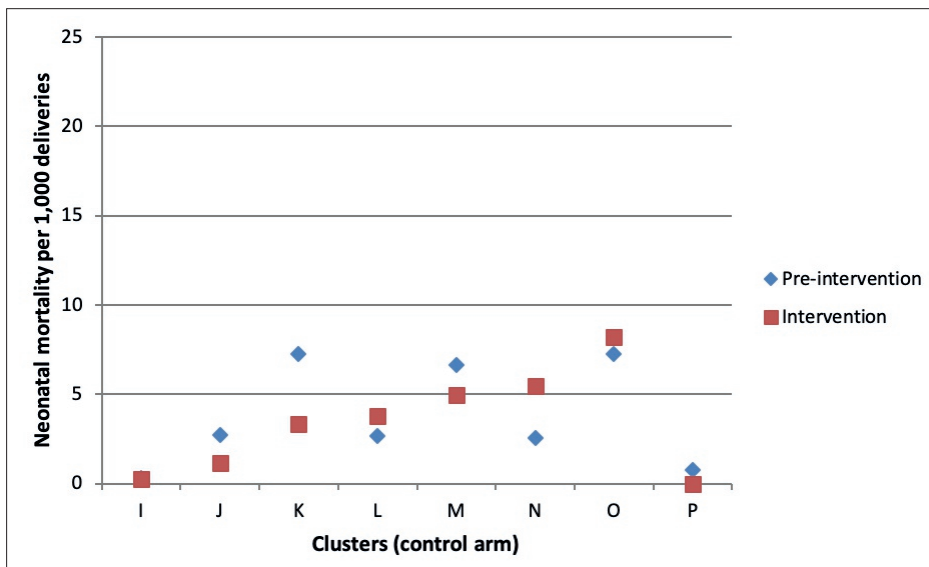
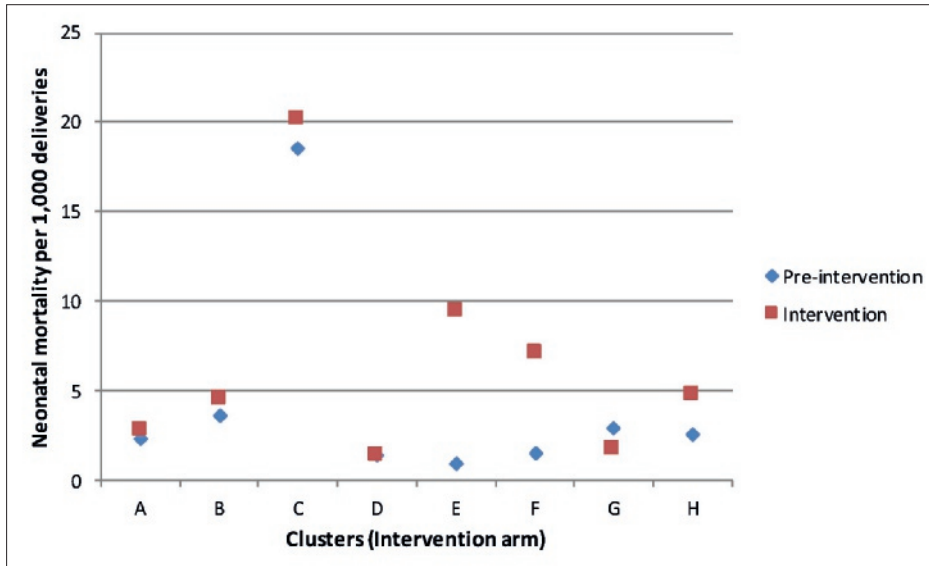
Table 4: Odds ratios of neonatal death during the 18-month intervention period

Variable	Number of neonatal deaths	Crude analysis			*Adjusted analysis		
		Odds ratio (95% CI)	p-value	Intra-cluster correlation (95% CI)	Odds ratio (95% CI)	p-value	Intra-cluster correlation (95% CI)
Arm							
Intervention (n=31,155)	198	2.10 (0.77- 5.77)	0.149	0.22 (0.10-0.41)	2.09 (1.00- 4.38)	0.051	0.12 (0.05 – 0.26)
Control (n=34,676)	150	1		1			
Prior risk of neonatal death							
	-	-	-	-	2.16 (1.42- 3.30)	<0.001	

*Adjusted for prior risk of neonatal mortality in clusters during the one year preceding implementation of the intervention

Analysis was performed using grouped binomial logistic regression with a random intercept per cluster and specifying the Laplacian approximation

Figure 4: Institutional neonatal mortality per 1,000 deliveries in intervention and control clusters one year before the start of the intervention and during the intervention period.



Utilization analysis

There were 5,329 requests made to the USSD from all clusters during the intervention period; the number of requests per intervention cluster ranged from 403 to 1,167. The correlation between the number of USSD requests (maternal and neonatal requests combined) and the total number of deliveries in the intervention clusters was 0.71 ($p=0.05$). The correlation between the number of USSD neonatal requests and the number of neonatal deaths was 0.48 ($p=0.23$).

DISCUSSION

The results of this cluster-randomized trial of the effects of perinatal mHealth support show that overall the risk of institutional neonatal mortality was higher in the intervention arm compared to the control arm. Lack of use of an intervention would be expected to leave mortality risks unaffected. In the text that follows we highlight possible explanations for the unexpected observed results.

Problems with registration of births and deaths

Births and deaths are captured in the DHIMS-2 according to the location these events occur irrespective of the primary residence of patients. Patient flow in and out of the clusters could have therefore influenced the observed effect. Four of the intervention clusters shared boundaries with non-study clusters that had no hospitals. These non-study clusters referred cases to intervention clusters as shown in the analysis of addresses. Frequent referral of cases from HCs, CHPS and even district hospitals to other hospitals is not uncommon⁴⁰ and could overburden referral hospitals, thereby hampering the quality of neonatal care services referral hospitals provide.⁴¹ High risk deliveries are usually the ones that also get referred;^{40,42} thus the prognosis for these cases by the time they reach referral hospitals in settings similar to the study context tends to be poor. Several of the control clusters were close to the regional capital (Koforidua in the New Juabeng Municipal), where the regional hospital (the main centre for referrals) in the Eastern Region is located (see figure 1). Three control clusters were close to the national capital (Greater Accra Region) that has the largest density of better resourced health facilities and the largest referral centre in Ghana. Patients from these control clusters are often referred to the regional hospital or to Greater Accra Region for treatment. Patient flow out of the control clusters might explain further, the lower neonatal mortality rates observed in the control clusters. The DHIMS-2 at the time of data extraction did not capture detailed information of maternal or neonatal referrals to enable further analysis regarding patient flow in and out of clusters and how that may have contributed to the observed effect.

Confounding not adjusted in analysis or unmeasured confounding

By chance, there was variability in known prognostic factors of neonatal mortality (education status of women, age, delivery type, pregnancy gestation, number and proportion of rural located health facilities and prior risk of neonatal mortality per cluster)^{43–47} between the study arms. However, in the DHIMS-2 database, individual level maternal data that provide the details of the aforementioned prognostic factors is not linked to neonatal data; neither are detailed characteristics of newborns captured in the database. This limitation in the data structure did not permit the correction for (potential) confounders in the analysis. Attempts to correct for confounding with propensity score methods⁴⁸ summarized at cluster level gave similar results possibly due to an ecological fallacy.⁴⁹ The correction of the aforementioned baseline imbalances in the study arms as well as other unmeasured confounders known to impact neonatal mortality (e.g., sex of neonate, APGAR scores, birth weight, multiple gestation)^{18,22} may have given different results. Stratification of key prognostic factors during randomization (in order to adjust for these prognostic factors in analysis) was not considered in the design phase of this study as any baseline imbalance observed was expected to be due to chance.

Inadequate use of the intervention

To understand how and why the intervention was used (or not) to help us interpret the results of this trial, a study was undertaken. Data collection involved key informant interviews and focus group discussions with intervention users and the data was manually analyzed for themes. The study showed that the phones were predominantly used for voice calls (64%), followed by data (28%), SMS (5%) and USSD to access protocols (2%) respectively.³⁶ Over time, use of all intervention components declined. Individual health worker factors (demographics, personal and work-related needs, perceived timeliness of intervention, tacit knowledge), organizational factors (resource availability, information flow, availability, phone ownership), technological factors (loss of phones, network quality) and client perception of health worker intervention usage explained the pattern of intervention use observed.³⁶ In this study we report significant correlation between the number of deliveries and use of the USSD, however, this does not preclude inappropriate use of the intervention protocols. Although unintended use of mHealth interventions is not uncommon,^{50,51} and strategies to improve appropriate use of mHealth interventions (such as reward schemes and reminders) are well documented in literature,^{52–54} overall, our findings suggest to carefully consider whether this kind of mHealth intervention is the most appropriate in the study context.

Figure 3 summarizes the limitations in the data structure of this study that led to the inability to measure and (or) adjust for differences in prognostic factors between the study arms to improve the quantification of effect size. Analyses, e.g. post-hoc and baseline comparability analysis, which are not conventionally performed as per the CONSORT guidelines were undertaken in

the context of this study to gain insight into possible explanations for the observed intervention effect. This study did not measure observed use (practical application of protocols in case management) or non-use of the intervention in this evaluation. Details of voice, data and SMS components of the intervention could not be ascertained to have been used by health workers to obtain clinical decision-making support³⁶ thus in the correlation analysis, we analysed only the USSD component of the intervention. The rise in institutional neonatal mortality observed in both study arms could not be explained by the methodology used in this study but warrants urgent attention. Concurrent neonatal health improvement interventions that may have been on-going in the Eastern Region particularly in the control clusters that could have influenced the findings of this study could not be accounted for. Despite these limitations, this large study provides valuable information about the impact of an mHealth intervention on health outcomes in a low resource setting. Previous documentation of mHealth interventions in low resource settings have been mainly small pilots with a focus on utilization of interventions.¹³ The few mHealth interventions that have measured outcomes have shown mixed results and could have possibly overestimated intervention effect size due to the relatively small study sample size.^{55,56}

CONCLUSION

This study showed that providing access to an mCDMSI to frontline health workers to facilitate clinical decision-making in a low-resource setting did not lead to an improvement in institutional neonatal mortality. The point estimate of the adjusted analysis even suggests an increased risk in the intervention group. We discussed various factors that could have influenced the results, though the exact impact of these factors remains uncertain. Our study highlights that technological innovation alone is not enough to affect health outcomes. It is important to understand the mechanisms influencing outcomes in context as shown in our linked study and to design and implement interventions that address the combined effect. As the paradigm of mHealth interventions shift from small pilots to larger studies in LMICs, careful evaluations to assess their impact on health outcomes and not merely their uptake are needed. Such large studies will require improvements in available databases leading to better data quality. Furthermore, lessons learnt from this study could inform design and evaluations of mHealth interventions in similar settings.

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Contributors

HBA, KKG, MAC, KAG, IAA, CS, DEG and EA designed and performed the study. HBA, JBR and NPAZ analysed the study. HBA drafted the manuscript and KKG, EA, JBR and NPAZ reviewed the manuscript. IAA, DEG, MAC, KAG, provided critical comments on the review of the manuscript. All authors have read and approved the final manuscript.

Declaration of interest

We declare no competing interests.

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PART 2

**Possible explanatory mechanisms for observed
effect of intervention**



CHAPTER 4

Using mobile health to support clinical decision making to improve maternal and neonatal health outcomes in Ghana: insights of frontline health worker information needs

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ABSTRACT

Background

Developing and maintaining resilient health systems in low-resource settings like Ghana requires innovative approaches that adapt technology to context to improve health outcomes. One of such innovations was a mobile health (mHealth) clinical decision-making support system (mCDMSS) that utilized text messaging (short message service, SMS) of standard emergency maternal and neonatal protocols via an unstructured supplementary service data (USSD) on request of health care providers. This mCDMSS was implemented in a cluster randomized controlled trial (CRCT) in the Eastern Region of Ghana.

Objective

This study aimed to analyze the pattern of requests made to the USSD by health workers (HWs). We assessed the relationship between requests made to the USSD and types of maternal and neonatal morbidities reported in health facilities (HFs).

Methods

For clusters in the intervention arm of the CRCT, all requests to the USSD during the 18-month intervention period were extracted from a remote server, and maternal and neonatal health outcomes of interest were obtained from the District Health Information System of Ghana. Chi-square and Fisher exact tests were used to compare the proportion and type of requests made to the USSD by cluster, facility type, and location; whether phones accessing the intervention were shared facility phones or individual-use phones (*type-of-phone*); or whether protocols were accessed during the day or at night (*time-of-day*). Trends in requests made were analyzed over 3 6-month periods. The relationship between requests made and the number of cases reported in HFs was assessed using Spearman correlation.

Results

In total, 5329 requests from 72 (97%) participating HFs were made to the intervention. The average number of requests made per cluster was 667. Requests declined from the first to the third 6-month period (44.96% [2396/5329], 39.82% [2122/5329], and 15.22% [811/5329], respectively). Maternal conditions accounted for the majority of requests made (66.35% [3536/5329]). The most frequently accessed maternal conditions were postpartum hemorrhage (25.23% [892/3536]), *other conditions* (17.82% [630/3536]), and hypertension (16.49% [583/3536]), whereas the most frequently accessed neonatal conditions were prematurity (20.08% [360/1793]), sepsis (15.45% [277/1793]), and resuscitation (13.78% [247/1793]). Requests made to the mCDMSS varied significantly by cluster, type of request (maternal or neonatal), facility type and its location, *type-of-phone*, and *time-of-day* at 6-month interval ($P < .001$ for

each variable). Trends in maternal and neonatal requests showed varying significance over each 6-month interval. Only asphyxia and sepsis cases showed significant correlations with the number of requests made ($r=.44$ and $r=.79$; $P<.001$ and $P=.03$, respectively).

Conclusions

There were variations in the pattern of requests made to the mCDMSS over time. Detailed information regarding the use of the mCDMSS provides insight into the information needs of HWs for decision making and an opportunity to focus support for HW training and ultimately improved maternal and neonatal health.

Keywords

mHealth; maternal health; neonatal health; health care systems; developing countries; decision making; information retrieval systems

INTRODUCTION

Background

Weak health systems are a major barrier to achieving improved health outcomes in low- and middle-income countries [1]. It is therefore not surprising that many countries that could not attain the Millennium Development Goals (MDGs) 3 and 4 which targeted improvements in maternal, neonatal, and child health (MNCH), were from the parts of the globe with poorly developed health systems such as sub-Saharan Africa and Southern Asia [2]. As global efforts to improve MNCH intensifies through the Sustainable Development Goals (SDGs) 3.1 and 3.2 [3], health system strengthening has become imperative to attain these SDGs.

Among the many interventions currently being implemented to address MNCH challenges, mobile health (mHealth) interventions have been widely used in low- and middle-income countries [4] as a potential solution to maximize health worker (HW) impact, efficiency, and health outcomes [5,6] and improve service utilization [7]. Common areas of application of mHealth tools include point-of-care decision-making support, provider-to-provider communication, and data collection [4,8,9]. Though mHealth interventions are well received by HWs and the community [9-12], data about their effectiveness with regards to patient health outcomes, improved efficiency of health systems, or their use by HWs are limited [5,7-9,13,14].

Ghana, a sub-Saharan African country, reports unacceptably high maternal and neonatal deaths that fell short of the MDGs targets [2]. Ghana's maternal mortality is presently estimated at 319 per 100,000 live births [15] and its neonatal mortality rate is 25 deaths per 1000 live births, with higher mortality rates being reported in rural areas of the country [16-19]. Though numerous training programs and maternal audits are performed in Ghana to improve the quality of MNCH services [20], health system constraints still remain. Health system constraints contributing to persistently high maternal and neonatal mortality in Ghana include cost, distance, availability of health facilities (HFs), attitude of nurses toward pregnant women [21,22], and nonadherence of HWs to clinical guidelines [23,24]. To address the constraint of poor adherence to clinical guidelines by HWs, we designed an mHealth intervention—a clinical decision-making support system (CDMSS) to facilitate easy access to maternal and neonatal guidelines for routine and emergency obstetric, antenatal, and neonatal care for frontline providers of maternal and neonatal care in Ghana [25].

Description of the Intervention

This mHealth clinical decision-making support system (mCDMSS) consisted of 4 components: (1) Phone calls (to facilitate verbal communication between frontline health workers, FHWs), (2) SMS text messaging (short message service, SMS; to facilitate communication between

FHWs during periods of nonsustained network connectivity), (3) Access to an unstructured supplementary service data (USSD) for standard emergency obstetric and neonatal protocols via SMS text messaging (to provide quick and easy access to the standard guidelines to maternal and neonatal health protocols in Ghana), and (4) Access to the internet (to facilitate access to health information that may not be found in the USSD protocols). All these components were embedded in a composite intervention on a project nonsmart mobile phone. The multifaceted nature of the mCDMSS was aimed to assure access to clinical decision-making support for HWs at all times following suggestions from FHWs for clinical decision-making support in a formative study [26]. Access to the USSD was considered to be the main intervention component. Health workers were expected to use the phones primarily to access neonatal and maternal health emergency protocols via the USSD and obtain additional support from colleagues and the internet via the other intervention components. The messages on the USSD were created by a team of FHWs, family physicians, obstetricians, and pediatricians in the Greater Accra Region, drawing on the Ghana's Safe Motherhood protocols [27]. The development of the intervention was done using an iterative process that piloted and tested the USSD messages among FHWs in the Greater Accra Region to assure comprehension and appropriateness of the USSD messages. The USSD was designed such that new protocol requests needed to be initiated if a request session was terminated prematurely. FHWs, mainly midwives were provided with 312 dedicated nonsmart mobile phones to access the intervention. These phones were classified by the research team as shared facility phones if dedicated for shared-use by all providers of maternal and neonatal health care services in a HF or, as individual-use phones if dedicated to personal use of midwives. Each midwife at post in each HF during baseline assessment was provided with 1 mobile phone (individual-use phone) as they work closely with maternal and neonatal patients. FHWs were assumed to be familiar with the basic functioning of a mobile phone (making calls, texting, and accessing the internet) as documented in previous studies [28,29], so the training concerning the use of the mCDMSS focused on how to use the USSD. Navigation through the USSD has been demonstrated in Multimedia Appendix 1.

We tested the intervention in a cluster randomized controlled trial (CRCT) in the Eastern Region of Ghana. The CRCT has been described in detail elsewhere [25]. Vodafone Ghana, a telecommunication company, provided technical support for the mCDMSS and collected routine data regarding how the intervention was used throughout the intervention period.

Study Objectives

The USSD component of the intervention explicitly and objectively provides insight into the information needs of FHWs. As details of protocols accessed from the USSD by FHWs are not known, we aimed to, first, describe the pattern of USSD protocol requests made by frontline providers of maternal and neonatal health services in district level HFs in the Eastern Region of

Ghana and second, to examine the relationship between the patterns of requests made and the incidence of maternal and neonatal morbidity in HFs accessing the intervention.

METHODS

Study Design and Sampling

This study was conducted within the context of the aforementioned CRCT, which aimed to assess the impact of the mCDMSS on institutional neonatal mortality in the Eastern Region of Ghana and comprised 16 districts randomized into 8 intervention and 8 control clusters. In a given cluster, all public and private HFs that work with the Ghana Health Service participated in the CRCT. We extracted all requests made to the USSD during the 18 months of intervention implementation (August 1, 2015 to January 31, 2017) from the USSD server of Vodafone Ghana; and all morbidity cases for the aforementioned timeframe for which requests were made, from the District Health Information Management System (DHIMS2) in Ghana. The DHIMS2 is a data recording, collection, collation, and analysis tool that hosts the entire national institutional health data of Ghana mainly from the public sector and a few private facilities [25].

This study was approved by the Ghana Health Service Ethics Review Committee before its commencement; study approval number GHS-ERC: 04/09/16.

Data Collection

Before data extraction, phone numbers assigned to various users was collated such that each intervention user, the HF as well as the district (cluster) the user worked in, was documented and coded in Vodafone Ghana's database. This ensured that requests made to the USSD could be traced back to the clusters, HFs, and FHWs using the phone. A total of 5 of the individual-use phones could not be traced back to the FHWs who received them as they were not signed for, and efforts to reach these numbers were futile. These 5 phone numbers were thus, not included in analysis. The USSD data were extracted monthly. Due to technical challenges at Vodafone Ghana, 22 days of data were lost during the first 6 months of the intervention. From the DHIMS2 database, maternal cases of postpartum hemorrhage (PPH), antepartum hemorrhage (APH), hypertensive disorders in pregnancy (HDP), and neonatal cases of prematurity, asphyxia, jaundice, cord sepsis, and sepsis occurring in the intervention period were extracted. In the DHIMS2, data captured regarding the aforementioned maternal cases cover hospital in-patients only. In the case of neonatal morbidity, the DHIMS2 captures data regarding neonatal cases of sepsis and prematurity at only hospital level, whereas neonatal cases of asphyxia, jaundice, and cord sepsis are captured as aggregate data for all types of HFs, that is, hospitals, health centers (HCs), and Community-based Health Planning and Services (CHPS) working with or within the Ghana Health Service. Due to challenges with the DHIMS2, some hospitals entered data

concerning morbidities of interest that were not captured or could not be extracted from the DHIMS2 onto Excel spreadsheets that were given to the project team for analysis. The data entry in such situations was done by the hospital health information officers responsible for entering those data into the DHIMS2, and the data were validated by the head of the health information unit in these hospitals.

