EVALUATION OF DATA QUALITY IMPROVEMENT INTERVENTIONS FOCUSING ON PREGNANCY OUTCOME AND PERINATAL MORTALITY DOCUMENTATION BY HEALTH SURVEILLANCE ASSISTANTS IN THE SALIMA AND BALAKA DISTRICTS OF MALAWI

by
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Abstract

Background

Perinatal mortality is a statistic that aggregates fetal deaths, commonly known as stillbirths, and early neonatal deaths. The emotional devastation of these events for women and families is compounded by socio-cultural beliefs and practices obscuring their existence in some societies and national health statistics. Community health workers engaged in pregnancy tracking and vital events documentation are in a position to capture these events if they are trained in correct event classification and supported in the data collection process.

In Malawi, the Institute for International Programs supported community health workers, known as Health Surveillance Assistants (HSAs), in the monthly documentation of pregnancies, births, and deaths to estimate annual rates of under-five mortality. We implemented a data quality documentation training and data editor verification process to evaluate documentation of vital events, namely adverse pregnancy outcomes. We also implemented a cluster randomized mHealth intervention designed to improve Real-time Mortality Monitoring HSA documentation of pregnancies and pregnancy outcomes. We present the results of these two data quality evaluations in this dissertation.

Methods and findings

To evaluate the documentation of adverse pregnancy outcomes— induced abortions, miscarriages, stillbirths, and early neonatal deaths— we compared HSA reported adverse pregnancy

outcomes against results from the data editor verification process. Classification of early pregnancy loss was poor in both districts, despite improving slightly in the post-training period. To evaluate the effectiveness of the mHealth intervention in improving documentation of pregnancy outcomes, we matched reported pregnancies with live births and adverse pregnancy outcomes. The mHealth interventions improved documentation of matched pregnancies in both treatment groups relative to the baseline period, yet improvements were not noted between groups during the intervention period.

Conclusions

Until a fully functional civil registration and vital statistic system is implemented in Malawi, HSAs are a potential source of perinatal mortality data but need substantial support to meet high data quality standards. This level of support was not achieved through the data quality training or mHealth intervention. Further research should be conducted to identify the most effective trainings and mHealth applications to support community health worker documentation of pregnancies and pregnancy outcomes, with a strong focus on adverse pregnancy outcomes.

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sister, and community member- and in my professional life, as
reflected in this dissertation.

Table of Contents

List of Tables

List of Figures

List of Abbreviations

APO	Adverse pregnancy outcome
CHW	Community Health Worker
CDFATD	Canadian Department of Foreign Affairs, Trade and Development
CSPro	Census and Survey Processing System
DHS	Demographic and Health Survey
DHIS-2	District Health Information System-2
DSS	Demographic Surveillance Site
ENND	Early neonatal death
HMIS	Health management information system
HSA	Health Surveillance Assistant
ICC	Intra-cluster correlation coefficient
ICD-10	International Classification of Diseases-10
IIP	Institute of International Programs
IRB	Institutional Review Board
JHSPH	Johns Hopkins Bloomberg School of Public Health
MDG	Millennium Development Goals
MoH	Ministry of Health
NND	Neonatal death
NSO	National Statistical Office
PN	Perinatal
PNM	Perinatal mortality
RMM	Real-time Mortality Monitoring
SB	Stillbirth
SMS	Short message service
U5M	Under-five mortality
VHC	Village health committee
VHR	Village health register
WHO	World Health Organization

Chapter 1 Introduction

Why evaluate perinatal mortality data collected by Health Surveillance Assistants in the Salima and Balaka districts of Malawi?

Perinatal mortality (PNM) is a vital statistic that combines data from two distinct events: late fetal deaths[1], deaths of viable fetuses from 28 weeks gestation and onward, and early neonatal deaths (ENND), deaths that occur during the first seven days of life [1]. Its burden of disease is great, claiming an estimated 4.7 million lives each year with an estimated 98% occurring in low and middle-income countries [2-4]. Measurement of this indicator is often limited by lack of data of good quality due to methodological issues, the use of multiple classification systems, stigma in recognizing and discussing these events, and weak or incomplete health information systems [5-8].