Statistical Analysis

The data were checked for errors and exported from Microsoft Excel (Microsoft Corporation) to Stata version 13 (StataCorp LLC) for cleaning and analysis. We classified HFs into 2 groups of remote and nonremote areas based on access. Remote facilities were either located more than 30-min' walk or more that 15-min motorbike ride from the main district township and had poor road access (uneven and untarred roads overcrowded with weeds and shrubs) leading to them. Nonremote HFs were either located within 30-min' walk or 15-min motorbike ride from the main district township and had good road access leading to them. Due to the similarities in organizational structure, personnel and health services provided by CHPS, and maternity homes, requests from these 2 facility types were combined for analysis. Time of accessing the USSD was coded as day if requests were made from 6 am to 6 pm; all other time periods were coded night. Maternal morbidities— gestational hypertension, chronic hypertension, eclampsia, pre-eclampsia, and hypertensive encephalopathy were all classified as HDP. Placenta praevia and abruption were considered as APH, and retained placenta was considered as PPH as patients are usually hospitalized because of bleeding from these conditions. Unspecified cause of bleeding and vomiting were excluded during analysis. The Vodafone data were not corrected for the 22 days of missing data in the first 6 months of intervention implementation as the data were considered missing completely at random [30].

Descriptive analysis of requests made to the USSD server from clusters, HFs, *type-of-phone* (individual-use or shared-use), HF location, and *time-of-day* (explanatory variables) was done and expressed in numbers and percentages, first, as a combined 18-month data and then at 6-month intervals. Trends in maternal and neonatal requests were assessed. Chi-square and Fisher exact tests were applied to these analyses to assess the significance of the observed pattern of USSD requests. Morbidity from aforementioned cases of interest were estimated from the DHIMS2. The relationship between USSD requests and morbidity from cases for which requests were made was also estimated using Spearman correlation. All analyses were performed using Stata 13 statistical software and using 2-tailed tests at $\alpha=.05$.

RESULTS

User Statistics

A total of 74 HF in all 8 intervention clusters were recruited into this study (Table 1). Each cluster included at least 1 district hospital but a varying mix of HCs and CHPS. In all, data from 307 mobile phones were analyzed; 74 were shared-use phones, whereas the rest were individual-use phones. At the end of the intervention period, a total of 5329 requests were made to the USSD. Of these requests, 2396 (44.96% [2396/5329]) were made during the first 6 months, 2122 (39.82% [2122/5329]) in the second 6 months, and 811 (15.22% [811/5329]) in the last 6 months. Throughout the intervention period, maternal requests (66.35% [3536/5329]) were made more frequently compared with neonatal requests (33.65% [1793/5329]). Requests per cluster ranged from 1167 (representing 21.90% [1167/5329] of total requests) to 403 (representing 7.56% [403/5329] of requests); the average request made per cluster was 667. All clusters made a request to the USSD. Of the 74 HF (combined from all clusters), 72 accessed the USSD at least once during the intervention period. The 2 HF that did not access the intervention included a privately owned maternity home that had no midwife at post throughout intervention implementation and a CHPS compound whose midwife shared during a routine supervisory visit by the research team that she trusted her competence in midwifery practice and so did not see the need to consult the USSD protocols. Among HF, requests from hospitals declined from the first to the last 6 months, whereas requests from HCs and CHPS increased. Close to hundred percent (98.44% [2904/2950]) of all requests made from hospitals were with individual-use phones compared with the proportion of requests made with individual-use phones in HCs (52.87% [654/1237]) and CHPS (30.74% [351/1142]; $P < .001$). At night, the proportion of requests made from HCs (27.81% [344/1237]) and CHPS (27.67% [316/1142]) was lower than the proportion of requests from hospitals (34.17% [1008/2950]; $P < .001$). There were similarities in the observed proportion of maternal protocols assessed by individual-use phones (65.49% [2560/3909]) and shared-use phones (68.73% [976/1420]; $P = .03$); and in the proportion of requests made at night by both phone types (27.62% [450/1630] for shared-use phones and 31.52% [1371/4350] for individual-use phones; $P = .003$). Shared-use phones were used more often in remote areas (78.24% [1111/1420]) compared with individual-use phones (11.49% [499/3909]) in accessing the intervention ($P < .001$). The frequency of shared-use phones accessing the intervention increased over time, whereas the frequency of individual-use phone decreased. The proportion of maternal requests from remote (69.81% [1089/1560]) and nonremote areas (64.92% [2447/3769]) as well as the proportion of requests made at night from remote (31.09% [485/1560]) and nonremote areas (31.39% [1183/3769]) were similar ($P = .001$ for request type, $P = .046$ for time of day requests were made). The frequency of remote areas accessing the intervention increased over time, whereas the frequency of nonremote areas decreased. Requests by clusters, HF and their location, type of request (maternal or neonatal), *type-of-phone*, and *time-of-day* varied significantly at 6-month intervals during the intervention period (Table 2).

Table 1: Background characteristics of clusters.

Cluster ^a	Number of health facilities				Demographic location of health facilities, n (%)		Number of deliveries per midwife ^b	Proportion of shared phones received, n (%)
	Hospital ^c	HCs ^d	CHPS ^e	Maternity home ^f	Remote,	Nonremote,		
A	1	1	7	0	7 (78)	2 (22)	80.0	9 ^g (43)
B	1	7	3	0	6 (55)	5 (45)	130.4	11 (38)
C	3	2	9	1	6 (40)	9 (60)	99.0	15 (26)
D	2	3	3	0	5 (63)	3 (37)	94.8	8 (20)
E	1	3	2	0	3 (50)	3 (50)	107.6	6 (24)
F	1	8	1	1	4 (36)	7 (64)	101.6	11 (22)
G	3	2	0	1	1(17)	5 (83)	75.0	6 (11)
H	1	3	3	1	4 (50)	4 (50)	96.4	8 ^g (26)

^aClusters have been named A-H for anonymity.

^bReference year is 2014.

^cIncludes both private and public hospitals.

^dHealth Centers.

^eCHPS: Community-based Health Planning and Services.

^fIncludes only private maternity homes.

^gThis may differ slightly from the sum of the number of midwives in the cluster and the number of health facilities as 2 individual-use phones from these clusters could not be traced.

Table 2: Distribution of unstructured supplementary service data requests at 6 monthly intervals.

Variable	First 6 months, frequency (%)	Second 6 months, frequency (%)	Third 6 months, frequency (%)	Total, frequency (%)	P value for χ^2 test
Cluster^a					
A	244 (10.18)	216 (10.18)	198 (24.41)	658 (100.00)	<.001
B	262 (10.93)	184 (8.67)	42 (5.18)	488 (100.00)	<.001
C	406 (16.94)	311 (14.66)	97 (11.96)	814 (100.99)	<.001
D	174 (7.26)	220 (10.37)	98 (12.08)	492 (100.00)	<.001
E	173 (7.22)	153 (7.21)	77 (9.49)	403 (100.00)	<.001
F	552 (23.04)	438 (20.64)	177 (21.82)	1167 (100.00)	<.001
G	261 (10.89)	468 (22.05)	48 (5.92)	777 (100.00)	<.001
H	324 (13.52)	132 (6.22)	74 (9.12)	530 (100.00)	<.001
Type of request					
Maternal care	1653 (68.99)	1322 (62.30)	561 (69.17)	3536 (100.00)	<.001
Neonatal care	743 (31.01)	800 (37.70)	250 (30.83)	1793 (100.00)	<.001
Type of facility					
Hospitals	1563 (65.23)	1069 (50.38)	318 (39.21)	2950 (100.00)	<.001
Health centers	418 (17.45)	587 (27.66)	232 (28.16)	1237 (100.000)	<.001
CHPS ^b and maternity homes	415 (17.32)	466 (21.96)	261 (32.18)	1142 (100.00)	<.001
Type of phone					
Individual-use	1921(80.18)	1531 (72.15)	457 (56.35)	3903 (100.00)	<.001
Shared-use	475 (19.82)	591 (27.85)	354(43.65)	1420 (100.00)	<.001
Demographic location					
Nonremote	1906 (79.55)	1435 (67.62)	457 (56.35)	3769 (100.00)	<.001
Remote	490 (20.45)	687 (32.38)	354 (43.65)	1560 (100.00)	<.001
Time of day					
Day	1573 (65.65)	1526 (71.91)	562 (69.30)	3661 (100.00)	<.001
Night	823 (34.35)	596 (28.09)	249 (30.70)	1668 (100.00)	<.001

^aClusters have been named A-H for anonymity.

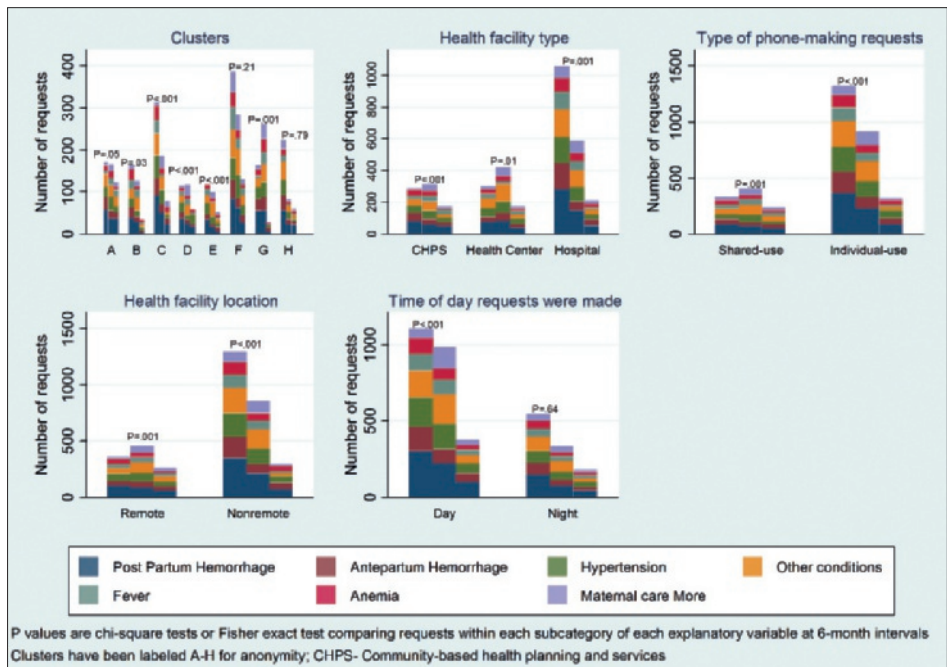
^bCHPS: Community-based Health Planning and Services.

Trends in Maternal Requests

Detailed analysis of maternal requests show that PPH protocols were accessed the most (27.22% [450/1653]) in the first 6 months, followed by *other conditions* protocols (16.76% [277/1653]) and HDP protocols (16.21% [268/1653]). This trend in requests was repeated in the second 6 months (PPH: 22.69% [300/1322], *other conditions*: 20.57% [272/1322], and HDP: 16.34% [216/1322]). In the last 6 months, HDP (17.7% [99/561]) was the second most accessed protocol after PPH (25.3 [142/561]), whereas APH and *other conditions* contributed 14.4% [81/561] each to requests made. Across clusters, this trend in maternal requests was significant at each 6-month interval ($P<.001$ for each timeframe). Across HFs, the trend of maternal requests aforementioned differed significantly only in the first and second timeframe ($P=.04$, $.03$, and $.15$, respectively); by *type-of-phone*, this trend varied at all 3 time points ($P=.05$, $.01$, and $<.001$, respectively);

and across HF, maternal request trends differed in the third 6th month alone ($P=.57$, $.42$, and $.001$, respectively, for each timeframe). There was no variation in maternal requests trends by *time-of-day* requests were made at 6-month intervals ($P=.16$, $.58$, and $.93$, respectively). Detailed analysis of maternal requests pertaining to *other conditions* shows that hyperemesis was the most frequently requested protocol accounting for 26.3% (47/179) and 37.4% (70/187) of requests in the first and second 6 months, respectively. This was followed by fetal distress, which accounted for 18.4% (33/179) and 13.9% (26/187) of requests and premature rupture of membranes for gestation <37 weeks, which accounted for 17.3% (31/179) and 13.9% (26/187) of requests for *other conditions* for the same timeframe. In the third 6 months, cord prolapse, hyperemesis, and premature rupture of membranes for gestation <37 weeks accounted for 28% (15/54), 28% (15/54), and 19% (10/54) of *other conditions* request, respectively. Figure 1 describes in detail the pattern of maternal requests made by the clusters, HF, and their location, *type-of-phone*, and *time-of-day* for each 6-month period. Overall, there was a 20.02% (331/1653) and a 57.56% (761/1322) decline respectively, in the number of maternal requests made from the first to the second 6 months and from the second to the third 6 months of intervention implementation.

Figure 1: Maternal requests at 6 months interval by cluster, health facility type and location, phone type and time of day requests were made.



Trends in Neonatal Requests

Trends in neonatal requests show that prematurity protocols were accessed the most (22.6% [168/743]) in the first 6 months, followed by *abnormal breathing* protocols (15.8% [117/743]) and neonatal sepsis protocols (16.2% [113/743]). In the second 6 months, prematurity was most requested (16.9% [135/800]), followed by neonatal sepsis (16.38% [131/800]) and then *neonatal more* (16.3% [130/800]). In the last 6 months, frequently requested protocols were prematurity, resuscitation, and asphyxia in descending order of 22.8% (57/250), 14.8% (37/250), and 14.0% (35/250), respectively. Across clusters, this trend in neonatal requests was significantly different during the first and second 6 months of intervention implementation ($P < .001$ in each interval and .12 in the third 6 months). Across HFs, this trend of neonatal requests was again significantly different during the first 6 months ($P = .001$, .07, and .15, respectively, per interval); by *type-of-phone*, the observed trend aforementioned varied significantly during the first 6 months ($P < .001$, .38, and .07, respectively, per timeframe); by HF location and *time-of-day*, requests varied during the second 6 months only (P values for location type = .31, .001, and .13, respectively; P values for *time-of-day* analysis = .20, $< .001$, and .78, respectively). Detailed analysis of *neonatal more* requests show that 55.4% (72/130) of requests concerned neonatal seizures and the rest concerned birth trauma. Figure 2 describes in detail the pattern of neonatal requests made by the clusters, HFs and their location, *type-of-phone*, and *time-of-day* for each 6-month period. Overall, there was a 7.7% (57/743) increase and then a 68.8% (550/800) decline, respectively, in the number of neonatal requests made from the first to the second 6 months and from the second to the third 6 months of intervention implementation.

Correlation Between Requests Made and Incidence of Cases

Generally, the number of maternal and neonatal cases exceeded the number of requests made except in the case of PPH. The correlation between requests made and actual number of cases recorded in HFs ranged from weak to strong positive and negative correlations. Spearman correlation was, however, significant for only asphyxia (Spearman $\rho = .44$; $P < .001$) and sepsis cases (Spearman $\rho = .79$; $P = .03$). Table 3 details the correlation coefficients for all outcomes of interest.

Figure 2: Neonatal requests at 6 months interval by cluster, health facility type and location, phone type and time of day requests were made.

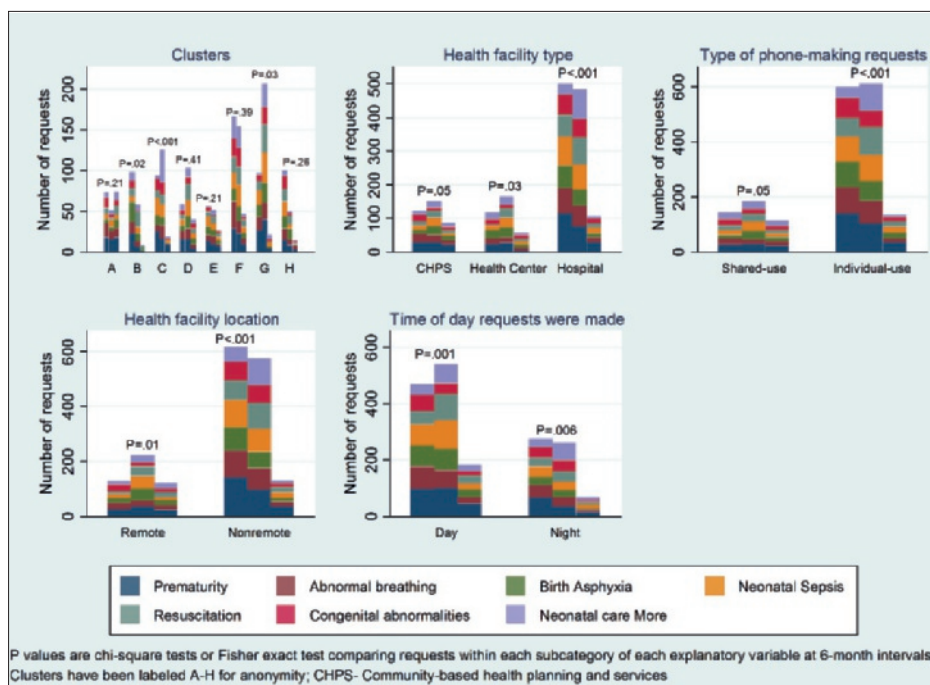


Table 3: Correlation between requests made to the intervention and actual number of cases recorded in health facilities.

Type of case	Number of requests ^a , n (%)	Number of cases, n (%)	Spearman rho	P value
Maternal^b				
Antepartum hemorrhage	231 (51.7)	242 (100.0)	.05	.90
Postpartum hemorrhage	438 (49.1)	298 (100.0)	-.03	.93
Hypertension	267 (45.8)	1339 (100.0)	-.32	.41
Neonatal				
Asphyxia	320 (100.0)	2004 (100.0)	.44	<.001
Jaundice	15 (100.0)	158 (100.0)	.18	.12
Cord sepsis	6 (100.0)	63 (100.0)	-.07	.57
Sepsis ^b	124 (40.4)	185 (100.0)	.79	.03
Prematurity ^b	208 (57.9)	831 (100.0)	-.22	.58

^aRepresents the proportion of requests from only health facilities included in analysis.

^bRepresents hospital level data excluding 3 of the 12 hospitals in the intervention arm. Two of these 3 hospitals are in the same district and are privately owned; data from hospitals excluded were unavailable to researchers as of time of data analysis (August 2018).

DISCUSSION

Principal Findings

This study describes the pattern of requests made to a SMS text messaging–based mobile CDMSS by FHWs providing maternal and neonatal health services in Ghana. We assessed the relationship between protocol requests made and types of maternal and neonatal morbidities for which requests were made. All clusters accessed the intervention, which is consistent with known findings of general acceptability of mHealth interventions among HWs and communities [9-12]. Maternal protocols were requested for more often than neonatal protocols, suggesting differences in information needs among FHWs with regards to maternal and neonatal care. Such differences in information needs was previously documented among community-level HWs in Nepal who seemed to be more knowledgeable in neonatal than maternal care matters [31]. This observation could also be a reaction of FHWs to the extensive maternal death audits conducted in Ghana [20]. Neonatal deaths, on the other hand, have not received such attention.

The high number of requests for protocols of PPH, HDP, prematurity, and sepsis in our study reflects the global and local trend in maternal and neonatal morbidity where these morbidities top the list [2,32-34]. This observation emphasizes the persistence of these morbidities in low-resource settings and the consequent need for health system strengthening in this regard and focus on these areas during HW training.

Within clusters, PPH and prematurity protocols were most commonly requested, suggesting that FHWs in the different clusters have a common information gap regarding these 2 morbidities that was bridged by this intervention. Differences in requests by category of HFs appear to reflect the differences in information needs of FHWs at the different levels of health care [35]. Surprisingly, the majority of requests emanated from hospitals where one would assume resource availability to be higher. The higher number of requests from hospital FHWs could indicate an unmet need for clinical decision-making support that is action-oriented even at higher levels of the health system. D'Adamo and his colleagues made similar findings of a near or complete lack of access to current useful information for district- and community-level HWs in their study [35]. It is striking that the trend in both maternal and neonatal requests did not differ significantly by HF location at all 3 time points in our study. A plausible explanation for this observation is similarities in competencies of FHWs in both remote and nonremote settings. This may be particularly true as in the Ghana Health Service, HWs may be freely transferred from 1 HF type to another. Similarities in FHW competencies across HFs may explain the absence of differences in request trends by the *time-of-day* requests were made. Detailed information about the FHWs who utilized the intervention could have provided more information regarding this analysis but was not collected in this study. The higher proportion of requests made by nonremote areas compared with remote

areas is most likely because of the higher proportion of individual-use phones in nonremote areas where there are generally higher numbers of midwives. Hence, a collinear relationship between requests made by *type-of-phone* and HF location can be observed. However, it is remarkable that nearly all requests from hospitals were made with individual-use phones implying a near absolute redundancy of shared-use phones in hospitals. This observation suggests that FHWs who were given the project phones are probably the same and only people who used the intervention in hospitals. Lack of knowledge transfer concerning the availability and use of the intervention with other FHWs who missed the project team's training sessions, the practice of keeping project phones under lock and key in senior colleagues offices, and the use of project phones as though they were individual-use phones by HWs who received these phones on behalf of the HFs, as documented in a study to understand how and why the intervention was used [36], could explain the low number of USSD requests by hospital shared-use phones. These observations are common health system challenges in low-resource settings that need to be addressed as not all HWs may attend the various training programs constantly organized for staff, and scarce resources have to be shared.

The setup of our intervention database is unique and allowed for in-depth analysis of requests made to the USSD by individual users unlike previous work [11]. Our study shows varying pattern of requests for emergency protocols across and within clusters, HFs and their location, *type-of-phone*, and *time-of-day* and type of request made at all 3 time points considered in this study. This reflects the dynamic nature of information needs of FHWs. Such dynamism has been reported [10,37,38] and is important to take into account in the design and maintenance of CDMSS [10,12,37,38] as well as training for FHWs.