Currently, Malawi does not have a complete and reliable source of information regarding perinatal mortality. It is currently establishing a civil registration system, which will take a substantial amount of time, financial investments, and health system strengthening to achieve completeness defined as over 90% [1,9]. Stillbirths (SB) and ENNDs are under-reported in Malawi health facilities, so the Ministry of Health (MoH) relies on survey data such as those from the Demographic and Health Survey (DHS) which in 2010 estimated the PNM rate as 40 per 1000 births [10]. In the past 30 years, various data collection

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[1] *Stillbirth is presented as late fetal death of 28 weeks (7 completed months) or greater as recommended by the WHO for international comparability*

methods have captured PNM estimates at the district and national level in Malawi, but close inspection reveals variations in classification thereby limiting the quality of the data and comparability of results for trend analysis [10-19].

Since January 2010, the Institute of International Programs (IIP) at the Johns Hopkins Bloomberg School of Public Health (JHSPH) and the Malawi National Statistical Office (NSO) have collaborated to support a community-level vital event surveillance system among 160 randomly selected Health Surveillance Assistants (HSAs) in two districts, Balaka and Salima, called Real Time Mortality Monitoring (RMM) [20,21]. For their scope of work set by the Ministry of Health, HSAs do various health and sanitation activities, including the tracking of pregnancies, births, and deaths [22]. RMM supports pregnancy tracking and vital event documentation already conducted by HSAs with additional supervision and regular quarterly review meetings. The one additional task required is completion of a monthly pregnancy, birth, and death reporting form submitted to the RMM team via RMM supervisors [20,21].

By design, HSAs supported through the RMM project have the potential to capture complete data on perinatal and childhood mortality given the HSA's involvement in maternal and child health monitoring during pregnancy and the first years of life within the community [23,24]. But the advantages of a community-level system are counterbalanced by disadvantages, such as weak supervision and support, which can potentially result in poor data quality not limited to the reporting of PNM [25,26]. In the

absence of a complete vital registration system further research is needed to identify a sustainable method that meets acceptable data quality standards and is appropriate for the socio-cultural context. Because RMM is based within the scope of work of HSAs who cover all catchment areas in Malawi, it has the potential to serve as a national PNM data collection method until the civil registration system captures complete births and deaths. If RMM stillbirth and ENND reporting by HSAs meets acceptable data quality standards, the Ministry of Health can consider using this method to complement DHS estimates until complete and accurate data can be collected in a vital registration system.

Why evaluate the classification of adverse pregnancy outcomes?

In most circumstances, the desired outcome of a pregnancy is a healthy live born infant. However, among the over 200 million pregnancies a year it is estimated that 64%, 16%, and 20% result in a live birth(s), stillbirth(s)/miscarriage, and induced abortion, respectively [27]. These results are presented as estimates since adverse pregnancy outcomes- induced abortions, miscarriages, stillbirths, and early neonatal deaths- are extremely challenging to capture in communities with weak and incomplete civil registration systems; limited health seeking behaviors; provider knowledge and preferences in identifying and reporting these events; influential socio-cultural beliefs on life; and linguistic discord between local languages and biomedical terms [5-8].

The global health agenda is increasing its demand for results with its increased focus on accountability [28]. This data demand is challenging in the field of perinatal mortality given the current limitations in data collection systems and the myriad of challenges in collecting these events [5,29]. Research has explored the cultural and methodological challenges in collecting these events, but a gap remains in the area of event misclassification and patterns of error. There is limited research assessing the misclassification of stillbirth and ENND within the broader context of adverse pregnancy outcomes [30]. Given the socio-cultural and linguistic considerations influencing the reporting of all adverse pregnancy outcomes, it is important to consider the accuracy of stillbirths and ENND within the broader context of adverse pregnancy loss to explore considerations for improving data quality of these events [7,31].

This dissertation presents results from a data quality improvement intervention to support accurate classification of stillbirths and ENND by HSAs. Through the RMM project, we implemented data quality improvements and training from September to November 2011 and conducted regular data quality reviews in quarterly meetings through December 2013. For this dissertation we assessed the accuracy of adverse pregnancy outcomes (APOs)- induced abortions, miscarriages, stillbirths, and ENND- reported by Health Surveillance Assistants in two districts in Malawi between January 2010 and December 2013 to evaluate APO classification results pre- and post- training and patterns of error.

Why evaluate a mobile health project?