The intervention phones were predominantly used for voice calls (64%), followed by data (28%), SMS text messaging (5%), and USSD to access protocols (2%), respectively [36]. Differential baseline technological literacy among FHWs may have impacted the use of the different intervention components [36]. The declined usage of the USSD over time can be explained by the so-called *novelty effect* associated with mHealth interventions [37,39-42]. Novelty effect is the tendency for performance to initially improve when new technology is instituted, not because of any actual improvement in learning or achievement, but in response to increased interest in the new technology [43]. However, the *novelty-effect* alone cannot be considered as the reason for the much lower number of requests made in the last 6 months of the study. Another possible explanation for this phenomenon may be *testing effect in learning* (that long-term memory is often increased when some of the learning period is devoted to retrieving the to-be-remembered information [44]). The much lower usage of the USSD in the last 6 months is most likely because of conversion of USSD protocols into tacit knowledge of FHWs [36]. Availability of specialist obstetricians, doctors, and senior midwives in hospitals and the need to conform

to instructions from superior colleagues (eg, doctors) can also explain this finding, particularly in hospitals where the observed decline in requests was highest [36]. Conflict from overreliance on CDMSS [37] by users of the CDMSS and provider knowledge and experience from nonusers of the CDMSS may lead to abandonment of the CDMSS in resolving such conflicts with the mindset that critical thinking of the human mind must not be taken over by a CDMSS [37]. Where there is a disconnect between protocols and the reality on the ground (such as lack of equipment), HW may also decide not to access electronic resources [10]. Technical and supervisory support to motivate users may also play a role in the decline in requests observed [12,36], and thus, this observation warrants further probing.

The moderate to strong correlation between the number of sepsis and asphyxia requests suggest that FHWs actually encountered these cases and used these protocols in their decision making for these morbidities. The converse may be true where weak and negative associations are observed; exploration of the USSD protocols to satisfy FHW curiosity and mobile network problems [11,45,46] necessitating that FHWs send multiple requests may explain these weak and negative associations.

Limitations

Though our study highlights important patterns of use of a SMS text messaging–based CDMSS, the use of information accessed in the care of patients or clients is undetermined in this study. Though this limitation is inherent in the design of this study, this study provides much needed insights as to how an mHealth SMS text messaging–based CDMSS functioned in a low-resource setting and quantifies the information needs of FHWs providing maternal and neonatal health care in this type of setting. Insight into the information needs of FHWs can inform the design of interventions mHealth (or otherwise) to meet these needs.

CONCLUSIONS

This study demonstrates that health care providers of maternal and neonatal health services in Ghana readily use a mobile SMS text messaging–based CDMSS in their clinical decision making. These FHWs used the mHealth tool to request emergency protocols depending on their information needs, which varied across and within clusters, HFs and their location, and with time. Thus, the information needs of HWs is not static but continues to change over time requiring health system strengthening strategies that take cognizance of this dynamism. Mechanisms to sustain utilization of similar mHealth CDMSS interventions must be designed to suit relevant context if such interventions will be up-scaled as health system strengthening strategies in future.

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Authors' Contributions

HBA, KKG, and EA designed and performed the study. HBA drafted the manuscript, and KKG and EA reviewed the manuscript. IAA, DEG, MAC, CS, EF, GAK, and EOM provided critical comments on the review of the manuscript. All authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

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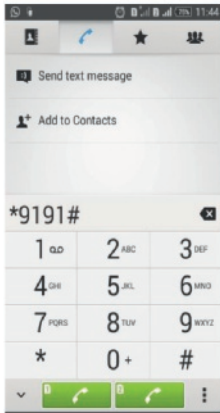
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SUPPLEMENTARY INFORMATION

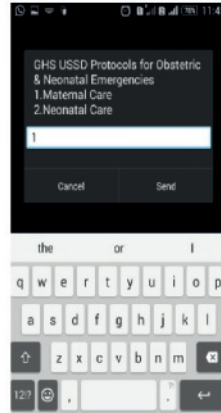
Appendix I: Steps to request for emergency maternal or neonatal protocols

Multimedia appendix: Steps to request for emergency maternal or neonatal protocols

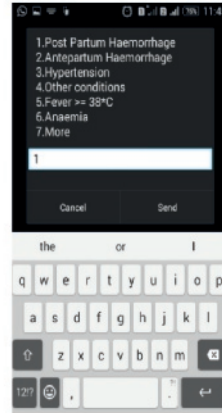
Step 1: Dial short code
(*9191#)



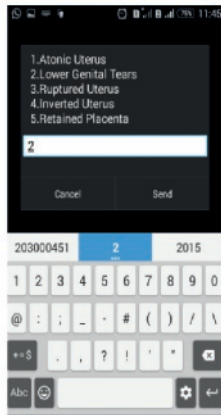
Step 2: Choose protocol type
(maternal or neonatal)



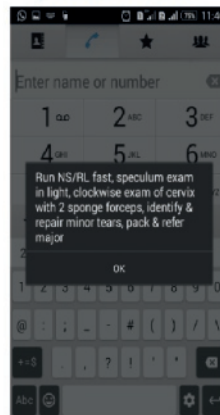
Step 3: Choose type of maternal
protocol of interest



Step 4: Choose suspected course
of maternal morbidity



Step 5: Read guidelines for
protocol assessed



Steps 1 and 2 must always be performed. The number of remaining steps to finally receiving protocols may differ depending on the pathway that must be navigated to reach the protocol for a specified maternal or neonatal morbidity.



CHAPTER 5

Can an mHealth clinical decision-making support system improve adherence to neonatal healthcare protocols in a low-resource setting?

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Submitted

ABSTRACT

Background

This study assessed health workers' adherence to neonatal health protocols before and during the implementation of an mHealth clinical decision-making support system (mCDMSS) that sought to bridge access to neonatal health protocol gap in a low-resource setting.

Methods

We performed a cross-sectional document review within two purposively selected clusters (one poorly-resourced and one well-resourced), from each arm of a cluster-randomized trial at two different time points: before and during the trial. The total trial consisted of 16 clusters randomized into 8 intervention and 8 control clusters to assess the impact of an mCDMSS on neonatal mortality in Ghana. We evaluated health workers' adherence (expressed as percentages) to birth asphyxia, neonatal jaundice and cord sepsis protocols by reviewing medical records of neonatal in-patients using a checklist. Differences in adherence to neonatal health protocols within and between the study arms were assessed using Wilcoxon rank-sum and permutation tests for each morbidity type. In addition, we tracked concurrent neonatal health improvement activities in the clusters during the 18-month intervention period.

Results

In the intervention arm, mean adherence was 35.2% (SD=5.8%) and 43.6% (SD=27.5%) for asphyxia; 25.0% (SD=14.8%) and 39.3% (SD=27.7%) for jaundice; 52.0% (SD=11.0%) and 75.0% (SD=21.2%) for cord sepsis protocols in the pre-intervention and intervention periods respectively. In the control arm, mean adherence was 52.9% (SD=16.4%) and 74.5% (SD=14.7%) for asphyxia; 45.1% (SD=12.8%) and 64.6% (SD=8.2%) for jaundice; 53.8% (SD=16.0%) and 60.8% (SD=11.7%) for cord sepsis protocols in the pre-intervention and intervention periods respectively. We observed nonsignificant improvement in protocol adherence in the intervention clusters but significant improvement in protocol adherence in the control clusters. There were 2 concurrent neonatal health improvement activities in the intervention clusters and over 12 in the control clusters during the intervention period.

Conclusion

Whether mHealth interventions can improve adherence to neonatal health protocols in low-resource settings cannot be ascertained by this study. Neonatal health improvement activities are however likely to improve protocol adherence. Future mHealth evaluations of protocol adherence must account for other concurrent interventions in study contexts.

Keywords

Adherence, neonatal health protocols, Ghana, mHealth, low-resource setting, jaundice, birth asphyxia, cord sepsis

BACKGROUND

The Sustainable Development Goals aim to reduce the current high global neonatal mortality from 18 per 1,000 to at least 12 per 1,000 live births by 2030 [1]. Concerted effort is being harnessed through many international, national, district and community collaborations to make this a reality particularly in low-resource settings like sub-Saharan Africa and Southern Asia which contribute most to the global burden of neonatal mortality [2, 3]. Infections, birth asphyxia and prematurity contribute to the majority of neonatal deaths in low-resource settings (90%) [4]. Although morbidity and mortality from these conditions are largely preventable, the scarcity of health resources (facilities, personnel, basic equipment and medicines, training programmes, protocols etc.), allow these preventable deaths to thrive in the health systems of poorly resourced countries.

MHealth is a potential tool to improve the efficiency of health workers and the health system as a whole in low-resource settings [5]. Many mHealth interventions have been applied in areas of vaccination, management of tuberculosis and HIV, monitoring of antenatal health services for pregnant women in low-resource settings and have been documented to have variable but largely good success [6–9]. In the field of clinical decision-making support (CDMS), few mHealth interventions have been implemented in low-resource settings [9–16], and even fewer studies report adherence to protocols or algorithms specified by these electronic CDMS systems.

Ghana is a lower middle-income country that reports high neonatal mortality rates of 25 per 1,000 live births [17]. Non-adherence to standard clinical protocols has been identified as a cause of Ghana's high neonatal mortality [18, 19]. Previous studies have shown the absence of standard health protocols (the Safe Motherhood Protocol) for about 44% of health workers at the point of service delivery [20]. To bridge this protocol access gap, the Ghana Health Service (GHS) in collaboration with her Dutch partners designed and implemented an mHealth clinical decision-making support system (mCDMSS) aiming to improve clinical decision-making and ultimately neonatal health outcomes that was tested in a cluster randomized controlled trial (CRCT) in the Eastern Region of Ghana [21].

Description of the intervention

The mobile clinical decision making support intervention (THE INTERVENTION for short for the rest of this paper) consisted of 4 components - phone calls (voice), text messaging (SMS), access to the internet (data) and access to an unstructured supplementary service data (USSD) that provided emergency protocols in response to selection from a short code drop-down menu. The messages on the USSD were created by a design team of frontline health workers, family physicians, obstetricians and paediatricians in the Greater Accra Region, drawing on Ghana's

Safe Motherhood Protocols [22]. All four components of the intervention were part of a single composite intervention delivered on a non-smart mobile phone. Researchers considered access to the USSD the main intervention component. Health workers were expected to use the phones primarily to access neonatal and maternal health emergency protocols via the USSD and obtain additional support from colleagues and the internet via the other intervention components. Each project mobile phone had a unique Subscriber Identification Module (SIM) card. All the SIM cards were networked in a Closed User Group (CUG) that allowed free and unlimited access to the USSD. Access to the intervention was, however, limited to the project SIM cards to avoid contamination.

Study objectives

Our objectives in this study were to assess the quality of neonatal healthcare in the Eastern Region of Ghana, by examining the change in health worker adherence to neonatal health protocols in both study arms of the CRCT from a pre-intervention period to an intervention implementation period, and to investigate differences in adherence within and between the study arms during these time frames. We also assessed whether and which concurrent neonatal health improvement activities (not related to the intervention) occurred during the trial period.

METHODS

Study design & setting

We designed a longitudinal study and performed a cross-sectional document review within two clusters selected from each arm of a cluster randomized trial at two different time points: before and during the trial. The trial aimed to assess the impact of an mCDMSS on neonatal mortality in the third most populous region in Ghana- the Eastern Region [23]. The Eastern Region has a neonatal mortality rate of 30 per 1,000 live births and ranks fourth highest in terms of neonatal mortality in Ghana [24]. The region was divided into twenty-one (21) geographic local administrative units called districts at the time of the study. The CRCT was implemented over 18-months (August 2015 to January 2017) in 16 of these districts randomized into 8 intervention and 8 control clusters. Each of the 16 districts formed one cluster of the CRCT. The CRCT has been previously described elsewhere [21].

Sampling of clusters

For logistic reasons, one well-resourced and one poorly-resourced cluster were purposively selected from each CRCT arm making two clusters per arm. The selection criteria were based on the number and mix of health facilities (hospitals, community health planning and services compounds (CHPS), health centres (HCs) and maternity homes) in the district and the midwife to the number of deliveries (per annum) ratio in a district (reference year was 2014). Following

cluster selection, district hospitals were sampled because initial assessment showed that almost all cases of neonatal morbidity of interest in this study were managed in the district hospitals.

Recruitment of study participants

All cases of in-patient neonatal morbidities of birth asphyxia, jaundice and cord sepsis that were managed in the district hospitals nine months before the intervention started and, nine months to the end of the intervention implementation period were studied to assess health worker adherence to protocols regarding morbidities. These morbidities were selected as the most common causes of neonatal morbidity in the study setting [25].

Data collection

Baseline data regarding the number and category of health workers providing neonatal health services in each cluster was collected using a checklist. We extracted data concerning the number of deliveries per study cluster during the two time frames of interest from the district health information management system 2 (DHIMS2). The DHIMS2 is a data recording, collection, collation and analysis tool that hosts the entire national institutional health data of Ghana [26].

We utilized a scoring system based on existing health protocols as done in previous studies [27–29]. In each hospital, the head of the maternity or paediatric unit and the health information manager were contacted to identify the medical records (registers and books) that are routinely used in the hospitals to document in-patient neonatal data. A list of all in-patient cases of birth asphyxia, jaundice and cord sepsis was then populated from the ‘in-patient admissions and discharge register’ which documents all admitted cases in a hospital. A document review of the management of these cases was done using a checklist to assess health worker adherence to neonatal protocols. This checklist was based on Ghana’s Safe Motherhood Protocol for management of neonatal morbidities. During data extraction, protocol items were assessed under the following themes where applicable for each morbidity type: i. Diagnosis (e.g., ‘Diagnosis documented’), ii. Signs and symptoms of disease (e.g., ‘Colour of baby’, ‘Cord assessed for odour, pus and wetness’), iii. Investigation (e.g., ‘Serum bilirubin checked’) iv. Treatment given (e.g., ‘Airway of baby cleared through suction’, ‘Phototherapy given or sunbath advised’, ‘Antibiotics given’). Assessment of adherence was only done for items that are considered mandatory in the management of each morbidity type (tables 2 to 4). Appendix I details the type of facility records utilized in the data collection process.

Data concerning other concurrent neonatal health improvement interventions such as trainings and workshops that took place in the study districts during the 18-month intervention period was collected using a checklist. The district public health nurse in each cluster and the in-service trainers of the four hospitals assisted in extracting the relevant data from their facility record books.

Data analysis

The data were checked for errors, cleaned and analyzed at health facility level. We calculated the number of deliveries per midwife and doctor to estimate the delivery related workload in the study clusters. Descriptive analysis of neonatal data was performed. Items for each morbidity protocol was scored as 'adhered to' and assigned a score of 1 if there was written documentation of adherence to the item in any of the medical records. A protocol item was scored 'not adhered to' and assigned a score of zero (0) only when there was no written documentation of adherence in all the medical records. When the records of a neonate could not be traced because a register or book for a neonate was not found, protocol items were scored as 'don't know' and assigned a score of zero (0). Appendix II details the 'don't know' responses which totalled 2.9% of the entire data collected. For each item, the proportion of neonatal cases for whom guidelines were adhered to, was estimated. The mean and median adherence to protocols per morbidity type were calculated. Total adherence to a specified neonatal morbidity protocol was estimated as the sum of scores per theme, presented as a percentage and rated (i.e. adherence status) high, moderate or low if total adherence was 90-100%, 89-60% and <60% respectively [30]. The difference in total adherence to neonatal protocols within and between the study arms during the time frame of interest was assessed using Wilcoxon rank-sum and permutation tests to determine the significance of these differences due to the small sample size. All analysis were done separately for the two time frames of interest (i.e., 9 months pre and 9 months to the end of the intervention) using two-tailed tests at $\alpha=0.05$ in Stata 13 [31].

We analysed the number, and described other activities aimed at improvement in neonatal health outcomes that were undertaken in both the intervention and control clusters during the intervention period.

RESULTS

One district hospital in each of the four clusters participated in this study. Three of the hospitals were public owned and one was operated by a religious body. There were 2,290 deliveries in the intervention arm hospitals and 4,440 deliveries in the control arm hospitals in the pre-intervention period. During the intervention period, the number of deliveries stayed about the same in the intervention arm, whereas the number of deliveries increased by 20% in the control arm (table 1). The number of deliveries per midwife was 76 and 109 in the intervention and control arm respectively during the pre-intervention period. During the intervention period, the number of deliveries per midwife was 66 and 115 in the intervention and control arm respectively. Cluster C recorded the highest delivery related workload during the pre and intervention periods. Table 1 details the characteristics, human resource availability and delivery related workload of the study clusters.

Adherence to asphyxia protocols

The prevalence of asphyxia was 3.5 and 15.1 per 1,000 deliveries in the intervention and control arm respectively during the pre-intervention period. The 10th and 90th percentile for adherence per theme varied from 0% to 100% in the intervention arm and 33.3% to 100%, in the control arm in this time frame (see table 2). In the intervention arm, the mean score for total adherence to asphyxia protocols was 35.2% (SD=5.8%) and in the control arm, it was 52.9% (SD=16.4%).

During the intervention period, the prevalence of asphyxia was 6 and 9.4 per 1,000 deliveries in the intervention and control clusters respectively. The range of values for the 10th and 90th percentile for adherence per theme remained the same during the intervention period. The mean average total adherence was 43.6% (SD=27.5%) in the intervention arm, and in the control arm, it was 74.5% (SD=14.7%).

Adherence status to asphyxia protocols was moderate to low in the pre-intervention period and high to low in the intervention period (figure 1). Overall, there was improvement in total adherence to asphyxia protocols in both study arms, however improvement in the intervention arm (figure 2) was not significant ($p=0.92$) while improvement in the control arm was significant ($p<0.001$). Between the study arms, the control arm sites were more adherent to asphyxia protocols compared to the intervention arm before and during the trial period ($p=0.002$ and $p<0.001$ respectively).

Table 1: Distribution of health personnel and delivery related workload in study clusters

Period	Cluster	Resource ranking	Operating authority	Number of doctors (n)	Number of obstetricians (n)	Number of paediatricians (n)	Number of midwives (n)	Number of deliveries	
Pre-intervention	Intervention arm								
	A	High -resource	Government	4	0	0	21	1,636	
	B	Low- resource	Religious	1	0	0	9	654	
	Control arm								
Intervention	Intervention arm								
	C	High -resource	Government	7	0	0	29	3,569	
	D	Low- resource	Government	2	0	0	10	671	
	Control arm								
Pre-intervention	Intervention arm								
	A	High -resource	Government	5	0	0	23	1,759	
	B	Low- resource	Religious	2	1	0	15	735	
	Control arm								
Intervention	Intervention arm								
	C	High -resource	Government	5	0	0	34	4,657	
Control arm	Intervention arm								
	D	Low- resource	Government	3	0	0	13	768	

Table 1: Continued

Period	Cluster	Resource ranking	Deliveries per midwife	Deliveries per doctor	*Workload	Proportion of pre and post intervention deliveries
Pre-intervention	Intervention arm					
	A	High -resource	78	409	Moderate	0.25
	B	Low- resource	73	654	Moderate	0.22
	Control arm					
Intervention	Intervention arm					
	C	High -resource	123	510	High	0.55
	D	Low- resource	67	336	Moderate	0.10
	Control arm					
Intervention	Intervention arm					
	A	High -resource	76	352	High	0.22
	B	Low- resource	49	368	low	0.09
	Control arm					
Intervention	Intervention arm					
	C	High -resource	137	931	High	0.59
Intervention	D	Low- resource	59	256	Moderate	0.10

*Estimated by the number of deliveries per midwife; Low <50, Moderate 50-90, High >90. The workload in each cluster is higher than the internationally recognized midwife-to-birth ratio of 29.5 per midwife. The categorization of workload used here is based solely on comparison between the estimated workload among the study clusters.

Table 2: Proportion of asphyxia protocol items adhered to and total adherence score to asphyxia protocols before and during intervention implementation

Protocol item	*Pre-trial period (N=75)		†Trial period (N=66)	
	Intervention n (%)	Control n (%)	Intervention n (%)	Control n (%)
Diagnosis				
Diagnosis documented	8 (100.0)	66 (98.5)	14 (93.3)	51 (100.0)
Signs and symptoms				
Description of difficulty in breathing	0 (0.0)	14 (20.9)	7 (46.7)	16 (32.0)
Heart rate neonate recorded	0 (0.0)	5 (7.5)	4 (26.7)	48 (94.1)
Tachycardia	0 (0.0)	11 (16.4)	4 (26.7)	48 (94.1)
Respiratory rate	0 (0.0)	45 (67.2)	5 (33.3)	48 (94.1)
Colour of baby	0 (0.0)	25 (37.3)	5 (33.3)	45 (88.2)
APGAR scores written	8 (100.0)	63 (94.0)	14 (93.3)	48 (94.1)
Liquor assessed for meconium staining	2 (25.0)	21 (31.3)	4 (26.7)	8 (15.7)
Treatment				
Airway of neonate cleared through suction	1 (12.5)	42 (62.7)	4 (26.7)	14 (27.5)
Warmth provided (using incubator or wrapping)	7 (87.5)	43 (64.2)	2 (13.3)	43 (84.3)
Oxygen given / Bag and mask resuscitation	5 (62.5)	55 (82.1)	9 (60.0)	49 (96.1)
Total adherence score				
1	-	-	1 (6.7)	-
2	-	3 (4.5)	3 (20.0)	1 (2.0)
3	2 (25.0)	6 (9.0)	3 (20.0)	2 (3.9)
4	5 (62.5)	7 (10.5)	1 (6.7)	-
5	1 (12.5)	10 (14.9)	3 (20.0)	-
6	-	14 (20.9)	-	-
7	-	13 (19.4)	-	3 (5.9)
8	-	13 (19.4)	-	23 (45.1)
9	-	1 (1.5)	3 (20.0)	15 (29.4)
10	-	-	1 (6.7)	7 (13.73)

*There were 2,290 and 4,440 deliveries in the intervention and control arm respectively in the pre-trial period

†There were 2,494 and 5,425 deliveries in the intervention and control arm respectively in the trial period

Adherence to jaundice protocols

There were 2.6 and 6.5 cases of jaundice per 1,000 deliveries in the intervention and control arms respectively during the pre-intervention period. Jaundiced neonates were on average 7.2 days old (SD=7.3 days). The 10th and 90th percentile for adherence per theme for jaundice protocol varied from 0% to 100% in both study arms (table 3). The mean total adherence to jaundice protocols was 25.0% (SD=14.8%) in the intervention arm, and in the control arm it was 45.1% (SD=12.8%). The cause of jaundice was not identified in 65.7% of cases; in 30.4% of cases, glucose-6-phosphate-dehydrogenase deficiency (G6PD deficiency) was the cause of jaundice and gastroenteritis in one case. Four jaundiced neonates (two in each arm) received no counselling for sunbathing, neither were they put in a phototherapy unit. Two of four neonates in the control arm whose caretakers were advised to give their babies a sunbath were not followed up as per

protocol. Most jaundiced neonates (33 (91.4%)) received antibiotic as part of their treatment although there was only one documented case of infection (gastroenteritis).

The number of jaundiced neonates decreased to 1.6 per 1,000 deliveries in the intervention arm and increased to 9.2 per 1,000 deliveries in the control arm during the intervention period. These jaundiced neonates were on average 5.1 days (SD=4.5 days) old at the time of the diagnosis. The 10th and 90th percentile for adherence per theme for jaundice protocol varied from 0% to 100% in intervention arm and 14.3% to 100% in the control arm. In the intervention arm, the mean score for total adherence to jaundice protocols was 39.3% (SD=27.7%); in the control arm it was 64.6% (SD=8.2%). In 45 (83.3%) of all cases of jaundice, the cause of the jaundice was classified 'unknown'. One case of physiological jaundice and one case of pathological jaundice were identified in the intervention arm, while one case of cord sepsis and one case of physiological jaundice were identified in the control arm; for the rest of the cases, the cause of the jaundice was not stated in any of the records found in the health facilities. There was no documentation of treatment (using phototherapy or by sun-bathing) of three neonates in the intervention clusters. In the control clusters, all jaundiced neonates received either of the aforementioned treatment options. All sunbathed neonates were followed up during the intervention period. All jaundiced neonates received antibiotics as part of their treatment although only one case of infection (cord sepsis) was identified as a cause of jaundice.

Overall, adherence status was low to moderate during the pre-intervention and intervention periods (figure 1). The improvement in adherence to jaundice protocols observed in the intervention clusters (figure 2) was not significant ($p=0.38$) while that observed in the control clusters was significant ($p<0.001$). Comparing the two study arms, control clusters scored higher in adherence to jaundice protocols before and during the intervention period (p -value=0.005 and 0.088 respectively).

Table 3: Proportion of jaundice protocol items adhered to and total adherence score to jaundice protocols before and during intervention implementation

Protocol item	*Pre-trial period (N=35)		*Trial period (N=54)	
	Intervention n (%)	Control n (%)	Intervention n (%)	Control n (%)
Diagnosis				
Diagnosis documented	6 (100.0)	29 (100.0)	4 (100.0)	50 (100.0)
Signs and symptoms				
Duration of jaundice stated	0 (0.0)	8 (27.6)	3 (75.0)	46 (92.0)
Temperature checked	3 (50.0)	14 (14.3)	2 (50.0)	11 (22.0)
Assessed for vomiting	1 (25.0)	5 (17.2)	2 (50.0)	1 (2.0)
Assessed for episode(s) of convulsion	1 (25.0)	0 (0.0)	2 (50.0)	0 (0.0)
Assessed for poor feeding	3 (60.0)	3 (10.3)	2 (50.0)	21 (42.0)
Assessed for excessive crying	1 (25.0)	2 (6.9)	1 (25.0)	28 (56.0)
Assessed for hypotonia	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.0)
Investigation				
Full blood count done	2 (33.3)	26 (89.7)	2 (50.0)	49 (98.0)
Blood grouping checked	0 (0.0)	22 (75.9)	1 (25.0)	49 (98.0)
Serum bilirubin checked	0 (0.0)	21 (72.4)	1 (25.0)	49 (98.0)
Samples for blood cultures taken	0 (0.0)		1 (25.0)	47 (94.0)
Samples for G-6-P-D deficiency screen taken	0 (0.0)	18 (62.1)	0 (0.0)	49 (98.0)
Treatment				
Phototherapy given or sunbath advised	4 (66.7)	27 (93.1)	1 (25.0)	50 (100.0)
Total adherence score				
1	1 (16.7)	-	-	-
2	1 (16.7)	1 (3.5)	1 (25.0)	-
3	1 (16.7)	2 (6.9)	-	-
4	2 (33.3)	1 (3.5)	1 (25.0)	1 (2.0)
5		4 (13.8)	1 (25.0)	-
6		7 (24.1)	-	-
7	1 (16.7)	5 (17.2)	-	-
8		7 (24.1)	-	13 (26.0)
9		2 (6.9)	-	19 (38.0)
10		-	-	14 (28.0)
11		-	1 (25.0)	3 (6.0)

*There were 2,290 and 4,440 deliveries in the intervention and control arm respectively in the pre-trial period

*There were 2,494 and 5,425 deliveries in the intervention and control arm respectively in the trial period

Figure 1: Adherence status per morbidity type before and during the intervention period

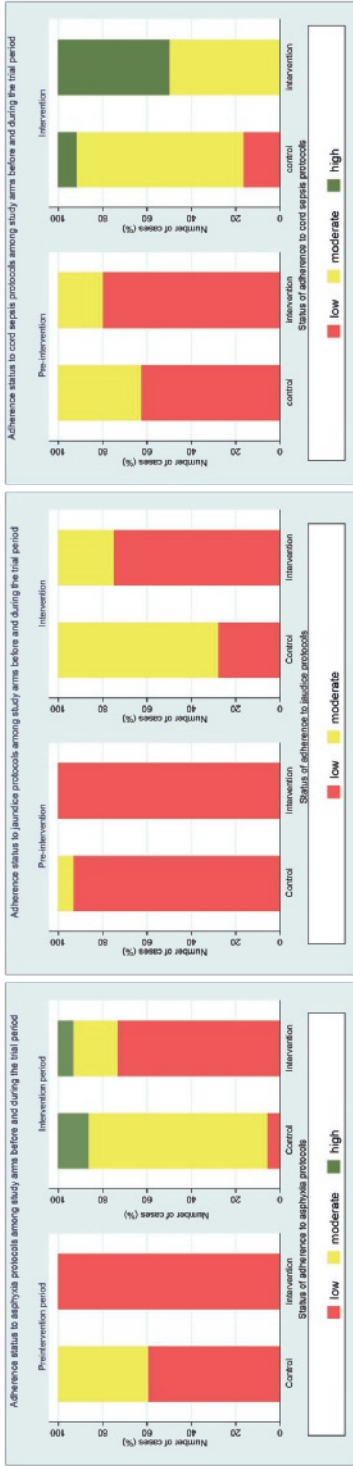
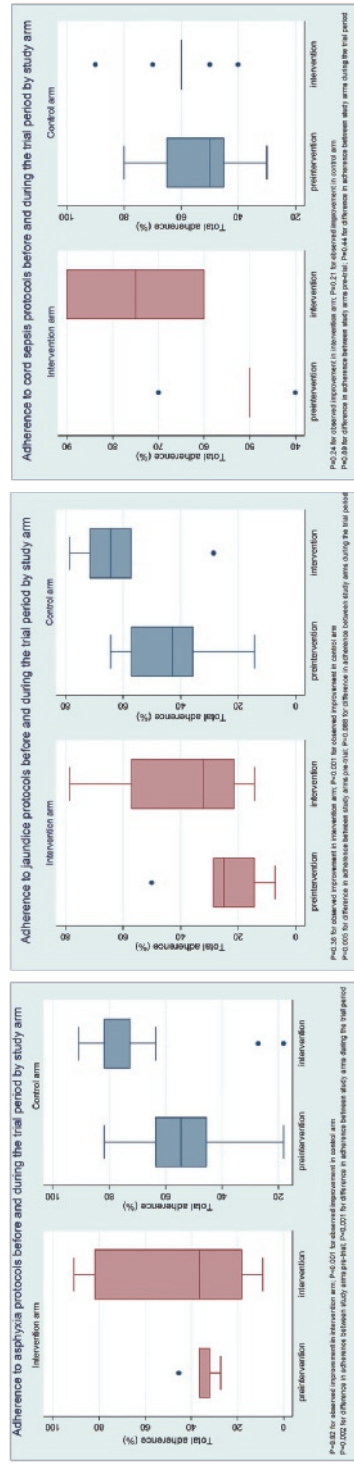


Figure 2: Distribution and change in total adherence to asphyxia, jaundice and cord sepsis cases in study arms before and during the intervention period



Adherence to cord sepsis protocols

The prevalence of cord sepsis was 2.2 and 1.8 per 1,000 deliveries in the intervention and control arms in the pre-intervention period. The average age of these neonates was 5.4 days (SD=3.8 days). The 10th and 90th percentile for adherence per theme for cord sepsis protocol varied from 16.7% to 100% in both study arms (table 4). Altogether, the mean total adherence to cord sepsis protocols in the intervention arm was 52.0% (SD=11.0%) and, 53.8% (SD=16.0%) in the control clusters.

There were 0.8 and 2.2 cases of cord sepsis per 1,000 deliveries during intervention implementation. The average age of these neonates was 5.9 days (SD=4.9 days). Altogether, the mean total adherence to cord sepsis protocols in the intervention arm was 75.0% (SD=21.2%) whereas, in the control arm, it was 60.8% (SD=11.7%). The 10th and 90th percentile for adherence per theme for cord sepsis protocol varied from 50% to 100% in the intervention arm and 33.3% to 100% in the control arm.

Adherence status was low to moderate during the pre-intervention and intervention periods (figure 1). Improvement in adherence to protocols was observed in both study arms (figure 2), however, these improvements were not significant ($p=0.24$ and $p=0.21$ for intervention and control arms respectively). Between the study arms, adherence to cord sepsis protocols were not significantly different ($p=0.89$ and $p=0.44$ for intervention and control arms respectively).

Table 4: Proportion of cord sepsis protocol items adhered to and total adherence score to cord sepsis protocols before and during intervention implementation

Protocol item	*Pre-trial period (N=13)		*Trial period (N=14)	
	Intervention n (%)	Control n (%)	Intervention n (%)	Control n (%)
Diagnosis				
Diagnosis documented	5 (100.0)	8 (100.0)	2 (100.0)	12 (100.0)
Signs and symptoms				
Cord assessed for odor, pus and wetness	3 (60.00)	2 (25.0)	1 (50.0)	9 (75.0)
Skin around cord assessed for redness	2 (40.0)	3 (37.5)	0 (0.0)	4 (33.3)
Assessment for fever	3 (60.0)	5 (62.5)	1 (50.0)	3 (25.0)
Heart rate, pulse rate, respiratory rate	2 (40.0)	7 (87.5)	2 (100.0)	11 (91.7)
Abdomen palpated	0 (0.00)	2 (25.0)	2 (100.0)	5 (41.7)
Conjunctiva or haemoglobin checked	0 (0.00)	1 (12.5)	2 (100.0)	1 (8.3)
Treatment				
Cord hygiene education given to mother	2 (40.0)	0 (0.0)	1 (50.0)	5 (41.7)
Antibiotics given	5 (100.0)	8 (100.0)	2 (100.0)	12 (100.0)
Monitoring of vitals	4 (80.0)	7 (87.5)	2 (100.0)	11 (91.7)
Total adherence score				
1	-	-	-	-
2	-	-	-	-
3	-	1 (12.5)	-	-
4	1 (20.0)	1 (12.5)	-	1 (8.3)
5	3 (60.0)	3 (37.5)	-	1 (8.3)
6	-	1 (12.5)	1 (50.0)	8 (66.7)
7	1 (20.0)	1 (12.5)	-	1 (8.3)
8	-	1 (12.5)	-	-
9	-	-	1 (50.0)	-
10	-	-	-	1 (8.3)

*There were 2,290 and 4,440 deliveries in the intervention and control arm respectively in the pre-trial period

*There were 2,494 and 5,425 deliveries in the intervention and control arm respectively in the trial period

Concurrent neonatal health activities in clusters

In the intervention clusters, there were two training programmes that were aimed at improving neonatal health outcomes during the intervention period while in the control clusters, training programmes aimed at improving neonatal health numbered more than 12 (table 5). Eight of these trainings (two in the intervention clusters and six in the control clusters) were intensive exercises aimed at improving new-born resuscitation and lasted six (6) to seven (7) days. These intensive training programmes were organized by a non-governmental agency. The rest of the training programmes in the control clusters usually lasted for one (1) day.

Table 5: Concurrent neonatal health improvement activities in study clusters during the intervention period

Arm	Cluster	Resource ranking	Total number of activities	Activities/topics discussed
Intervention	A	High	1	Making every baby count initiative
Intervention	B	Low	1	Making every baby count initiative
Control	C	High	>7	Policy on breast feeding and Hepatitis exposed babies; Assisted Vacuum Delivery; [†] Helping babies breathe training; Bi-weekly continuous professional training aimed at reducing the incidence of birth asphyxia and improving new-born resuscitation
Control	D	Low	5	Accelerating the achievement of Millennium Development Goal 4; Provider training; Helping babies breathe and essential care for every baby; 7th District Hospital provider training; Maternal and Neonatal audit workshop

[†]There were a total of at least 5 rounds of this training with a new group of midwives being trained each time

DISCUSSION

Adherence to asphyxia protocols

We observed fairly good adherence to asphyxia diagnosis protocol in this study. However, adherence to ‘signs and symptoms’ protocols was sub-optimal in both study clusters particularly in the pre-intervention period. Several of the ‘signs and symptoms’ assessments culminates in the APGAR score of neonates [32]. Not assessing these signs and symptoms can lead to inaccurate APGAR scores and inappropriate treatment of neonates who require resuscitation. Surprisingly, the APGAR scores were usually documented, thus one could argue that these signs and symptoms assessments were done but not documented because the natural focus is to treat the patient and not record [33], however, video recording of neonatal resuscitation has shown otherwise [33–35]. In the intervention clusters, adherence to treatment protocols worsened during the intervention period. Lack of knowledge about asphyxia as documented in Malawi could be an explanation for this observation [36]. The intervention (mCDMSS) was intended to bridge such knowledge gap, however, the absence of knowledge transfer (about the intervention) implies persistence of lack of knowledge and access gap in the intervention clusters possibly through suboptimal use of the intervention [37]. Monthly reminders concerning the availability of the mCDMSS for the use of health workers and, re-training of health workers at post in health facilities during supervisory visits by the project team, seem not to have been effective in

addressing the challenge of suboptimal use of the intervention [37]. Poor adherence as observed suggests focused support for health workers in the management of asphyxia in order to improve adherence to its protocols.

Adherence to jaundice protocols

Protocols for management of Jaundice were least adhered to among the three morbidity protocols understudied. There was poor adherence to protocol items for the theme ‘Signs and symptoms’ of jaundice in all clusters in both time frames. Of note is the assessment of neonates for convulsion and hypotonia. While the diagnosis of convulsion may be difficult in neonates [38, 39], hypotonia can be objectively assessed; the lack of documented evidence of assessment of these two critical signs of the central nervous system (CNS) is undesirable given disabilities associated with CNS complications (kernicterus) from jaundice [40]. Failure of the health workers to recognize at-risk infants and poor management of hyperbilirubinemia is a known cause of kernicterus [40]. The observed complete non-adherence to jaundice investigation protocols in the intervention arm during the pre-intervention period and poor adherence to these protocols in the intervention period could be due to the absence of the rapid tests or laboratory equipment to run these tests in the hospitals. Lack of required equipment is associated with non-adherence to protocols [41–43]. Neonates with mild jaundice may have been the ones not treated in this study; the absence of follow-up of jaundiced neonates has been previously documented and can be associated with dire consequences should the jaundice worsen [40]. We report indiscriminate use of antibiotics in cases of jaundice and this suggests the need for training on rational use of antibiotics in the study setting.

Adherence to cord sepsis protocols

Prevalence of cord sepsis in this study was low. This may be due to on-going interventions in the GHS to promote good cord hygiene practises [44, 45]. This low prevalence of cord sepsis may however lead to poor recall of assessments for cord sepsis cases as observed in the low adherence score for ‘signs and symptoms’ in this study. Local signs of cord sepsis are associated with mortality [46], therefore lack of assessment for these local ‘signs and symptoms’ can be potentially catastrophic for neonates as important complications from the cord infection that may warrant urgent attention or treatment modification may be missed. All cases of cord sepsis were treated with antibiotics which indicates that once a diagnosis is made, treatment will be initiated and the vitals of patients will be monitored as observed. The non-adherence to protocol item regarding cord hygiene education for caregivers presents a missed opportunity to teach cord hygiene in a setting where poor cord hygiene still exists in some communities [47]. Caregivers are known to be inappropriately educated by health workers about the morbidities, treatment and associated complications their wards may experience [40, 41].

Adherence to protocols in general

We found no case of complete adherence to protocols for all three morbidity types (asphyxia, jaundice, and cord sepsis) in this study using data of 257 neonates in the four district hospitals. A similar observation was made in another study where every resuscitation had an error [33]. Improvement in adherence to all three morbidity type protocols during the intervention period in both the control and intervention arms is possibly due to training programmes of the GHS and her partners in this area. Such efforts must be documented and reviewed to optimize their effect on improvement in neonatal healthcare services. Cluster C recorded the highest proportion of deliveries, and the highest work load but the best adherence to protocols before and during the intervention period. Low workloads can influence competence and high workloads can influence ability to respond adequately; the high workload of cluster C could have positively influenced the cluster's observed adherence to protocols.

Contribution of concurrent activities to improvements adherence to neonatal care protocols

“Even if you know everything you can forget” [48]. Frequent reminders, trainings and refresher trainings are a means to improve health outcomes in general. The observed higher improvements in adherence to protocols in the control clusters compared to the intervention clusters may reflect differences in knowledge across the intervention and control clusters resulting from the training programmes that were more frequently undertaken by hospital management, the GHS and her partners in control clusters. Commensurate efforts on neonatal health improvement training programmes in addition to the mCDMSS in the intervention clusters may have led to significant improvements in adherence to protocols in the intervention clusters as well.

Limitation

We sought to understand the pattern of health worker adherence to neonatal health protocols before and during the implementation of an mCDMSS, but our study has certain limitations. Differences in adherence to protocols by resource allocation type per study arm were not assessed due to the low prevalence of cases among the various subgroups. We did not evaluate the type of health care provider in relation to the care provided neither did we measure the factors that may have influenced adherence to neonatal protocols. Qualitative analyses of why the observed pattern of adherence occurred could have provided more insight into the results we have obtained and are recommended for future studies.

CONCLUSION

The question of whether mHealth interventions can improve adherence to neonatal health protocols in a low-resource setting remains difficult to answer from the evidence generated in this study, but, during the study, adherence improved irrespective of intervention allocation.

This was particularly observed for the control clusters, and concurrent neonatal improvement interventions that took place in the study clusters may explain this effect. It is therefore essential to document and review all ongoing interventions whose goals are to improve health worker adherence to neonatal health protocols in study settings. Concurrent neonatal health improvement activities must be taken into account in similar mHealth evaluations. Future studies should relate adherence with patient outcomes.

DECLARATIONS

Ethics approval and consent to participate

This study was approved by the Ghana Health Service Ethics Review Committee (approval number number: GHS-ERC: 04/09/16). Institutional heads of the various hospitals consented to participate in this study.

Competing interests

None declared.

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Authors contribution

HBA, KKG, MAC, KAG, and EA designed and performed the study. HBA drafted the manuscript and KKG, EA reviewed the manuscript. IAA, DEG, MAC, KAG, JBR, provided critical comments on the review of the manuscript. All authors have read and approved the final manuscript.