Mobile technology for health, commonly called mHealth, is a growing field in public health in which mobile technology is used for health care delivery, improving efficiency and data quality, minimizing bottlenecks, and supporting continuous education and adherence [32-36]. The applications are diverse and creative, although most mHealth applications fall within one of six domains: education and awareness; data collection; monitoring; community health worker (CHW) communication and training; disease surveillance and outbreak tracking; and diagnostic and treatment support [37]. mHealth is a newer method of delivering public health interventions, so many mHealth projects have been implemented as pilots and rigorous evaluations have been limited until recently [38]. While mHealth effectiveness evidence grows on a monthly basis and contributes to this new field in public health, conclusions on effectiveness vary and research gaps remain. Current evidence points to a need for further qualitative and quantitative evaluations to understand the effectiveness of mHealth interventions and their social, technological, and cultural influences [35,39].

This study presents results from a cluster randomized mHealth intervention that falls within the domain of CHW communication and training. It was designed to improve RMM HSA documentation of pregnancies after a midline evaluation concluded that RMM HSAs are under-reporting under-five mortality (U5M) by 24-49% [20]. RMM HSAs in the intervention group receive short message service (SMS) with motivational and data quality content,

an intervention comparable to an mHealth job aid. RMM HSAs in the control group receive SMS that were motivational only and did not directly address data quality. Results from the analysis of implementation elucidate programmatic and costing considerations that arise from technical and contextual issues that arose during the mHealth intervention.

Conclusions

The previous President of Malawi, Joyce Banda, is a strong supporter of women's health and a vocal advocate of the Global Safe Motherhood Initiative to improve the health of mothers and newborns. She was successful in strengthening interest and investments in improving the pregnancy and peripartum experience for the Malawian mother, fetus, and infant. This opened up an opportunity to advocate for PNM data collection within the Malawian health system since this vital statistic encompasses the health status of neonates, maternal health, and health system access, utilization, and quality.

Given the potential challenges of capturing complete and accurate data on perinatal events in a range of contexts, the interventions presented in this dissertation are important in determining whether RMM meets acceptable data quality standards to be considered as a method for PNM data collection in Malawi. Moreover, this research fills in current gaps in evidence in the fields of vital event classification and mHealth. Results from these studies can inform policymakers and program managers in

Malawi and other resource-limited settings committed to high quality vital event data, namely stillbirths and ENNDs.

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Chapter 2 Background

Overview of global PNM data and data quality considerations

Of the 4.7 million perinatal deaths that are estimated to occur annually, 98% happen in low and middle-income countries [1,2]. Among these estimated deaths, an estimated 2 million are ENND and an estimated 2.7 million are late fetal deaths, also termed stillbirths (Table 1)[1-4]. Although these are the best estimates available, they do not fully capture the magnitude of the burden. There is evidence of under-reporting of stillbirths and ENND given the sensitive nature of these pregnancy losses, which would therefore increase the current estimate beyond 4.7 million perinatal deaths each year [1].

PNM is a profound physical and emotional loss that was quantified a decade ago as accounting for 7% of the total global burden of disease [5]. Now, the burden should be greater given the change in the proportion of ENND among U5M [1]. In the past couple of decades with strong investments in child survival and global action with the Millennium Development Goals (MDGs) and other strategies, U5M has decreased significantly but the rate of reduction among neonatal deaths (NNDs), those occurring in the first 28 days, is slower. In fact, the proportion of NNDs among U5M is expected to increase from 45% of U5M in 2015 to 52% in 2030 [1]. Since 75% of NNDs occur during the first seven days of life, the burden of disease of PNM is greater given the larger proportion of ENND among U5M [1].

There are various data sources for PNM, the most common being vital registration systems, health facility data, surveillance data, and surveys such as a pregnancy history or a live birth history with a contraceptive calendar [6]. Each has strengths and limitations (Table 2) [7,8]. Since PNM events are often hidden or not discussed, it is recommended that pregnancies are tracked prospectively to improve the capture of pregnancy loss outcomes [9-10]. Additionally, since in a country like Malawi 25% of births occur at home, it is recommended that pregnancy loss data are collected at the community level [11]. In countries where vital registration systems are incomplete, validation studies have been conducted to assess data completeness and accuracy of birth and death documentation in surveys (pregnancy histories and full birth histories) and surveillance sites (i.e., Demographic Surveillance Sites) with mixed results [12-16]. Contextual and health systems factors can strongly influence data collection of vital events, especially PNM which is considered more challenging to capture for various reasons.