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SUPPLEMENTARY INFORMATION

Appendix I: Type of medical records from which data was extracted before and during intervention implementation

*Type of medical record	Morbidity type		
	Asphyxia n (%)	Jaundice n (%)	Cord sepsis n (%)
Admissions and discharge book	99 (70.2)	63 (70.8)	20 (74.5)
Asphyxia book	8 (5.7)	-	-
Clinical notes	2 (1.4)	2 (2.3)	-
Delivery book	41 (28.1)	1 (1.1)	1 (3.7)
Lab results	-	1 (1.1)	-
Neonatal intensive care unit form	5 (3.6)	-	-
New-born examination form	1 (0.7)	-	-
Nurses notes	26 (18.4)	55 (61.8)	12 (44.4)
Patient folder	63 (44.7)	19 (21.2)	16 (59.30)
Patient information sheet	14 (9.9)	10 (11.2)	6 (22.2)
Postnatal book	1 (0.7)	-	27 (100.0)
Referral book	5 (3.6)	-	1 (3.7)
Regulation form	3 (2.1)	-	-
Report book	100 (70.9)	57 (64.0)	11 (40.7)
Summary or Labour form	31 (22.0)	9 (10.1)	4 (14.8)

*Medical records include both Ghana Health Service recognized registers and registers or books used locally in the hospitals to collect data as deemed relevant by the individual hospital management

Appendix IIa: Proportion of 'don't know' responses to asphyxia protocol items before and during intervention implementation

Protocol item	*Pre-intervention period		*Intervention period	
	Intervention n (%)	Control n (%)	Intervention n (%)	Control n (%)
Diagnosis				
Diagnosis documented	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Signs and symptoms				
Description of difficulty in breathing	0 (0.0)	0 (0.0)	0 (0.0)	6 (12.0)
Heart rate neonate recorded	0 (0.0)	0 (0.0)	3 (20.0)	0 (0.0)
Tachycardia	0 (0.0)	0 (0.0)	3 (20.0)	1 (2.0)
Respiratory rate	0 (0.0)	0 (0.0)	3 (20.0)	1 (2.0)
Colour of baby	0 (0.0)	0 (0.0)	3 (20.0)	1 (2.0)
APGAR scores written	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Liquor assessed for meconium staining	0 (0.0)	0 (0.0)	3 (20.0)	9 (17.7)
Treatment				
Airway of neonate cleared through suction	0 (0.0)	0 (0.0)	3 (20.0)	6 (11.8)
Warmth provided (using incubator or wrapping)	0 (0.0)	0 (0.0)	2 (20.0)	3 (3.9)
Oxygen given / Bag and mask resuscitation	0 (0.0)	0 (0.0)	3 (20.0)	1 (2.0)
Total missing data	0 (0.0)	0 (0.0)	23 (13.9)	28 (5.0)

Appendix IIb: Proportion of 'don't know' responses to jaundice protocol items before and during intervention implementation

Protocol item	¹ Pre-intervention period		¹ Intervention period	
	Intervention n (%)	Control n (%)	Intervention n (%)	Control n (%)
Diagnosis				
Diagnosis documented	0 (00.0)	0 (0.00)	0 (0.0)	0 (0.00)
Signs and symptoms				
Duration of jaundice stated	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Temperature checked	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Assessed for vomiting	0 (0.0)	0 (0.0)	0 (0.0)	4 (8.0)
Assessed for episode(s) of convulsion	0 (0.0)	0 (0.0)	0 (0.0)	4 (8.0)
Assessed for poor feeding	0 (0.0)	0 (0.0)	0 (0.0)	4 (8.0)
Assessed for excessive crying	0 (0.0)	0 (0.0)	0 (0.0)	4 (8.0)
Assessed for hypotonia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Investigation				
Full blood count done	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood grouping checked	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Serum bilirubin checked	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Samples for blood cultures taken	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Samples for G-6-P-D deficiency screen taken	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Treatment				
Phototherapy given or sunbath advised	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Total missing data	0(0.0)	0 (0.0)	0 (0.0)	16 (2.3)

Appendix IIc: Proportion of 'don't know' responses to cord sepsis protocol items before and during intervention implementation

Protocol item	¹ Pre-intervention period		¹ Intervention period	
	Intervention ⁵ n (%)	Control ⁸ n (%)	Intervention ² n (%)	Control ¹² n (%)
Diagnosis				
Diagnosis documented	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Signs and symptoms				
Cord assessed for odour, pus and wetness	0(0.0)	1 (12.5)	1 (50.0)	2 (16.7)
Skin around cord assessed for redness	0 (0.0)	2 (25.0)	1 (50.0)	8 (66.7)
Assessment for fever	0(0.0)	1 (12.5)	0 (0.0)	0 (0.0)
Heart rate, pulse rate, respiratory rate	0(0.0)	1 (12.5)	0 (0.0)	1 (8.3)
Abdomen palpated	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctiva or haemoglobin checked	0 (0.00)	0 (0.0)	0 (0.0)	2 (16.7)
Treatment				
Cord hygiene education given to mother	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Antibiotics given	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Monitoring of vitals	0 (0.0)	1 (8.3)	0 (0.0)	0 (0.0)
Total missing data	0 (0.0)	6 (7.5)	2 (10.0)	13 (10.8)



CHAPTER 6

How and why frontline health workers (did not) use a multifaceted mHealth intervention to support maternal and neonatal health care decision-making in Ghana

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ABSTRACT

Introduction

Despite increasing use of mHealth interventions, there remains limited documentation of ‘how and why’ they are used and therefore the explanatory mechanisms behind observed effects on beneficiary health outcomes. We explored ‘how and why’ an mHealth intervention to support clinical decision-making by frontline providers of maternal and neonatal healthcare services in a low-resource setting was used. The intervention consisted of phone calls (voice calls), text messaging (SMS), internet access (data) and access to emergency obstetric and neonatal protocols via an Unstructured Supplementary Service Data (USSD). It was delivered through individual-use and shared facility mobile phones with unique Subscriber Identification Module (SIM) cards networked in a Closed User Group.

Methods

A single case study with multiple embedded sub-units of analysis within the context of a cluster randomized controlled trial of the impact of the intervention on neonatal health outcomes in the Eastern Region of Ghana was performed. We quantitatively analyzed SIM card activity data for patterns of voice calls, SMS, data and USSD. We conducted key informant interviews and focus group discussions with intervention users and manually analyzed the data for themes.

Results

Overall, the phones were predominantly used for voice calls (64%), followed by data (28%), SMS (5%) and USSD (2%) respectively. Over time, use of all intervention components declined. Qualitative analysis showed that individual health worker factors (demographics, personal and work-related needs, perceived timeliness of intervention, tacit knowledge), organizational factors (resource availability, information flow, availability, phone ownership), technological factors (attrition of phones, network quality) and client perception of health worker intervention usage explain the pattern of intervention use observed.

Conclusion

How and why the mHealth intervention was used (or not) went beyond the technology itself and was influenced by individual and context specific factors. These must be taken into account in designing similar interventions to optimize effectiveness.

Keywords

mHealth, maternal health, neonatal health, clinical decision-making, low-resource setting

INTRODUCTION

Background

The use of mobile technology (mHealth) based interventions to support delivery of healthcare services has become increasingly popular in low-resource settings where it is envisaged as a tool to improve health worker efficiency and health service utilization.[1–3] MHealth has been applied in diverse areas such as, the care of people living with HIV/AIDS, maternal and child health, tuberculosis management, vaccination programmes, data collection, provider-to-provider communication, provider-to-client communication and clinical decision-making support.[2,4–8]

While there is some literature about how mHealth interventions were utilized,[9,10] information regarding why these patterns of use were observed are scarce. MHealth interventions are expensive to start up [11] and expensive to maintain. Their potential to bridge the gap in the provision of quality healthcare services in low-resource settings however, makes them appealing. Despite the attractiveness of mHealth interventions, evaluations of their effectiveness on health outcomes have shown mixed results.[12] Where mHealth interventions made positive impact on health outcomes, gains observed were only marginal.[13–15] To increase the effectiveness of mHealth interventions on health outcomes requires improvement in their design. Knowledge of ‘how and why’ mHealth interventions are utilized (or not) to produce their observed effects can inform the much needed design improvements.

In Ghana, a lower middle-income country, maternal and neonatal mortality rates (319 per 100,000 live births [16] and 25 deaths per 1,000 live births [17] respectively) are still unacceptably high despite recent improvement. Following initial formative work in the Greater Accra Region to understand frontline health worker (FHW) decision-making for mothers and newborns,[18] the Accelerate Project developed an mHealth intervention whose components were based on suggestions for clinical decision-making support by respondents in the formative study.[18] The mHealth intervention thus aimed to support improved clinical decision-making among FHWs to further reduce maternal and neonatal mortality.[19,20] After piloting and finalizing the development of the intervention in the Greater Accra Region of Ghana with the active engagement of FHWs in that region, it was evaluated for its effects on neonatal mortality in a cluster randomized controlled trial (CRCT) in the neighbouring Eastern Region of Ghana.

Description of the intervention

The mHealth intervention consisted of 4 components- phone calls, text messaging, access to the internet and access to an unstructured supplementary service data (USSD) that provided emergency protocols in response to selection from a short code drop down menu. Unstructured supplementary service data is a communications protocol that allows two-way exchange of

data between phone users and information linked to the pre-designed short codes stored on a remote computer of a telecommunications company. This makes USSD more interactive than text messaging. Each response message linked to a short code is limited to a length of 150 to 182 alpha numeric characters. The messages in this intervention were created by the design team of frontline health workers, family physicians, obstetricians and paediatricians in the Greater Accra Region, drawing on the Ghana Safe Motherhood protocols. All four components of the intervention were part of a single composite intervention delivered on a non-smart mobile phone (table1). Health workers were expected to use the phones primarily to access neonatal and maternal health emergency protocols via the USSD and obtain additional support from colleagues and the internet via the other intervention components. Each project mobile phone had a unique Subscriber Identification Module (SIM) card. All the SIM cards were networked in a Closed User Group (CUG) that allowed free and unlimited access to the USSD and voice calls between all the unique SIM cards registered to the intervention. In this regard, all intervention users were members of the CUG. Free credit on the phones also allowed calling and text messaging numbers outside the CUG; thus FHWs could use the phones for personal purposes. Monthly reminders regarding the availability of the USSD protocols were sent via text-messaging to FHWs.

Each midwife at post in each health facility during the CRCT baseline assessment was provided with one mobile phone for their personal use labelled 'individual-use' phones. The CRCT baseline assessment showed that overall, 30% of health facilities in the intervention arm (i.e. all intervention districts combined) already had a shared functional work phone (range was 13% to 55% by district). The project provided one mobile phone as a shared facility phone for all cadres of frontline providers of maternal and neonatal healthcare services in all facilities in the intervention districts. These shared facility phones were often received by the head of the facility's maternal unit or a community health officer (CHO) on behalf of the health facility. All mobile phones were distributed during training sessions organized by the researchers prior to the start of the intervention. During the training sessions, FHWs were taught how to use the intervention. Frontline health workers were assumed to be familiar with the basic functioning of a mobile phone (making calls, texting, and accessing the internet) so the trainings focused on how to use the USSD.

Each of the eight local government districts that formed the intervention clusters (table 2) had at least one district hospital and varying mix of Health Centres (HCs) and Community Health Planning and Services (CHPS) facilities. In all, 312 mobile phones were distributed to the eight intervention clusters that participated in the CRCT. Seventy-four (74) were shared-use phones and the rest (238) were individual-use phones. Five of the individual-use phones (including their SIM cards) could not be traced back to the FHWs who received them at the start of the

intervention as the users did not sign for them and efforts to reach these SIM card numbers were futile. These five SIM cards could also not be traced on the Vodafone database as they never logged onto the Vodafone server. A total of 307 SIM cards could thus be traced back to the facilities and FHWs who received them. Overall, hospitals, health centres and CHPS (and maternity homes) received 190, 66 and 51 SIM cards respectively. Three extra SIM cards were assigned to the research team to facilitate communication with the FHWs and were excluded in analysis.

Research Question

Despite several documentations of use of mHealth interventions and some evaluations, very few studies document 'how and why' these interventions were utilized (or not).[9,10] Previous multifaceted mHealth interventions have not included as many options for accessing clinical decision-making support [21–23] as the Accelerate Project's mHealth intervention. In this study, we asked the question 'how and why' was the Accelerate mHealth intervention used (or not)? Our specific objective was to describe patterns of use of the different components of the mHealth intervention by FHWs and explore the reasons for the observed patterns of use.

Study context

Ghana is a lower middle-income country with a population of about 28 million people. Her gross national income per capita in 2016 was estimated at \$1,390.00 (US dollars)[24] and her per capita health expenditure in 2015 was \$79.59 (US dollars).[25] Like many low and low- and middle-income countries (LMIC), Ghana faces constraints with her health workforce. Her estimated number of doctors and nurses/midwives per 1,000 people in 2010 was 0.096 and 0.926 respectively.[24] The country is further characterized by poor maternal and neonatal health indices which have improved over time but still fell short of the Millennium Development Goals (MDGs). During the era of the MDGs (1990 to 2015), Ghana's maternal mortality ratio steadily declined from 634 per 100,000 live births to 319 per 100,000 live births.[26] Neonatal mortality, however, declined marginally from 30 per 1,000 live births [17,27] to 25 per 1,000 [17] live births from 1999 to 2017. The study region, the Eastern Region lies in the south of Ghana and its population is approximately 10.7% of the total national population [28] making it the third most populous region in Ghana. The Eastern Region ranks fourth in terms of high neonatal mortality rate in Ghana [29] and stands to benefit from interventions aimed at improving neonatal healthcare. Table 2 summarizes meso-context (health facilities, human resources, workload i.e. deliveries per midwife) of the 8 intervention districts.

Table 1: Components of the intervention

Intervention component	Description
Cell phones	Distribution of the non-smart mobile phones by the research team to health facilities in the intervention clusters (districts) either as a shared-use phone or as individual-use phone. Each midwife was provided an individual-use phone and each health facility had a shared-use phone
Closed User Group (CUG)	A network of SIM cards with unlimited access to make free phone calls to other SIM cards within the network. All intervention users constituted membership of the CUG
Text messaging	Sending of up to 100 free SMS per month to SIM cards in as well as outside the CUG
Data bundle	System that provides up to 25 megabytes of free data per month to the project SIM cards
Monthly credit top-up	*An automated system from the telecommunication company that topped up 2.50 cedis (0.70 US dollars) worth of Vodafone credit on project SIM cards each month. This top up credit could be used at the discretion of the health worker for making calls, texting or browsing the internet beyond the limits set for text messaging and data bundle aforementioned
Reminders	Monthly reminders sent to the intervention users reminding them of the availability of the USSD protocols
Training	Health workers were trained on how to use the intervention firstly at a group gathering in each intervention district capital before the start of the cluster randomized controlled trial and then at least once during monitoring visits in their individual health facilities during intervention implementation
Unstructured Supplementary Service Data (USSD)	A communications protocol that allows a two-way exchange of data between a phone user and pre-programmed information linked to short codes stored on a remote computer of a telecommunication company. This makes it more interactive than text messaging. Each response message linked to a short code is limited to a length of 150 to 182 alpha numeric characters. In the intervention districts it was used for requesting and receiving text-message based standard emergency obstetric and neonatal protocols on the request of a health worker. Access to the USSD was limited to only project SIM cards (CUG members). For CUG members access to the USSD was free and with no limits to the number of times the USSD could be accessed

*Exchange rate of 1 US dollar = 3.56 cedis is based on the Bank of Ghana exchange rate at start of the intervention in August 2015

METHODS

Study design

This study design was an exploratory and explanatory single case study with multiple embedded units of analysis. The case was defined as 'how and why a mobile phone based frontline health worker clinical decision-making support intervention was used (or not)'. Each embedded sub-unit of analysis was defined as 'a district in which the intervention was deployed'. This case study was conducted within the broader context of a CRCT of the impact of the intervention on neonatal

Table 2: Background characteristics of clusters (districts) in the Eastern Region of Ghana at intervention baseline

District (Cluster)	Number of health facilities			Demographic distribution of health facilities		Number of midwives	*Number of doctors	Number of deliveries per midwife	**Number of project phones received	
	Hospital	Health centers	CHPS	*Maternity home	Remote (n, %)					Non-remote (n, %)
Afram Plains North	1	1	7	0	7 (77.8)	2 (22.2)	14	1	80.0	21
Asuogyaman	1	7	3	0	6 (54.5)	5 (45.5)	18	3	130.4	29
Birim Central	3	2	9	1	6 (40.0)	9 (60.0)	42	9	99.0	57
Denkyembaour	2	3	3	0	5 (62.5)	3 (37.5)	33	-	94.8	41
Kwaebibiraem	1	3	2	0	3 (50.0)	3 (50.0)	19	2	107.6	25
Kwahu West	1	8	1	1	4 (36.4)	7 (63.6)	38	9	101.6	49
Lower Manya Krobo	3	2	0	1	1 (16.7)	5 (83.3)	47	10	75.0	54
West Akim	1	3	3	1	4 (50.0)	4 (50.0)	25	3	96.4	31

* Includes both private and public hospitals

** Includes only private maternity homes

Number of doctors from main district hospital not provided by hospital management in the case of Denkyembaour district

∞ This may differ slightly from the sum of the number of midwives and the number of health facilities in the cluster as some individual-use phone could not be traced as in the case of Afram Plains North and West Akim districts

health outcomes in sixteen districts in the Eastern Region of Ghana randomized into 8 intervention and 8 control districts (clusters). Each of the eight intervention districts was treated as an embedded sub-unit of analysis of the case study. The CRCT has been described in detail elsewhere.[20] A cluster in the CRCT and in this study is a district. Ghana is divided into 10 regions, each of which is further divided into geographic local government administrative areas known as districts.

Data collection methods and sampling

We used mixed quantitative and qualitative methods of data collection in each of the eight districts. Data sources included routine Vodafone call log data, key informant interviews (KIIs) with FHWs and facility managers, and focus group discussions (FGDs) with FHWs.

Vodafone call log data

The call log data was routinely collected by Vodafone Ghana, the telecommunication company that provided technical support for the intervention throughout the CRCT. We analysed all mobile call detail record subtypes (mCDRs) as logged on the Vodafone archived database regarding utilization of the project's SIM cards for any purpose (phone calls, texting, accessing the USSD or use of data) during the first 8 months of an 18-month intervention period. Data regarding closed user group (CUG) communication was included in this archived data. Prior to the data extraction, phone numbers assigned to the various users were collated such that each intervention user (FHW), the health facility as well as the cluster the user worked in was documented and coded in the Vodafone database. This ensured that SIM cards and phone numbers could be traced back to the cluster, health facility and FHW using the project phones.

Focus group discussions and Key informant interviews

Focus group discussions and KIIs aimed to provide explanatory insights into the patterns of use of the phones observed from analysing the call log data. We initially thought that perspectives and experiences of facility nurse managers might be different from those of frontline midwives. Since there were usually only one or two facility nurse managers to several frontline midwives, we planned to hold KIIs with the facility nurse managers and FGDs with the frontline midwives. The FGDs were to stimulate frank discussions of experiences and opinion about the intervention, while KIIs were used to obtain insight on how and why the intervention was used from a managerial view and shared-phone user's experience. No theories regarding the observed pattern of use of the intervention were postulated prior to qualitative interviews.

We conducted the qualitative interviews immediately after the CRCT closed to avoid introducing a confounding element into the intervention. We considered it important to reflect the 3 levels of healthcare delivery at district level in Ghana i.e. hospitals, Health Centres and Community Health

Planning and Services compounds and zones and the differences between them. We therefore aimed to purposively select a facility from each of the three levels in each of the eight districts. Within each of the three levels in a given district, there was no clear indication of differences that required purposive selection. We therefore randomly selected one health facility from the several at each level within each of the eight districts to participate in KII, and two health facilities from each level to select respondents to participate in FGD. We sampled health facilities for KIIs and FGDs using a random sequence generator in Microsoft Excel [30] and sampled health facilities for KIIs first. After health facility selection for KIIs, the head of the maternity unit and the holder of a shared-use phone in hospitals and HCs were purposively sampled to be interviewed. In the CHPS compound, only the head of the maternity unit was interviewed as typically each CHPS compound had only one-shared use phone allocated to them by the project team.

Regarding FGDs, health facilities already selected for KIIs were excluded from the sample except where there were very few health facilities in a cluster. To ensure representation of health facilities from all levels of the healthcare system in FGDs, where there was one hospital in a cluster, the hospital was purposively selected to participate in FGDs. In instances where the same health facility was selected for both FGD and KII, the respondents for FGDs and KIIs were different. Following sampling of health facilities for FGDs, any FHW or midwife who had knowledge about the use of the project mobile phone was invited to participate in FGDs; the decision as to who exactly would attend the FGDs was made by the head of the health facility sampled.

At least one focus group discussion and two KIIs were scheduled to be conducted in each of the eight districts (clusters) at a location arranged by the district health management team. The arranged venues were usually the district health administration office or hospital conference rooms in the cluster. We collected all qualitative data from April 9, 2018 until April 27, 2018. Each FGD consisted of FHWs from the different health facilities sampled within the district. We aimed to keep conducting FGDs and KIIs until no new themes were emerging (saturation). We estimated that this would mean about 4 – 8 FGDs[31] and 6 – 10 KIIs. We analysed the data from each interview immediately after it closed to inform whether to keep going or not. By the time we had completed data collection and analysis of one FGD in each of the 8 districts, we realized we were finding the same themes in the analysis. We therefore stopped the FGDs. In the case of the KIIs, by the time we had completed 9 KIIs in 3 districts we realized the themes were the same across the KIIs, across the districts and between the KIIs and the FGDs. We therefore stopped the KIIs and invited planned KII respondents in the remaining 5 districts to join their district FGD. Three of the investigators (HBA, LY, and IAA) worked with one research assistant to collect the qualitative data. All FGDs and KIIs were conducted face-to-face and audiotaped to facilitate transcription of data collected with notes being taken by HBA as well. All KIIs and

FGDs were conducted and transcribed in English. The KIIs lasted on average 28 minutes, while FGDs lasted averagely 1 hour 26 minutes.

Ethics approval for this study was obtained from the Ghana Health Service Ethics Review committee (Approval number: GHS-ERC: 04/09/16) before this study commenced. Written informed consent was obtained from all FGD and KII participants prior to interviews and FGDs. No respondent declined participation in this study.

Data analysis

Qualitative data analysis was done on a rolling basis after each FGD or KII. All data analysis was initially done by each of the eight districts for themes, commonalities and contrasts. The data was then compared across the eight districts for commonalities and contrasts. We triangulated the quantitative findings from the Vodafone call log data analysis and the qualitative findings from the FGD and KII.

Vodafone Call log

Data was checked for errors and exported from Excel spreadsheets [30] to Stata version 13 [32] for cleaning and analysis. The category and the number of staff in maternity homes and CHPS are similar. Both facility types usually have 1-2 midwives who run the health facility post assisted by 2-3 community health officers to provide antenatal, neonatal and conduct routine normal uncomplicated deliveries. Some CHPS may however not have a midwife at post; in such situations deliveries are only conducted if a pregnant woman presents in second stage of labour with the head of the baby in the perineum. In the case of some maternity homes, trained traditional birth attendants who work under the supervision of a midwife may be present. Due to the similarities in organizational structure, personnel and health services provided by CHPS and maternity homes participating in this study, the call log data from these two facility types were combined for analysis. We further classified health facilities into two groups of remote and non-remote areas based on access. Remote facilities were either located more than 30 minutes' walk, or more that 15 minutes motor-bike ride from the main district township, and had poor road access (uneven and untarred roads overcrowded with weeds and shrubs) leading to them. Non-remote health facilities were either located within 30 minutes' walk, or 15 minutes motor-bike ride from the main district township, and had good road access leading to them. Mobile call detail record subtypes (mCDRs) for all explanatory variables of interest (clusters, level and location of health facility, type-of-phone (individual-use or shared-use)) were analysed and expressed in numbers and percentages. Analyses of the mCDRs was performed for the combined 8 months data and also disaggregated into monthly intervals for each explanatory variable. Chi-square tests were applied to these analyses to assess the significance of the observed pattern of intervention usage. The SIM cards that utilized these mCDRs were analysed and expressed as

percentages. Descriptive analysis of the CUG communication within and across each category of explanatory variable was also performed and expressed as number of voice and SMS mCDRs records and their percentages. Chi-square and Fisher's exact tests were applied to these analyses to assess the significance of the pattern of CUG communication. To further understand how the CUG communication was utilized in each cluster, we identified SIM cards that used the CUG and the health facilities they communicated with. No tests were applied to this in-depth analysis as there were several empty cells.

Focus group discussions and Key informant interviews

The voice recordings were transcribed during and continued after data collection. Transcriptions were done verbatim by non-data collectors. Each transcription was cross-checked by two persons (data collectors- including HBA). Data were manually analysed by thoroughly reading each transcript to identify themes, commonalities and contrasts emerging from the data that shed insights into the patterns of use of the intervention observed from the Vodafone call log data and why and how these patterns occurred using an inductive approach. Three of the study investigators performed the data analysis. Consensus on emerging themes was reached if a minimum of two of the data analyst agreed on an emerging theme.

RESULTS

In aggregate, 94% of the 307 SIM cards ever accessed the intervention during the first 8 months of intervention implementation. Of the 307 SIM cards, 90%, 87%, 73% and 74% ever used voice, SMS, data and USSD mCDRs respectively. The number of SIM cards accessing the intervention declined marginally each month from 84% to 77% in the first seven months. In the eighth month, the number of SIM cards accessing the intervention abruptly declined to 67%.

Pattern of use of different intervention components

The 307 SIM cards logged unto the Vodafone server 127,668 times altogether during the intervention period. Most of the time, the SIM cards were used to make phone calls (voice mCDRs -64%), access the internet (data mCDRs - 28%), send SMS (5%) and to access the USSD protocols (2%) (table 3). This pattern of utilization of the intervention components was observed when the Vodafone call log was analyzed by district (except in the Asuogyaman district), category of health facility (hospital, CHPS or HCs), location of the health facility (remote or non-remote) and the type of phone used (individual-use or shared-use phone) (See table 3). In the Asuogyaman district, the difference in pattern of utilization of the intervention components was that, the frequency of use of voice and data mCDRs were similar. Shared-use phones and phones designated to remotely located health facilities used the intervention less often compared to individual-use phones and non-remotely located health facilities.

When the data was analyzed month by month for trends in utilization of the intervention, it showed trends that were fairly steady in the first six months with some increase in use of voice calls around the third month and then an abrupt decline in all use around the sixth month. Figure 1 summarizes these patterns of use of the different components of the intervention over time observed in all the eight intervention districts.

Figure 1: Trend in mobile call detail record use during the first 8 months of intervention implementation

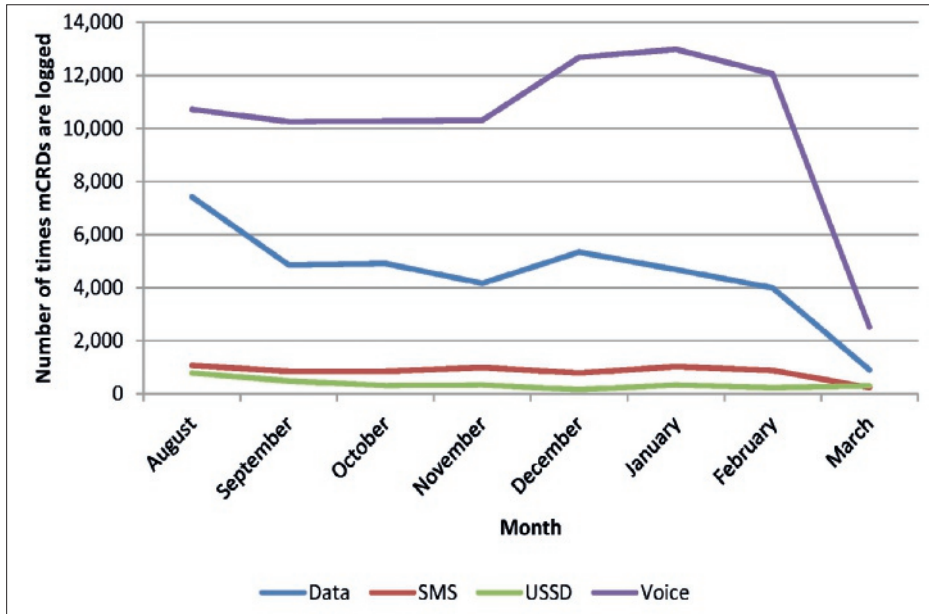


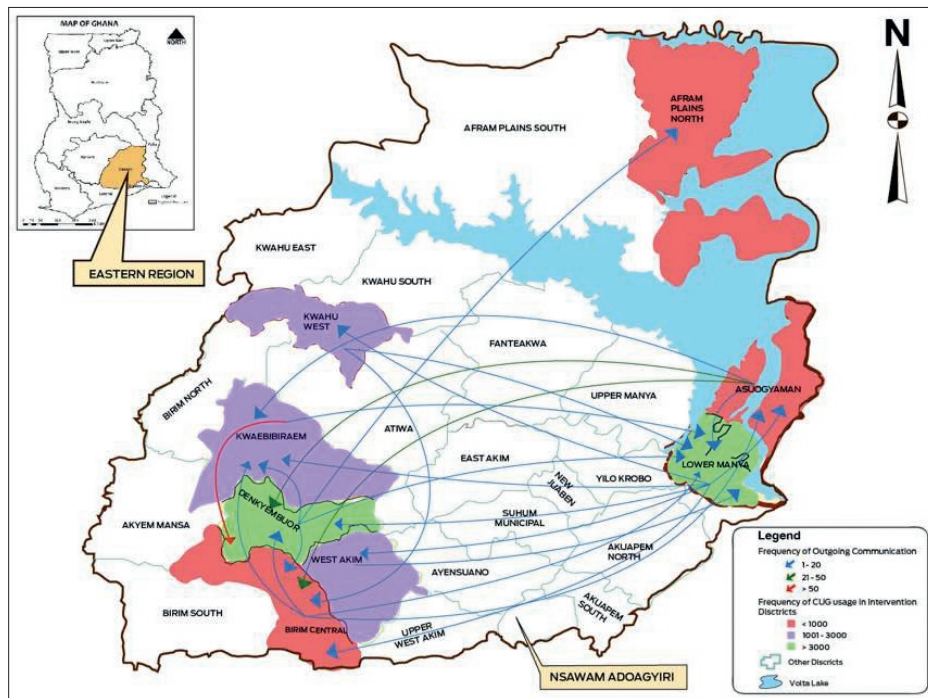
Table 3: Pattern of mobile call detail record subtype use in the first 8 months of intervention implementation

Variable	Data		SMS		USSD		Voice		*Total		Total frequency per phone
	Frequency(%)		Frequency(%)		Frequency(%)		Frequency(%)		Frequency(%)		
District (Cluster)											
Afram Plains North	929 (13.2)		414 (5.9)		290 (4.1)		5,431 (76.9)		7,064 (5.5)		336.4
Asuogyaman	5,990 (44.9)		1,056 (7.9)		372 (2.8)		5,922 (44.4)		13,340 (10.5)		460.0
Birim Central	6,191 (33.1)		890 (4.8)		549 (2.9)		11,089 (59.2)		18,719 (14.7)		328.4
Denkyembaour	4,028 (24.5)		1,219 (7.4)		195 (1.2)		11,003 (66.9)		16,445 (12.9)		401.1
Kwaebibiraem	2,487 (29.2)		289 (3.4)		206 (2.4)		5,524 (64.9)		8,506 (6.7)		340.2
Kwahu West	5,036 (21.9)		744 (3.2)		607 (2.6)		16,622 (72.2)		23,009 (18.0)		469.6
Lower Manya Krobo	8,096 (29.2)		1,757 (6.3)		305 (1.1)		17,603 (63.4)		27,761 (21.7)		514.1
West Akim	3,517 (27.4)		304 (2.4)		399 (3.1)		8,604 (67.1)		12,824 (10.0)		413.7
Type of health facility											
Hospitals	25,144 (28.4)		4,574 (5.2)		1,841 (2.1)		58,342 (64.1)		89,901 (70.4)		6,915.5
Health Centres	6,276 (30.6)		1,003 (4.9)		568 (2.8)		12,648 (61.7)		20,495 (16.1)		706.7
CHPS & Maternity homes	4,854 (28.1)		1,096 (6.4)		514 (3.0)		10,808 (62.6)		17,272 (13.5)		539.8
Type of phone											
Individual-use	30,613(29.0)		4,914 (4.7)		2,311 (2.2)		67,573 (64.1)		105,411 (82.6)		452.4
Shared-use	5,661 (25.4)		1,759 (7.9)		612 (2.6)		14,225 (63.9)		22,257 (17.4)		300.8
Demographic location											
Non-remote	31,233 (29.0)		5,392 (5.0)		2,306 (2.1)		68,730 (63.8)		107,661 (84.3)		2,833.2
Remote	5,041 (25.2)		1,281 (6.4)		617 (3.1)		13,068 (65.3)		20,007 (15.7)		555.8

*Column percentages presented

Pattern of Closed User Group communication

Figure 2: Mapping of pattern of closed user group communication via phone calls and text messaging among clusters



This pattern of closed user group communication via phone calls and text messaging is significant (p -value < 0.001). The district colours indicate the frequency of closed user group communication per cluster. The arrows show the direction of communication flow from one cluster to the other. The colour of the arrows indicate the frequency of inter-cluster communication with a given cluster

Fifteen percent of the 88,471 records of voice and SMS communication with the projects phones were within the CUG. Nearly all CUG were voice mCDRs (97%). At cluster level, majority of CUG communication was intra-cluster related (p -value < 0.001) (table 4). The mean proportion of intra-cluster CUG communication was 0.96. Figure 2 maps the pattern of closed user group (CUG) communication between the clusters indicating inter-cluster communication, its frequency and the proximity or otherwise of clusters involved in the communication. Although CUG communication among the health facility types was varied (p -value < 0.001), there was little CUG communication across the different levels of health facilities. For example there was little CUG communication between hospitals and HCs or between HCs and CHPS. With regard to health facility location, while non-remote areas communicated mostly (99% of the time) within themselves (p -value < 0.001), remote areas communicated with other remote areas as often as they communicated with non-remote areas. Within the CUG, the pattern of shared-use and

individual-use phone communication was not significantly different (p -value= 0.065). Details of SIM cards that utilized the CUG communication system in each cluster can be found in appendix 1a to 2.

Characteristics of FGDs and KII participants

Eight FGDs with a total of 54 respondents and nine (9) KIIs were conducted in total (table 5). Respondents were mainly midwives or community health nurses aged 26 to 76 years (mean age 38 years; $SD=11$ years). Five respondents were male, the rest were female. Majority of respondents (31) held a certificate in midwifery or community health nursing as educational qualification. Most respondents maintained their key roles at work during the intervention period, although 12 of them changed work posts.

Why were the patterns of use of intervention observed?

The themes that emerged from our FGDs and KIIs analysis explaining the observed pattern of use of the intervention are summarized in figure 3. The text that follows expands on each of these themes.

Table 4: Closed- user- group voice and SMS mobile call detail record communication using project mobile phones

Variable	Voice			SMS		
	Intra-communication Frequency (%)	Inter-communication Frequency (%)	p-value for X ² test	Intra-communication Frequency (%)	Inter-communication Frequency (%)	p-value for Fisher's exact test
District (Cluster)	35 (100.0)	0 (0.0)	<0.001	-	-	
Afram Plains North						
Asuogyaman	437 (86.2)	70 (13.8)		215 (99.1)	2 (0.9)	<0.001*
Birim Central	636 (96.1)	26 (3.9)		20 (90.9)	2 (9.1)	
Denkyemhour	3,781 (95.2)	192 (4.8)		42 (97.7)	1 (2.3)	
Kwaebibiraeam	1,306 (92.8)	102 (7.2)		24 (100.0)	0 (0.0)	
Kwahu West	1,406 (99.3)	10 (0.7)		30 (100.0)	0 (0.0)	
Lower Manya Krobo	3,743 (98.7)	48 (1.3)		73 (90.1)	8 (7.9)	
West Akim	1,248 (99.8)	2 (0.2)		14 (93.3)	1 (6.7)	
Type of health facility						
Hospitals	12,460 (99.0)	61 (1.0)	<0.001	416 (100.0)	0 (0.0)	<0.001
Health Centres	156 (48.9)	163 (51.1)		1 (14.3)	6 (85.7)	
CHPS & Maternity homes	81 (57.0)	61 (43.0)		9 (100.0)	0 (0.0)	
Type of phone						
Shared-use	13 (2.8)	452 (97.2)	0.065	0 (0.00)	4 (100.0)	1.00
Individual-use	11,993 (95.4)	584 (4.6)		418 (97.7)	10 (2.3)	
Demographic location						
Remote	164 (49.4)	168 (50.6)	<0.001	2 (100.0)	0 (0.0)	<0.001
Non-remote	101 (0.8)	12,777 (99.2)		430 (100.0)	0 (0.0)	

*Chi-square test performed in this case

Table 5: Characteristics of respondent of focus group discussions and key informant interviews

District (Cluster)	Number of Participants	*Age (years)	Professional training			Educational qualification		Number of respondents who received a project phone, n (%)		
			[¶] KII	Midwife	[†] CHO	[†] Other	[‡] Certificate		Diploma in nursing	Degree in nursing
Afram Plains North	3	-	30.0	1	2	-	1	2	-	1 (33.3)
Asuogyaman	6	3	38.0	4	5	-	7	-	2	5 (55.6)
Birim Central	6	-	29.0	4	2	-	4	2	-	5 (83.3)
Denkyemboour	6	-	31.5	4	2	-	3	2	1	6 (100.0)
Kwaebibiraem	6	-	45.0	6	-	-	5	1	-	5 (83.3)
Kwahu West	11	-	34.0	7	1	3	8	2	1	7 (63.6)
Lower Manya Krobo	5	4	48.0	7	1	1	8	1	-	8 (88.9)
West Akim	11	1	39.5	9	2	1	9	3	-	8 (66.7)

*Median age reported

*Focus group discussion

**Key informant interview

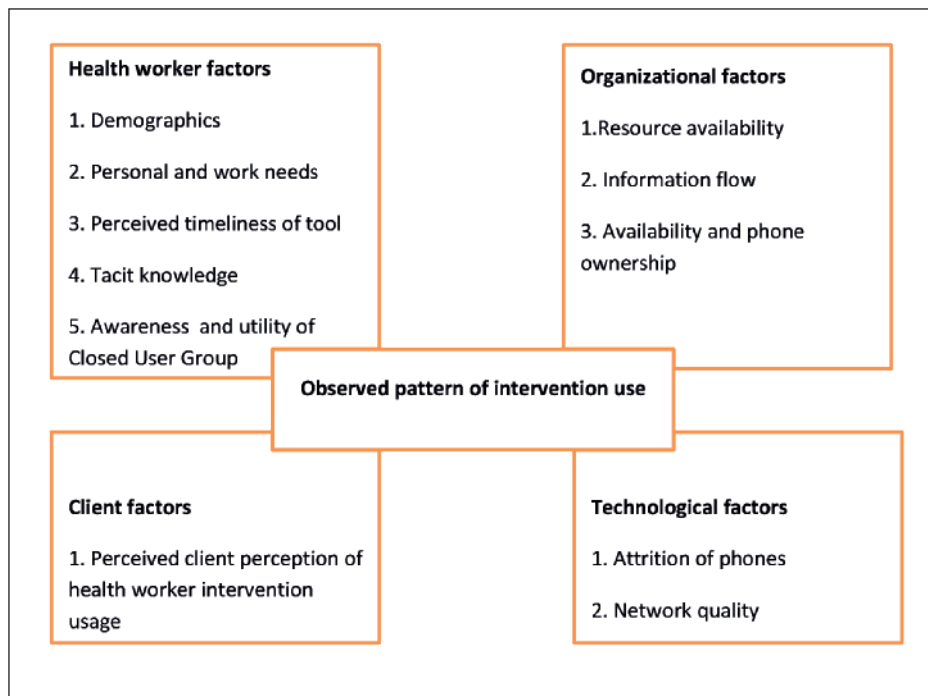
†Community health officer

‡Includes 3 enrolled nurses, 1 ophthalmic nurse and medical assistant

§Certificate or post-basic qualification in midwifery or community health nursing

¶One focus group discussion was conducted in each cluster; 9 key informant interviews was conducted in 3 clusters

Figure 3: Factors explaining the observed pattern of mHealth intervention usage



Health worker factors

Health worker demographics

Older midwives in the FGDs and KIIs reported that they made a lot of phone calls to their colleagues, friends and family. These older midwives often did not use data or send text messages because of unfamiliarity with the use of the internet or texting.

'I knew but I am not conversant with the use of the internet, I was born before the computer. I wanted XXXXX to teach me, but she thought I was joking.'

Midwife, 50 years, HC (FGD 6)

'...I did not know how to use it, that is why. I am now trying to learn it... so my little my son is teaching me.'

Midwife, 55years, HC (FGD 7)

Younger midwives were more curious and explored the use of data on social media particularly Facebook.

'I was using it for Facebook...because you will get free data to access Facebook... we were enjoying small, small... it is very fine because I liked the data.'

Midwife, 29 years, hospital (FGD 5)

Personal and work-related needs of health worker

Most FHWs made related phone calls to chat with friends within and outside the CUG, or transmit information to their colleagues about work-related matters. For most FHWs, the phones bridged the communication gap at work and relieved the economic burden of having to use personal phones to make work-related phone calls especially in cases of non-functioning or non-existent work phones at the facility.

'It was useful because when you do the call because this one you are not thinking about the credit on it so when you call you explain yourself to the person. Then the person can answer you clearly for you to understand what you are asking for.'

Midwife, HC (KII 1)

'For me it really helped because before then the calls I was making to my clients at times I felt I was incurring a lot of cost. So when it came I was not incurring any cost so I felt free and had no fear when calling any of my clients.'

CHO, CHPS (FGD 3)

The FHWs explained that they used the project phones to follow up defaulting antenatal clients, call doctors on duty to review cases, send reminders to clients to bring their neonates to the health facility for BCG vaccination, notify referral health facilities of pending referrals, clarify treatment given to referred patients and also make enquiries concerning action to be taken before referring a case to the referral center as well as clarify handing over notes.

When non-functioning or non-existent work phones were replaced, fixed or supplied by health facility management (as was the case in a few health facilities in a few districts), then FHWs ceased to use the project phones for these calls.

Perceived timeliness of the different intervention components to FHWs needs

The voice mCDRs was perceived to be fast and timely by some FHWs whilst others thought that the USSD was faster. For those who preferred to make voice calls, they indicated that one was assured of contact with the person who was being called and hence information flow and rapid response to questions was guaranteed. All FHW preferred voice calls to text messaging. They cited delays in text message delivery and not being sure the receiver of the text message would see the text at the time it was delivered as a preference for using voice mCDRs.

'If you make a call, it will bell so even if she is asleep she will hear it and wake up but with the texting, if it is somewhere she wouldn't hear.'

Midwife 2, HC (FGD 3)

'If you text that means the case is not so important, maybe you want to refer... But if I know the case is a bleeding case or the condition is ...that is not the time to be pressing. I have to call to tell her.'

Midwife, HC (FGD 1)

Frontline health workers who preferred to access the USSD indicated that the ease of use of the USSD platform, the simplified language of the protocols and the diversity of the USSD protocols was their motivation to use the USSD. These FHWs said they bypassed the inconvenience of having to access the protocols with gloved hands by learning the protocols beforehand.

'It is not a long sentence. It is very short so you quickly read and you could just apply. "Check her vital sign, FH, how is it?" "Do this - give antibiotics, after you are done refer her to the next level" so it was very quick... It was simple with no big English.'

Midwife 2, hospital (FGD 3)

Conversion of USSD protocols into 'mindlines'/tacit knowledge

Initial use of the USSD component of the intervention was higher compared to its use in the subsequent months of intervention implementation. The USSD was used as a tool for revision and a reference to cross-check patient management. Over time, the FHWs memorized the protocols and did not have to refer to the USSD when confronted with cases. Some also wrote down the protocols and stopped consulting the phone.

'It got to a point and it was like the protocols were stuck in my head. In our health center for instance, it was one-way cases. It's only once a while that we get something different. Like the PPH, asphyxia and others I have learnt it so it has stuck. As soon as it comes I know the protocol to use.'

Midwife, HC (FGD 6)

CUG communication

In two of the eight clusters, all FGD respondents knew about the CUG component of the intervention. In the remaining clusters, fifty percent or more of FGDs respondents were unaware of this communication system. Most respondents who knew of the CUG thought there was a limit to the duration of the voice calls that could be made for free, which was not the case.

'For us, when we use to call, we think we are using the credit on the phone, but we didn't know it was free.'

Midwife, hospital (FGD 8)

As phone numbers of the various users of the intervention were often not saved on the project phones, FHWs did not fully utilize the CUG communication system but called the personal phones of their colleagues using the project phones.

'...sometimes you might be calling and she is not picking so you have to try her personal line because maybe the person is closer to her personal phone than project phone. So when you call and she is not picking then you call her personal line.'

Midwife, in HC (FGD 1)

In a few clusters, FHWs saved the project SIM numbers of their colleagues on their project phones.

'...for those numbers, we gave them to our other colleagues who are at the health centers... so we also stored their numbers and their names. When they want to refer a case, maybe if they want something then they call through the project...'

Midwife 1, hospital (FGD 1)

Organizational factors

Resource availability of health facilities

In endowed hospitals where specialist obstetricians, pediatricians, doctors and senior midwives were readily available, FHWs found it more convenient to call their colleagues and doctors to review cases rather than check for protocols on their phone via USSD. These hospitals also had many protocols and regular morning meetings as a resource for continuing professional education.