Challenges in PNM data collection

Data quality is the assurance that the information gathered represents the event, context, and actors that are being captured. Although variations exist, a common set of criteria used to evaluate data quality includes accuracy, reliability, completeness, precision, timeliness, and integrity [17]. Studies have shown the various challenges in the collection of PNM data

that meet the standards of these criteria [18-20]. These challenges can be classified as originating from the side of data collection or from the PNM data provider and his/her environment. Table 3 and the following chapter sub-topics present ways in which the data collection method and data collection provider can affect the quality of perinatal mortality data, namely accuracy, reliability, and completeness [7,8,18,21-25].

Event misclassification

In essence, the basic distinction between stillbirths and early neonatal deaths is the presence of life at the time of birth [3]. An early neonatal death is the death of a newborn during the first week of life, days zero to six, regardless of gestational age or birth weight. The latter are used in the classification of stillbirths to distinguish them from early pregnancy loss of non-viable births. The International Classification of Disease (ICD-10), developed by the World Health Organization (WHO) and used by 117 countries to report mortality, has terminology for stillbirth with gestational age and birth weight criteria to differentiate between early and late fetal deaths [4]. For international comparability, the general criteria of 28 weeks gestation (or 7 completed months)- the gestational age criteria of late fetal death- is recommended since it is most applicable in low resource settings [4].

A review of stillbirth and ENND research reveals the influence of cultural preferences, legal considerations, provider

understanding, and linguistic and socio-cultural issues in the misclassification of stillbirths and ENND as the alternate event [22,25-27]. The SB:ENND ratio is a measure of data quality used to assess potential misclassification of events. Using historical data, researchers have calculated a general ratio of 1.2 SB:ENND as a benchmark to assess PNM data quality in countries with high mortality [28]. Lawn et al. found a ratio of 3.2 in Moldova which indicates a misclassification of ENND as stillbirths [28]. Velkoff et al. similarly found a similarly erroneous ratio of 2 in other eastern European countries, indicating misclassification of ENND as stillbirths [29]. The exact SB:ENND ratio for a country might actually vary from the reference value. However, the application as a data quality measurement is very useful to gauge potential misclassification of PN events.

Given tendencies for intentional misclassification, criteria used to classify stillbirths and ENND should be closely reviewed to assess for misclassification. However, in a recent systematic analysis of perinatal mortality audits Aminu et al. found that 27% of studies in a recent systematic review of perinatal mortality audits did not include a description of criteria used to classify stillbirth [27]. For accurate comparability of events, stillbirth criteria should be clearly described. In an epidemiological study of stillbirths in Vietnam, Hirst et al. used the ICD-10 definition of stillbirth but also included late termination pregnancies [30]. Their results would

overestimate rates of stillbirth if compared with ICD-10 defined stillbirth rates.

To avoid errors due to misclassification, some recommend using PNM [6,19] yet this term would still obscure misclassification of stillbirth and ENND with other adverse pregnancy outcomes. In a comparison of DSS and DHS data, Espeut found a small percentage of stillbirths and induced abortions reported as live births in the DHS [12]. An even greater number of stillbirths reported in the DSS were classified as induced abortions in the DHS.

Correct terminology; variations in criteria

A cut-off of 28-weeks gestation is recommended for standardization and global comparability, but in reality a range of cut-offs is applied [25]. Aminu et al. found that among 142 studies, 14% used 20 weeks gestation cut-off, 1% used 21 weeks, 12% used 22 weeks, 5% used 24 weeks, and 34% used 28 weeks. This range of gestational age cut-offs can positively or negatively bias stillbirths and PNM rates depending on the gestational cut-off that is applied [27]. Ekure et al. note in their study on PNM in Nigeria the recommendation to use 28 weeks gestation and/or 1000 gram birth weight as criteria to facilitate international comparison, but instead use 500g and 20 weeks gestation [31]. As expected, the resulting PNM is high.

In a study conducted in Zambia, the authors noted that a decline in stillbirths from 23 to 16 stillbirths per 1000 live

births was due to improvements in terminology used to classify stillbirths [22]. If the decline in stillbirths resulted in an increase in ENND, then events should be evaluated for misclassification. Trend analysis of stillbirths should incorporate an assessment of classification criteria and ENND trends to determine whether changes are due to changes in terminology or classification of events.

Linguistic and socio-cultural issues

Socio-cultural beliefs on life and linguistic factors influence the recognition and classification of PN events. A qualitative study conducted in Tanzania revealed discordance between biomedical terms such as stillbirth and neonatal death and local terms [32]. This is the case in Malawi where three terms can be used to identify a stillbirth: "chitayo," a dead fetus, which is considered a miscarriage or stillbirth; "kuchila masika asanakwane," a fully formed baby born alive, which is considered a premature birth or stillbirth; and "kupita pachabe," defined as "[g]one without come" which is considered a stillbirth [23]. Linguistic discordance can result in inaccurate PNM data with the misclassification of events.

Studies in Jamaica, Thailand, and Cameroon found that newborns who died soon after birth were not recognized as being born or ever existing [9, 33-35]. This can result in under-reporting of events as is seen in retrospective surveys such as the DHS whereas a prospective surveillance could otherwise

capture this event by following up on a pregnancy that had previously been identified [36]. McCaw-Binns also found that newborns that weighed less than 1000g or were less than 28 weeks gestation were sometimes classified as induced abortions rather than early fetal deaths [35].

Witchcraft has been identified as a concern for pregnant women and mothers of newborns in Tanzania, Ghana, and South Africa [26,37,38]. Women hide their pregnancies and newborns to protect them against witchcraft. This discretion combined with the lack of recognizing PNM as an event is an obstacle for the collection of PNM data in prospective surveillance systems and retrospective surveys.

Methodological issues

An estimated 75% of neonatal and child mortality data are collected from surveys due to weak or nonexistent civil registration systems in low and middle income countries [39]. The aforementioned linguistic factors, socio-cultural beliefs, and variations in terminology can greatly influence the capture of events depending on the method but methods also strongly impact the completeness and accuracy of the captured PNM. In fact, the reliance on surveys greatly impacts the availability of stillbirth data as most surveys employ birth histories. A full birth history will not capture a stillbirth regardless of cultural norms surrounding that event since it is limited to live births.

17

The use of the contraceptive calendar in the DHS allows for the capture of stillbirth data although under-reporting is evident [9,20] Surveys also allow for intentional misreporting by women since events are self-reported. In a survey a woman can misreport an induced abortion as another adverse pregnancy outcome, but this level of discretion is more difficult to maintain when presenting at a health facility with vaginal bleeding and signs of an induced abortion [40]. In the DHS used in Tanzania, there is one question in the women's history on the occurrence of pregnancy loss [24]. The question is not followed by one on the intentionality of loss and thereby groups intentional and unintentional pregnancy losses. Given legal and socio-cultural norms surrounding induced abortion globally, women may intentionally under-report stillbirths when intentionality of pregnancy loss is not incorporated in the sequence of questions.

In addition to surveys, PNM can also be collected at the level of health facilities. This method also fails to collect complete data since an estimated 40% of births occur at home [39]. Even if a PN loss occurs under the care of a provider, events may be under-reported or misreported due to provider knowledge, systems level policies, and patient level considerations.

Lawn et al. found that providers did not consistently report fetal deaths if fetuses weighed less than 500 grams because of uncertainty of reporting requirements [6]. At the systems level, Velkoff et al. found that in hospitals that were

evaluated by the infant mortality rates, providers misclassified an ENND as a stillbirth [29]. At the patient level, others have found that providers misclassify ENND as stillbirths to avoid blame or the need to fill a death certificate [22]. In Jamaica, doctors are required to certify neonatal deaths that happen under the care of midwives but may be reluctant to do so since they were absent during the delivery [35]. Due to these various methodological and socio-cultural challenges, community-based, prospective collection of stillbirths and ENND is recommended in communities with incomplete vital registration and PNM data quality issues [9,10].

PNM estimates in Malawi

The Malawian health information system is going through an extended period of transition. The Malawian government is currently establishing a civil registration system which will take many years of investment before it captures complete birth and death data. The Health Management Information System (HMIS) is being improved and is called the District Health Information System-2 (DHIS-2). The DHIS-2 is being scaled-up and, in theory, should capture stillbirths and ENND. However no stillbirths were reported by health facilities from July 2012 to December 2012 [41]. The reasons for under-reporting can be due to the new system, socio-cultural reasons, a true absence of stillbirths, or classification issues. Nonetheless, the data are unreliable so the Ministry of Health currently relies on the DHS for PNM estimates [11].