'Every Monday we used to have a presentation on the condition, so we are already abreast with whatever we are doing...We had the protocols on the wall, when we are less busy we compared the ones we had on the phone to the ones we had at the wards and since we have studied it, when the condition comes, there is no need of us going to look at the protocols before we manage the condition. We manage it because we know the steps.'

Midwife, hospital (FGD 8)

Information communication across the levels of the healthcare system

At the health facilities, knowledge about the use of the phones was not readily shared with colleagues who were not present at the training; this included those who were newly posted to health facilities. Knowledge was also not transferred when trainees were posted out of their facilities even though they often left the project phones behind.

'She went on pension...she didn't even hand it over. The other midwife also came, and she was like "she did not hand over to me, so I will not touch it"...'

Midwife, hospital (FGD 5)

'Also the person using the phone at the beginning was out of office and the one who succeeded him couldn't get that training so he couldn't apply like the first person.'

CHO, CHPS (FGD 3)

Efficiency of communication from the project team to the various health facilities through the district health administration (DHA) fell short with FHWs reporting to not have received follow up information such as the list of all users of project phones and navigation menu for accessing the USSD sent to them. Likewise, reporting and handling of problems with the project phones (including reported cessation of monthly credit top-up) was ineffective as most respondents reported during the FGDs and KIIs that they had forgotten about the reporting system.

Availability and ownership of shared-use phones

Several FGD respondents (ranging from 0%-70% per group) were unaware of a shared-use phone in their facilities and thus never assessed these phones. Many who were aware of these phones had personalized the phones and used them like individual-use phones. In other cases the phone was kept under lock and key in a senior colleague's office cabinet.

'...because she personalized it, when she is not around, you do not want to touch it unless the person is around then you ask her, if she gives you the permission, then you can touch it but if the person is not around you cannot touch it because you think it is her property.'

Midwife, hospital (FGD 5)

'...the facility phone was in the matron's office... It is still in the box actually. The facility one was under lock and key...'

Midwife 2, hospital (FGD 7)

Where shared-use phones were readily available for use in health facilities, they were usually kept at a place known to all FHWs in the facility and someone was delegated to charge the phone. Readily available shared-use phones were usually used for community outreach purposes.

Client perception of intervention

In one cluster, respondents indicated that their preference for the voice mCDRs was because, clients and their relatives might think that they were engaged in other activities like chatting on social media instead of attending to them if they saw them fiddling with their phones. However, when they made phone calls, client could hear that the conversation was about them (the client) and so clients felt that the FHWs were making an additional effort in their interest.

'You see if you call and the person is standing there she won't get angry because she knows you are saying something about her relative. But when you are texting, the person will say the nurse is punching her phone and she is not minding us. If you are making the call then she will know it is either you have called a colleague or asking something from someone.'

Midwife 1, hospital (FGD 1)

'But the moment she sees you pressing your phone...they really hate it.'

Midwife 2, hospital (FGD 1)

This finding was however peculiar to only this cluster. Even within this cluster, one key informant did not think clients would have this perception if the midwife explained why she was taking a minute to fiddle with her phone.

Technological factors

Attrition of mobile phones

Over time, respondents reported loss or theft of their individual-use phones usually in public transport vehicles. Most phone theft occurred at home. Project phones were also reported to have malfunctioned; commonly reported problems were charging issues, blank screens, freezing of phones, unresponsive keypads and non-functioning SIM cards. Some respondents also reported not being able to access the USSD platform despite obvious functioning of their project phones.

Mobile Network quality

For most locations across the study site, the Vodafone network was good. Network quality, however, was poor in several rural areas; FHWs needed to stand or place the intervention phones at specific locations in order to be able to access network. For some, it was a 5 minutes' drive on

a motor bike to get good reception to access protocols. For others, being able to access network meant moving around the compound of the health facility in order to find a good spot.

‘Sometimes we have to move from the facility to a far place before we can access the network to do whatever we want to do. That is, it is the network which is affecting us.’

CHO, HC (FGD 8)

DISCUSSION

Pattern of use of different intervention components

The high use of voice calls compared to all other components of the intervention suggests that in the study setting at least consideration should be given to mHealth interventions that allow voice calls. The preference for voice mCDRs for communication we observed is similar to findings from India, Bangladesh and Indonesia where mobile phone users preferred to use mobile phones for making calls than to text.[33–35] Differential baseline knowledge and familiarity with use of mobile technologies among FHWs may have influenced the pattern of intervention usage observed. In this regard, FHW most likely to use data (internet) in this study were mainly younger respondents.

Client perception of utilization of mobile phones by HWs during consultation is documented in the literature. In India, patients were reported to have respect and confidence in health workers when they saw them accessing mHealth interventions during their consultation.[21,36] Patients in Kenya, India and Indonesia believed that they will be provided the optimum care because FHWs accessed current information management choices using mHealth.[22,37,38] We identified a different reported client perception of health worker’s utilization of mHealth in this study. A small group of FHWs in our study were concerned that clients would think that they were engaged in other activities unrelated to their care if they accessed the USSD whilst attending to clients. The limitation of this observation to one cluster suggests that there were perhaps peculiar client-health worker dynamics in that cluster.

Declined utilization of mHealth intervention

Over time, the use of all 4 mCDRs type declined. The attrition of mobile phones through theft, loss, malfunctioning phones and SIM cards problems could explain the decline in the number of SIM cards accessing the intervention and the decline in use of the intervention. Similar hardware challenges with electronic devices have been reported in other mHealth studies in low-and middle-income countries (LMICs) and negatively impacted implementation of these interventions.[21,39,40] Feedback, refresher training, and reminders for mHealth intervention users are known to sustain use of interventions;[22,40–42] in this regard, monthly reminders

to FHWs and on-site training performed during routine supervisory visits by the project team during intervention implementation was good. However, the absence of a feedback mechanism to FHWs concerning how the intervention was being utilized could have negatively impacted its sustained use.

In low-resource settings such as the study setting it is not uncommon that an essential tool such as a work phone may be absent or non-functional because of challenges with maintaining these phones due to the high recurrent cost of phone calls and replacement of malfunctioning phones. Health workers in these settings often resort to using their personal phones and funds howbeit reluctantly, for work-related matters.[22] It is therefore not surprising that FHWs in this study readily used the project phones to make phone calls related to work- calling their clients, other colleagues, doctors, and referral points as noted in other studies.[22,43] The decline in voice mCDRs, in this study was partly related to the replacement of malfunctioning work phones removing the need to use project phones for phone calls. When FHWs did not receive the monthly top-up on their phones to assure free calls outside the CUG, it was a demotivation to use the intervention. This demotivation was further reinforced by FHWs lack of knowledge that CUG communication was free and unlimited.

This study shows that the USSD protocols become part of FHWs' tacit knowledge very quickly. Health workers often use tacit knowledge in clinical decision-making.[18] The rapid internalization of the protocols not only explains the decline in accessing the USSD but also suggests that the protocols were useful, simple and easy to memorize. Poor network quality may have reinforced the need to commit the protocols into memory. Previous studies have found that network quality influenced the uptake and confidence in mHealth interventions studies.[6,22,23,34]

Pattern of CUG communication

Most (85%) communication with other SIM cards using the project phones was non-CUG related. Contact made with clients, friends and family explains the high proportion of non-CUG communication observed. The majority of FHWs did not save the project phone numbers of their colleagues on their project phones, as such, in communicating with colleagues who were intervention users, they keyed the personal numbers of their colleagues on the project phones. This further pushed up the proportion of non-CUG voice mCDRs. Health workers may have not saved the phone numbers of their colleagues on the project phone because they knew they could access it on their personal phones. We report low awareness of the CUG communication system in this study. The limited knowledge of the CUG is demonstrated by the low number of SIM cards involved in the CUG communication in the clusters (Appendix 1 and 2). Perhaps knowledge of the CUG and a mechanism that allowed FHWs to easily search and find their colleagues within the CUG would have been a motivation to use the CUG more often. Low awareness of mHealth

interventions and their functions has been documented as a barrier to mHealth intervention use. [44] Reminders and reward schemes (tangible or intangible) can motivate users to utilize mHealth applications.[42,44,45] The reasons for using the voice and SMS intervention components could be situated in the mapping of the CUG communication. For example one could anticipate the proximity or otherwise of work related use (e.g. support and referrals) and non-work related use of the phones between the various clusters from the CUG map and the possible consequence of this pattern of CUG communication on outcomes estimated in future analysis of the impact of the intervention on beneficiary outcomes.

Pattern of utilization of project phones according to sharing status of phone and health facility location

Our observed higher use of individual-use phones compared to shared-use phones as well as the tendency to personalize or lock up shared phones for safety suggests that mHealth intervention designs delivered through individualized rather than shared device may be more effective. MHealth interventions that allow FHWs access with their own phones could also assure universal access for users in this regard. The low intervention usage in remotely located health facilities correlates with the sharing status of phones; most remotely located health facilities lacked midwives and so received shared facility phones. Poor network quality also negatively influenced the use of phones in remote areas.

Limitations

There are some limitations to this study. Firstly, the analysis of the Vodafone call log is limited to the first 8 months of an 18-month intervention. It would be useful to analyse data for the entire 18 months, however, this was impossible due to constraints of data retrieval from Vodafone Ghana at the time of analysis. Our quantitative data analysis cannot determine whether the content of phone calls made were work-related or not. Neither are we able to ascertain the degree to which phone numbers called outside the CUG were indeed numbers of other health workers. While the use of project phones for non-related calls may be undesirable from management's view, one may argue that unrestricted use of phones could motivate target groups of mHealth interventions to use the interventions. Thirdly, facility heads selected respondents for this study; the criteria for respondent selection is unknown and may have influenced results. Lastly, in-depth understanding of how and why the phones were used in context required a qualitative study. We have obtained this understanding. However we cannot assume that our results are transferable beyond the study setting. Despite these limitations, this study provides valuable information regarding preference and usability of a multifaceted mHealth intervention among FHWs in a low-resource setting. The findings from this study can inform recommendations in the design and scale up of mHealth interventions in low-resource settings.

CONCLUSION

How and why m-Health interventions are used (or not) goes beyond the technology itself and are influenced by individual and context specific factors. We identified factors that influenced the uptake of a multifaceted mHealth intervention for clinical decision-making. Knowledge of these factors can guide the design of mHealth interventions whose components are similar to the individual components of this mHealth intervention. This study further reinforces the need for usability studies to optimize successful implementation of affordable mHealth solutions in LMICs.

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Authors contribution

HBA, KKG, EA, LY and IAA designed and performed the study and analysed the data. HBA drafted the manuscript and KKG, EA and IAA reviewed the manuscript. DEG and LY provided critical comments on the review of the manuscript. All authors have read and approved the final manuscript.

Conflict of interest

None declared.

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SUPPLEMENTARY INFORMATION

Appendix 1: Details of pattern of voice mobile call detail record CUG communication in study districts (clusters)

Cluster	*Health facility calling	Number of SIM cards making calls	Frequency of intra-facility communication	Frequency of intra-cluster communication by health facility type involved in the communication				Frequency of inter-cluster communication by health facility type involved in the communication				†Total CUG communication
				CHPS		Hospital		CHPS		Hospital		
				HC	Hospital	HC	Hospital	HC	Hospital	HC	Hospital	
Afram Plains North	CHPS A	1	2	2	2	0	0	0	0	0	0	6
	Health Centre A	2	1	7	0	0	0	0	0	0	0	8
	Hospital	4	21	0	0	-	0	0	0	0	0	21
Asuogyaman	CHPS A	2	0	0	9	4	4	8	48	0	0	73
	CHPS B	1	0	0	13	0	0	0	0	0	0	13
	Health Centre A	1	2	0	0	0	0	0	0	0	0	2
	Health Centre B	2	0	0	9	0	0	0	0	0	0	9
	Health Centre C	1	0	0	28	0	0	0	1	0	0	29
	Health Centre D	1	0	0	3	0	0	0	0	0	0	3
Hospital	6	368	0	1	-	0	0	0	9	0	378	
Birim Central	CHPS A	1	0	0	0	0	1	0	0	0	0	1
	CHPS B	1	1	0	0	0	0	0	0	0	0	1
	CHPS C	1	0	1	0	0	0	0	0	0	0	1
	CHPS D	1	1	0	0	0	0	0	0	0	0	1
	Hospital A	14	548	0	0	0	0	0	0	0	24	572
Hospital B	5	84	1	0	0	0	1	0	0	1	86	

* Health facilities have been named with alphabets for anonymity

† Sum of frequency of intra-facility, intra-cluster and inter-cluster communication
This table combines the use of both shared and individual use phones within the CUG

Appendix 1: Continued

Cluster	*Health facility calling	Number of SIM cards making calls	Frequency of intra-facility communication		Frequency of inter-cluster communication by health facility type involved in the communication				†Total CUG communication
			Frequency of intra-facility communication		Frequency of inter-cluster communication by health facility type involved in the communication				
			CHPS	Hospital	CHPS	HC	Hospital	HC	
Denkyembaour	CHPS A	1	0	0	1	2	0	0	5
	Health Centre A	1	0	0	5	0	0	0	5
	Hospital A	21	3,773	0	1	0	0	189	3,963
Kwaebibraem	Health Centre A	1	0	0	0	0	0	0	1
	Hospital	5	1,306	0	0	0	0	101	1,407
Kwahu West	CHPS A	2	1	1	1	2	0	0	5
	CHPS B	2	55	3	2	0	0	0	60
	Health Centre A	1	6	0	0	0	0	0	6
	Health Centre B	2	22	2	0	0	0	0	24
	Health Centre C	1	0	0	0	5	0	3	8
	Health Centre D	2	3	5	0	0	0	0	8
	Health Centre E	1	0	0	0	2	0	0	2
	Health Centre F	2	9	1	0	0	0	0	10
	Health Centre G	1	1	0	0	0	0	0	1
	Health Centre H	1	2	6	0	0	0	0	8
Hospital	28	1,253	11	13	0	0	7	1,284	

*Health facilities have been named with alphabets for anonymity

†Sum of frequency of intra-facility, intra-cluster and inter-cluster communication

This table combines the use of both shared and individual use phones within the CUG

Appendix 1: Continued

Cluster	*Health facility calling	Number of SIM cards sending SMS	Frequency of intra-facility communication	Frequency of intra-cluster communication by health facility type involved in the communication		Frequency of inter-cluster communication by health facility type involved in the communication		†Total CUG communication		
				CHPS	HC	Hospital	CHPS		HC	Hospital
Lower Manya Krobo	Hospital A	16	2,020	0	0	12	0	1	44	2,077
	Hospital B	13	902	0	0	88	0	0	15	1,005
	Health Centre A	3	66	0	1	0	0	2	0	69
	Health Centre B	2	3	0	0	0	3	0	1	7
	Hospital C	11	586	0	0	41	0	0	6	633
West Akim	Hospital	16	1,205	0	13	-	0	13	2	1,220
	Health Centre A	4	10	0	4	15	0	0	0	29
	Health Centre B	1	0	0	1	0	0	0	0	1

*Health facilities have been named with alphabets for anonymity

† Sum of frequency of intra-facility, intra-cluster and inter-cluster communication
This table combines the use of both shared and individual use phones within the CUG

Appendix 2: Details of pattern of SMS mobile call detail record CUG communication in study districts (clusters)

Cluster	*Health facility sending SMS	Number of SIM cards sending SMS	Frequency of intra-facility communication	Frequency of intra-cluster communication by health facility type involved in the communication			Frequency of inter-cluster communication by health facility type involved in the communication			†Total CUG communication
				CHPS	HC	Hospital	CHPS	HC	Hospital	
Asuogyaman	Hospital	4	215	0	0	-	0	0	2	217
Birim Central	CHPS B	1	3	4	0	0	0	0	0	7
	CHPS D	1	1	0	0	0	0	0	0	1
	Hospital A	8	12	0	0	0	0	0	2	14
Denkyembour	Hospital A	9	42	0	0	0	0	0	1	43
Kwaebibiraem	Hospital	6	24	0	0	-	0	0	0	24
Kwahu West	CHPS B	1	1	0	0	0	0	0	0	1
	Health Centre A	1	1	0	0	0	0	0	0	1
	Hospital	9	28	0	0	-	0	0	0	28
Lower Manya Krobo	Hospital A	11	29	0	0	2	0	0	6	37
	Hospital B	6	17	0	0	5	0	0	0	22
	Hospital C	7	19	0	0	1	0	0	2	22
West Akim	Health Centre A	1	6	0	0	0	0	0	0	6
	Hospital	4	8	0	0	-	0	0	1	9

*Health facilities have been named with alphabets for anonymity

† Sum of frequency of intra-facility, intra-cluster and inter-cluster communication

This table combines the use of both shared and individual use phones within the CUG



CHAPTER 7

General discussion

Can mHealth interventions support improvements in neonatal health outcomes in low resource settings?

NEONATAL MORTALITY, LOW RESOURCE SETTINGS, MHEALTH: WHERE ARE WE NOW?

As part of the Sustainable Development Goals (SDGs), the world aims to end preventable newborn deaths by 2030 and for all countries to reduce neonatal mortality to 12 per 1,000 deaths (SDG 3.2) [1]. Many interventions spanning the continuum of care of neonates [2–6] have been and continue to be implemented to achieve this goal in regions of the world that bear the greatest burden of global neonatal mortality [7,8,17,9–16]. Are we making enough progress to reach the SDG 3.2? The simple answer is no [18]. It is estimated that 60 countries are likely to miss the SDG target for neonatal mortality by 2030 and about half of these countries will not make these targets by 2050 [18]. The regions in the world making slow progress towards reduction in neonatal mortality are low resourced regions (Sub-Saharan Africa and Southern Asia) that contribute the most to the global burden of neonatal mortality [19,20]. In order to accelerate attainment of the SDG 3.2 where it counts the most, there is the need to generate evidence that shows the most efficient ways to utilize known interventions in the context of low resource settings, design new innovations, and explore the gaps in the health delivery system that must be fixed.

Implementation of mHealth interventions in low resource settings have been on the increase in recent years with the aim to improve healthcare delivery (including neonatal healthcare) [7,8,17,9–16]. However, evaluations of the effect of mHealth interventions have shown mixed results [21] and questions arise about the role of mHealth in improving healthcare in low resource settings. Notably, these include what accounts for the mixed results documented in literature and how barriers to successful implementation could be overcome to achieve a positive impact.

Possibly, the mixed results observed in mHealth studies is because documentation of mHealth interventions in Africa and other low resource settings is fairly recent [22,23]. Most mHealth intervention studies that have been conducted were implemented in high income countries. The design and implementation of mHealth interventions to suit low resource contexts is thus evolving as researchers and implementers learn to navigate their way in this field. Also, documentation of the factors that influence uptake of mHealth interventions in low resource setting is limited [10]. Moreover, most mHealth intervention studies have been small pilots [10,15,21,24–27] with relatively narrow focus on potential benefits to be derived from the intervention. To improve the effectiveness of mHealth interventions in low resource settings, more extensive documentation of mHealth interventions regarding their usability and the factors that influence their usability and uptake is required, with the use of more robust techniques to assess their impact on health outcomes in low resource settings. In this light, this thesis sought to contribute evidence to improve neonatal health in a low resource setting through the implementation and evaluation of an mHealth clinical decision-making support system.

LESSONS LEARNT

High rates of neonatal morbidity, prematurity, birth asphyxia and infection persist in Ghana and other countries in Sub-Saharan Africa. There also remains an unmet need for guidelines and use of guidelines for effective management of these morbidities across different levels of the healthcare delivery system. Health workers need platforms to assess credible evidence-based information regarding the care of their patients to avert preventable neonatal deaths. We designed one such simple mHealth platform as described in this thesis and then evaluated its impact and tried to understand the “how” and “why” of the observed impact. We have learned several valuable lessons of significance not only in the study setting but well beyond. Although the mHealth intervention in this thesis was not taken up as intended, we have demonstrated that information needs of health workers in low resource settings can be met using mHealth with basic training about how the intervention works. This thesis emphasizes the need for continuous training on the main causes of neonatal mortality in low resource settings as observed by frequent health worker requests for guidelines about these top three neonatal morbidities.

However, guaranteeing the availability of a knowledge platform via a clinical decision-making support intervention does not guarantee that health workers will utilize the knowledge platform, or necessarily adhere to guidelines [28,29]. Varying levels of adherence to neonatal protocols in Ghana were observed in this thesis. Adherence to guidelines is influenced by many factors such as resource availability, cadre of staff treating patients, type of neonatal morbidity and its prevalence, attitude of health workers to patients and in some cases the health seeking behavior of care-givers of neonates who are unwell [28,30]. Our study setting appears to be no different and the complexity of adherence behaviour in the context of other interventions ongoing in the study setting seem to have influenced the impact of the clinical decision-making support intervention on health outcomes. In order to avert neonatal deaths, complete adherence to neonatal morbidity management guidelines is a must. The factors that contribute to non-adherence must be addressed by national, district level and facility level managers. Regular medical audits and neonatal death audits have a vital role to play in this regard. These audits help raise red flags in the healthcare delivery system creating opportunities to address the root causes of these red flags. In Ghana, maternal death audits are regularly done, however, neonatal death audits have not received similar attention [17] and this must be addressed urgently and, must include audits of routine medical care to highlight trends in provider adherence. The reasons for non-adherence to guidelines must also be explored in order to be able to deal with the root cause of these factors. Incentives and sanctions could be potentially incorporated in the health system to promote adherence to protocols. For instance in Brazil and Argentina, there is a reward system to give extra health funding to districts and health personnel that do well [31,32]. Comprehensive assessment of regional health performance by peers from other regions has recently started in

Ghana as a quality improvement technique in a bid to improve health outcomes in the country and must be encouraged [33]. The reasons for inadequate uptake of the mHealth intervention in this thesis were linked to individual health worker factors, organizational factors, technological factors and client perception of health worker intervention usage [34]. These reasons are similar to what has been found previously underpinning the need to incorporate strategies such as reminders, user feedback and refresher training to improve uptake of mHealth interventions [24,25,35].

Adopting technology to suit context is crucial in the design of mHealth interventions. This thesis has shown that mHealth interventions, although well received and utilized (albeit adequately or not) by end users, could suffer from unintended modes of use and researchers must plan for this. One way to mitigate this risk is to assure that interventions be designed with a bottom-up approach. This was done in the design phase of this intervention [36]. The use of the intervention still not as designed may reflect the complexity of implementation of mHealth interventions and the learning process that must be undergone in order to improve their uptake in low resource settings. Such implementation complexities may require the use of qualitative techniques to understand the causal relationships affecting how mHealth interventions are used to produce their observed effects. Realist evaluation of programs and projects may provide a solution to understanding these complex mechanisms [37]. MHealth interventions should therefore have incorporated in their design a system for rapid identification of any unintended effects they may cause so potential solutions to prevent these unintended effects can be timely identified and implemented. Stakeholder involvement in the design of mHealth interventions also needs to be extensive and should include healthcare providers at the different levels of the health system and from the spectrum of demographic regions in a given setting (e.g., urban, peri-urban and rural areas).

A common critique of mHealth interventions is the scarcity of evidence of their effectiveness [23]. This thesis has not only generated evidence regarding effectiveness of mHealth interventions but has highlighted several challenges in assessing effectiveness of mHealth interventions in a complex setting. These challenges included the movement of patients in and out of clusters due to the portability of healthcare in Ghana and how that may have influenced evaluation of the intervention. Another challenge was the interpretation of the insignificant but concordant relationship between requests made to the unstructured supplementary service data (USSD) platform and the number of deliveries. The (un)availability and structure of data in the district health information system-2 (DHIMS-2) and how that influenced the analysis and results obtained thereof, as well as the multiple sources of medical records needed to extract data regarding adherence to neonatal protocols were yet other notable challenges. These are all important lessons learnt from this study that can inform design and evaluation of similar interventions in low resource settings.

National databases like the DHIMS-2 database in Ghana are very useful tools in monitoring progress towards the SDGs targets. This thesis has demonstrated that there are challenges

with the database. Completeness of data in the DHIMS-2 needs to be improved particularly for individual patient level data. This could be facilitated by linking-up of individual patient level data with unique identifiers that span the entire database (irrespective of the data subtype and location where patient seeks treatment). This will help track patients meaningfully and enable more complex analysis of data in the DHIMS-2 to answer important questions regarding neonatal healthcare among others.

Many agencies including the United Nations International Children's Emergency Fund (UNICEF), United States Agency for International Development (USAIDS), the European Union (through the European Development Fund), non-governmental organizations, and academic institutions among others collaborate with the Ghana Health Service to improve healthcare in Ghana. There is the need to coordinate and align interventions implemented by these agencies at all levels of the healthcare delivery system i.e., national, regional and district. This will improve efficient use of resources for the benefit of healthcare workers and their clients (patients). This is particularly important because the implementation and effect of every intervention depends on the local context. Activities that are not well aligned or seem to be competing may result in unintended effects, such as the inability to adequately evaluate the usefulness of individual interventions put in place as in the case of the mHealth intervention in this thesis. The findings from this thesis stress the need to evaluate supposedly effective interventions in context before being pushed for scale up. For interventions that are proven to be effective in context, there is a need for coordinated and harmonized rather than fragmented efforts to scale up these interventions.

CONCLUSION

MHealth has the potential to accelerate attainment of the Sustainable Development Goal to end preventable new-born deaths and reduce neonatal mortality in low resource settings. However, mHealth interventions by themselves cannot improve neonatal health outcomes without the required improvements in other contextual and health system factors. In the case of the intervention evaluated in this study which aimed to provide clinical decision-making support through rapid access to emergency protocols and consultation through an mHealth intervention, we have identified several health system and contextual factors that may have contributed to the failure to make an impact. Future mHealth interventions must be developed with a focus on how the context into which they will be implemented could influence their implementation, use and evaluation. This will require a multi-disciplinary and participatory action type research approach. This kind of approach will ensure a process of co-design, evaluation and continuous quality improvement plan- do, check and act cycles, that can inform adaptation of the intervention with users to fit it to context and the systems in which it is expected to be implemented and make a difference.

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APPENDIX

Summary
Samenvatting
Acknowledgements
Curriculum Vitae
List of publications

SUMMARY

Progress towards ending preventable new-born deaths and reducing the global neonatal mortality to at least 12 per 1,000 births is slower than expected in order to achieve the Sustainable Development Goal 3.2. The burden of neonatal mortality is greatest in low- and middle-income countries and this calls for a focus of neonatal health improvement interventions that fit the context of low resource settings. MHealth interventions are potential solutions to improving neonatal health in low resource settings but, there is scarcity of data of their effectiveness on health outcomes in general and particularly in low resource settings.

In **Part 1** of the thesis the effect of an mHealth clinical decision-making support intervention on neonatal mortality in a low resource setting (Ghana) was assessed.

Chapter 2, describes how an mHealth clinical decision-making support system (mCDMSS) was implemented and evaluated in Ghana. The mCDMSS aimed to improve access to neonatal and maternal health protocols among district level frontline providers of maternal and neonatal healthcare services in Ghana and ultimately improved neonatal health outcomes. The mCDMSS was a multi-faceted intervention that consisted of free access to phone calls, text messages, internet and an unstructured supplementary service data (USSD). The USSD consisted of preformed messages that were abridged emergency protocols for the care of maternal and neonatal clients (patients) as stated in the Safe Motherhood Protocol of Ghana. The messages on the USSD were formulated and designed by a team of health professionals from the different levels of the healthcare system in Ghana. The USSD was regarded as the main component of the intervention as its use could be objectively assessed. The intervention was implemented in a two arm cluster-randomized controlled trial that included 16 districts (8 intervention and 8 control clusters) in the Eastern Region of Ghana. Outcome data was planned to be extracted from the district health information management system-2 of Ghana which hosts the national health data of the country. Further the quality of neonatal healthcare before and during the intervention was assessed. The trial was registered at clinicaltrials.gov (registration number: *NCT02468310*) and Pan African Clinical Trials Registry (registration number: *PACTR20151200109073*).

In **Chapter 3**, we evaluated the utilization of the intervention and its effect on institutional neonatal mortality in the Eastern Region of Ghana. During the 18-month intervention period, neonatal deaths increased from 4.5 to 6.4 deaths and, from 3.9 to 4.3 deaths per 1,000 deliveries in the intervention arm and control arm respectively. The odds of neonatal death was 2.09 (95% CI (1.00;4.38); $p=0.051$) times higher in the intervention arm compared to the control arm (adjusted odds ratio). The correlation between the number of protocol requests and the number of deliveries per intervention cluster was 0.71 ($p=0.05$). We conclude that the higher

risk of neonatal death observed in the intervention clusters should be taken at face value and that problems with birth and death registration, unmeasured and unadjusted confounding, unintended use of the intervention, and concurrent neonatal health improvement activities not related to our intervention (and not measured in this study) could explain the observed intervention effect. Thus, our findings underpin the need for careful and rigorous evaluation of mHealth intervention implementation and effects.

In **Part 2** of the thesis, the possible explanatory mechanisms of the effect of the mHealth clinical decision-making support intervention on neonatal mortality were explored.

In **Chapter 4**, the pattern of protocol requests made to the unstructured supplementary service data (USSD) component of the intervention was assessed to provide insights into the information needs of end users of the intervention (frontline health workers). In total, 5,329 requests were made from 97% of the 74 health facilities in the intervention clusters. Maternal conditions accounted for most of the requests made (66.4%) and included frequent requests for postpartum haemorrhage protocols (25.2%), 'other conditions' (17.8%) and hypertension (16.5%) protocols. The most frequently accessed neonatal conditions were prematurity (20.1%), sepsis (15.5%) and resuscitation (13.8%). The pattern of USSD requests varied significantly by cluster, type of request (maternal or neonatal), facility type and its location, 'type-of-phone' and 'time-of-day' the requests were made at intervals of 6-months. We conclude that there is a dynamic and unmet need for clinical decision-making support among health workers across the different levels of the health care system that could be potentially bridged using mHealth. The information needs of health workers identified provide an opportunity to focus support for health worker training.

In **Chapter 5**, we sought to find out whether mHealth could improve health provider adherence to neonatal health protocols. We answered this question by assessing health provider adherence to three neonatal morbidities (birth asphyxia, jaundice and cord sepsis) before and during the implementation of the clinical decision-making support intervention (CDMSI). We also assessed and described other neonatal health improvement activities unrelated to the CDMSI that were on-going during the intervention period. We found that during the pre-intervention period, the mean adherence was 35.2% (SD=5.8%) and 52.9% (SD=16.4%) for asphyxia; 25.0% (SD=14.8%) and 45.1% (SD=12.8%) for jaundice; 52.0% (SD=11.0%) and 53.8% (SD=16.0%) for cord sepsis protocols in the intervention and control clusters respectively. During the intervention period, the mean adherence was 43.6% (SD=27.5%) and 74.5% (SD=14.7%) for asphyxia; 39.3% (SD=27.7%) and 64.6% (SD=8.2%) for jaundice; 75.0% (SD=21.2%) and 60.8% (SD=11.7%) for cord sepsis protocols in the intervention and control clusters respectively. In the intervention clusters (compared to the control clusters), adherence to asphyxia and jaundice protocols was significantly lower, while adherence to cord sepsis protocols was nonsignificantly higher before and during the

intervention period. There was nonsignificant improvement in protocol adherence in the intervention clusters but significant improvement in protocol adherence in the control clusters. There were 2 concurrent neonatal health improvement activities in the intervention clusters compared to over 12 neonatal health improvement activities in the control clusters during intervention implementation. We conclude that it is difficult to assess whether the mHealth interventions could improve adherence to neonatal health protocols in the study setting given that there were several neonatal improvement activities unrelated to our intervention on-going in the control clusters.

Chapter 6, answers the question ‘how and why was the multi-faceted intervention used to produce its observed effect’. In the study context, health workers preferred to use the voice component of the clinical decision-making support system compared to the other intervention components (voice calls, internet, text messages and the unstructured supplementary service data consisted 64%, 28%, 5% and 2% of utilization statistics respectively). Over time, the use of all four intervention components declined. Individual health worker factors (demographics, personal and work-related needs, perceived timeliness of intervention and tacit knowledge), organizational factors (resource availability, information flow, availability, phone ownership), technological factors (attrition of phones, network quality) and client perception of health worker intervention usage explained the pattern of intervention use observed. Individual and context specific factors must therefore be considered in designing mHealth interventions to optimize their effectiveness.

Finally in **Chapter 7**, we discuss the potential of using mHealth interventions to improve neonatal health outcomes in low resources settings and the lessons that have been learnt from the sub-studies in this thesis. We emphasize the need for a focus on how the context into which mHealth interventions will be implemented could influence their implementation, use and evaluation. We further stress the need to evaluate supposedly effective interventions in context before they are pushed for scale up and the need for coordinated and harmonized rather than fragmented efforts to scale up those mHealth interventions that have been proven to be effective in context.

SAMENVATTING

Sustainable Development Goal (SDG) 3.2 beoogt de neonatale mortaliteit terug te brengen tot maximaal 12 per 1,000 levend geboren, maar de vooruitgang die geboekt wordt om overlijden in pasgeboren baby's te voorkomen is langzamer dan verwacht. De neonatale mortaliteit is het hoogst in lage en midden-inkomst landen, en daarom is er aandacht nodig voor interventies die als doel hebben de gezondheid van neonaten in deze werelddelen te verbeteren. Interventies die gebruik maken van mHealth zijn mogelijk geschikt om de gezondheid van neonaten in ontwikkelingslanden te bevorderen. Er zijn echter nog onvoldoende onderzoeksgegevens over de effectiviteit van deze mHealth interventies in het algemeen, laat staan in de context van een ontwikkelingsland.

Deel 1 van dit proefschrift evalueert een interventie waarin het proces van klinische besluitvorming wordt ondersteund door mHealth. De effectiviteit van deze interventie op het verlagen van de neonatale mortaliteit in een ontwikkelingsland (Ghana) wordt onderzocht.

Hoofdstuk 2 beschrijft de implementatie en evaluatie van een mHealth support tool (afgekort als mCDMSS) in Ghana waarin het klinische besluitvormingsproces wordt ondersteund. De mCDMSS had als doel om protocollen over neonatale en maternale gezondheid beter toegankelijk te maken voor hulpverleners op district niveau in Ghana. Het uiteindelijke doel was de neonatale gezondheid te verbeteren. De mCDMSS was een stapsgewijze interventie bestaande uit gratis telefoongesprekken en sms'en, gratis internet en *unstructured supplementary service data* (USSD). De USSD bestond uit standaard sms berichten met hierin de meest essentiële onderdelen uit de eerste-hulp protocollen voor de zorg aan moeders en baby's, zoals opgesteld in het *Safe Motherhood Protocol of Ghana*. De standaard sms berichten in de USSD waren opgesteld door een team van zorgprofessionals uit verschillende lagen van de gezondheidszorg in Ghana. De USSD werd beschouwd als het belangrijkste onderdeel van de interventie omdat het gebruik hiervan objectief kon worden vastgesteld. De interventie werd geïmplementeerd in een cluster gerandomiseerde, gecontroleerde klinische trial met 2 groepen waarin 16 districten (8 interventie en 8 controle clusters) in de oostelijke regio van Ghana werden geïncorporeerd. Het plan was om de uitkomsten te extraheren uit het *district health information management system-2* van Ghana, waarin de landelijke volksgezondheidsdata geregistreerd worden. Hiernaast werd de kwaliteit van maternale en neonatale zorg voorafgaand en gedurende de interventie geëvalueerd. De studie werd geregistreerd op clinicaltrials.gov (registratie nummer: *NCT02468310*) en in het Pan African Clinical Trials Registry (registratie nummer: *PACTR20151200109073*).

In **hoofdstuk 3** wordt het gebruik van deze interventie, en het effect van de interventie op neonatale mortaliteit in de oostelijke regio van Ghana geëvalueerd. Tijdens de 18 maanden

durende interventie periode nam de neonatale mortaliteit toe van 4,5 tot 6,4 doden in de interventie arm, en van 3,9 tot 4,3 doden per 1000 bevallingen in de controle arm. De odds op neonatale mortaliteit was hoger in de interventie arm dan in de controle arm (aangepaste odds ratio 2,09, 95% betrouwbaarheidsinterval (BI) 1,00 – 4,38, $p=0,051$). De correlatie tussen het aantal keer dat het protocol was opgevraagd en het aantal bevallingen per interventiecluster was 0,71 ($p=0,05$). We concluderen dat het toegenomen risico op neonatale mortaliteit in het interventie cluster niet geheel te verklaren is. De volgende redenen kunnen overwogen worden om de uitslag te interpreteren: problemen met geboorte en overlijdens registratie, ongemeten confounding, onterecht gebruik van de interventie, en andere activiteiten die beogen de gezondheid van neonaten te bevorderen die niet gerelateerd zijn aan de huidige interventie. Onze bevindingen benadrukken de noodzaak voor een grondige evaluatie van het effect van een mHealth gebaseerde interventie.

In **deel twee** van dit proefschrift worden de mogelijke mechanismen die ten grondslag liggen aan het effect van mCDMMS op neonatale mortaliteit in kaart gebracht.

In **hoofdstuk 4**, wordt onderzocht of er een patroon te herkennen is in het gebruik van USSD om zo inzicht te krijgen in wat voor informatie nodig is voor de gebruikers van de interventie (de hulpverleners in de eerste lijn). Bij elkaar werden 5,329 verzoeken ingediend afkomstig uit 74 gezondheidscentra (97% van alle centra in het interventie cluster). De protocollen die het meest werden opgevraagd betroffen protocollen met informatie over maternale aandoeningen (64,4%) waaronder post partum fluxus (25,2%), ‘overige aandoeningen’ (17,8%) en hypertensie (16,5%). Voor neonatale condities werden de volgende protocollen het meest opgevraagd: prematuriteit (20,1%), sepsis (15,5%) en acute opvang (13,8%). Het patroon van USSD verzoeken verschilde significant per cluster, soort verzoek (voor moeder of baby), type en locatie van het gezondheidscentrum, het soort telefoon dat gebruikt werd en het tijdstip van de dag. We concluderen dat er bij hulpverleners in verschillende lagen van de gezondheidszorg behoefte is aan ondersteuning in het klinische besluitvormingsproces. MHealth kan hier mogelijk een rol in spelen. Het identificeren van de onderwerpen waarover behoefte is aan informatie geeft de mogelijkheid hierop te focussen bij herscholing van hulpverleners.

In **hoofdstuk 5** werd onderzocht of mHealth resulteerde in het beter naleven van de richtlijnen gericht op neonatale zorg. Deze vraag is onderzocht door na te gaan hoe goed hulpverleners zich hielden aan de richtlijnen voor drie veelvoorkomende neonatale aandoeningen: asfyxie na de geboorte, geelzucht en navelstreng sepsis. Dit werd geëvalueerd voorafgaand aan en tijdens een interventie waarin het klinische besluitvormingsproces werd ondersteund met een mHealth tool (CDMSI). Tegelijkertijd werden andere activiteiten geïdentificeerd en geëvalueerd die gericht waren op het verbeteren van neonatale gezondheid, maar niet gerelateerd waren aan CDMSI.

We vonden in de periode voorafgaand aan de interventie de volgende naleving van de richtlijnen: voor asfyxie 32,5% (standaard deviatie (SD) 5,8) in de interventie groep en 52,9% (SD 16,4) in de controle groep; voor geelzucht 25,0% (SD 14,8) in de interventiegroep en 45,1% (SD 12,8) in de controle groep; en voor navelstreng sepsis 52,0% (SD 11,0) in de interventiegroep en 53,8% (SD 16,0) in de controle groep. Gedurende de interventie periode was de gemiddelde naleving van de richtlijn 43,6% (SD 27,5) en 74,5 (SD 14,7) voor asfyxie; 39,3% (SD 27,2) en 64,4% (SD 8,2) voor geelzucht en 75% (SD 21,2) en 60,8% (SD 11,7) voor navelstreng sepsis in de interventie groep en controle groep respectievelijk.

In **hoofdstuk zes** wordt de vraag behandeld hoe en waarom de zorgverleners de stapsgewijze interventie gebruikt hebben. In de context van de studie bleken hulpverleners de voorkeur te geven aan de gesproken gedeeltes van tool die het klinische besluitvormingsproces ondersteunde. De modaliteiten werden in de volgende frequenties gebruikt: telefoongesprekken (64%), internet (28%), sms (5%) en USSD (2%). In de loop van de studies nam het gebruik van alle vier de modaliteiten af. Het gebruik van de interventie tool werd beïnvloed door factoren gerelateerd aan individuele hulpverleners (afkomst, persoons- en werk gerelateerde behoeften, opvattingen over de duur van het onderzoek en basis kennis), organisatie gerelateerde factoren (beschikbaarheid van hulpmiddelen, informatie voorziening, beschikbaarheid, bezit van een telefoon), technische factoren (beschikbaarheid van een telefoon, kwaliteit van het netwerk) en de opvatting van de cliënt over het gebruik van de tool door de hulpverlener. Om deze redenen moet rekening gehouden worden met individuele en context specifieke factoren bij het ontwikkelen van een mHealth gebaseerde interventie om een optimaal effect te bereiken.

Tot slot wordt in **hoofdstuk 7** de waarde van mHealth interventies in een ontwikkelingsland besproken als een middel om de neonatale gezondheid te verbeteren. Hiernaast wordt besproken wat er geleerd is over mHealth door de studies die in dit proefschrift zijn besproken. De aanbeveling is om bij het implementeren van een mHealth gebaseerde interventie vooraf zorgvuldig te overwegen hoe de context de implementatie, het gebruik en de evaluatie van de interventie kan beïnvloeden. Hiernaast benadrukken we de noodzaak om nieuwe interventies te testen in een specifieke context voordat ze op grote schaal toegepast worden. Tot slot is het belangrijk dat de krachten en de kennis gebundeld worden om te bereiken dat mHealth interventies, die bewezen effectief zijn in een specifieke context, op grote schaal geïnitieerd en geïmplementeerd kunnen worden.

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CURRICULUM VITAE

Hannah Brown Amoakoh was born on the 11th of April 1980 in Accra, Ghana. She holds a Bachelor in Human Biology and a Bachelor of Medicine and Surgery (MBChB) from the Kwame Nkrumah University of Science and Technology in Kumasi, Ghana. As part of her training in medical sciences, she spent time in the United States of America (University of Texas Southwestern Medical Center, Dallas, Texas). She subsequently obtained a Master of Public Health degree from the University of Ghana. She has extensive clinical practice in general medicine and public health through her 9-year service as a clinician first at the Komfo-Anokye Teaching Hospital and then at the Ministry of Defence of Ghana. At the Ministry of Defence, she provided healthcare services for serving and retired military personnel, and members of the diplomatic corps at the United Nations level 4 hospital (37 Military hospital). She also served as a member of the Ebola response training team during her stay at the Ministry of Defence. Four and half years ago she took up the position of a clinical trials coordinator for the Accelerate Project and subsequently combined her clinical coordinator role with a PhD position on the Project. For the past three and a half years she has pursued a PhD in clinical epidemiology at the Julius Center for Health Sciences and Primary Care, Utrecht University with a focus on improving neonatal health outcomes in her home country of Ghana. Hannah is currently a member of the working group of the Lancet Commission on Synergies between universal health coverage, health security and health promotion. Hannah has a keen interest in maternal and child-health research as well as cardiovascular research among ethnic minorities. Hannah volunteers her time as a member of two religious medical outreach teams- The Lighthouse medical outreach team and the Calvary Baptist Church medical outreach team. She is married with 3 children.

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