Table 4 summarizes published studies that measured PNM and were conducted in Malawi over the past three decades [11,42-51]. A review of these estimates highlights some of the data quality limitations previously described. Only the three DHS conducted in the 2000s and the cross-sectional survey (date unspecified) are community based. The use of the WHO definition of PNM is not consistently used. These are significant limitations in an assessment of the burden of disease since these methods affect accuracy, reliability, and data completeness. Notably absent from the table is the Karonga Heath and Demographic Surveillance Survey (DSS) which has collected PNM data over the past decade. The DHS is the only community-based method that uses the ICD-10 code but their use of a birth history and contraceptive calendar is known to limit data completeness of stillbirths [9, 27]. Table 4 illustrates the methodological variations that result in a range of estimates. One can deduce that the range of estimates is due to the limitations of each method, socio-cultural norms, linguistic factors, and provider knowledge.

Recommended PNM data collection method for Malawi

HSAs have been a part of the Malawi Health System since 1950 when they were first recruited to support vaccination campaigns. Although the education criteria have changed over the years, they are now required to have 12 years of education. They are paid government employees trained during 10-week long course and supported by a supervisor and district coordinator [52,53]. HSAs are responsible for environmental health promotion and

health surveillance in their catchment area. Within the HSA scope of work defined by the MoH, HSAs are required to track pregnancies and document births and deaths in their Village Health Register (VHR) in addition to completing other activities. For RMM, HSAs must complete an additional task of extracting data from their VHR and completing the RMM extraction form that includes tables for pregnancies, births, and deaths [54,55]. These extraction forms are submitted on a monthly basis to supervisors who review and submit the forms to the RMM district coordinator for submission to the National Statistical Office (NSO).

In principle, HSAs should be a good source of PNM given their engagement in the community, which should minimize barriers women or families might feel in discussing stillbirths and ENND. The continuous surveillance of pregnancies should facilitate the identification of PNM, which would otherwise remain hidden or difficult to capture with cross-sectional surveys or routine health information systems at health facilities [9,10]. HSAs also are located in all communities within Malawi, even those considered hard-to-reach, which would allow for a PNM data collection method within the health system of Malawi until the vital registration system is strengthened and includes PNM as an event.

Community-based Real-time Mortality Monitoring method

Since January 2010, the Institute of International Programs (IIP) and the National Statistical Office of Malawi (NSO) have collaborated on the Real-time Mortality Monitoring (RMM) project funded by the Canadian International Development Agency (CIDA) (now part of Department of Foreign Affairs, Trade, and Development). One component of RMM evaluates the accuracy and reliability of under-five mortality collected by Health Surveillance Assistants (HSAs) in the Salima and Balaka districts [54,55]. These districts were selected based on the criteria of high fertility, high mortality, full coverage of HSAs in district catchment areas, ease of access by the IIP/NSO team based in Zomba, and the average district population. The sample of 160 HSAs (80 in each district) was calculated to assess annual under-five mortality estimates from HSAs within an 80% accuracy of the gold standard, a full pregnancy history conducted at the midline [54].

The method and was implemented in two phases in the two districts, Balaka and Salima (Figure 1). The first phase covered the period from January 2010 to August 2012 and ended with a midline validation survey with full birth history revealing substantial under-estimation of under-five mortality by the RMM community-based method. Due to these results, we conducted a situation analysis to identify adjustments needed to the approach for increased reporting and completeness in the mortality results. The second phase ran from September 2012 to December 2013. An endline validation survey with pregnancy history was

conducted in November 2013 – January 2014 to validate data from this second phase [55].

RMM Phase II was officially introduced in September 2012 and included four categories of incentives to improve supervision, community engagement, and HSA capacity to strengthen data quality, namely the completeness and accuracy of vital event reporting (Table 5) [55]. Among these supports was a mHealth intervention designed as a cluster randomized, constrained trial to test the effectiveness of frequent SMS on data quality.

mHealth as tool to support RMM data quality
Description of mHealth and examples of applications

Mobile technology for health, commonly called mHealth, is the used of mobile phones or mobile devices to improve or facilitate health care delivery, efficiency, data quality, and to mitigate health systems limitations [56]. In many health care settings and contexts, mHealth interventions have been implemented due to improved cellular network coverage, increased access to mobile phones by individuals in all socio-economic strata, and overall lower costs than other methods of intervention implementation [57-59]. The proliferation of mHealth over the past decade is impressive with applications ranging from basic instrument replacement, such as mobile phones replacing paper-based tools, and creative applications, such as the use of a smartphone application for the diagnosis of respiratory diseases [60,61]. Most mHealth applications fall within one of six domains: education and awareness; data collection;

monitoring; CHW communication and training; disease surveillance and outbreak tracking; and diagnostic and treatment support [62]. Table 6 presents examples of mHealth applications in each domain [57,63,64].

Example of mHealth intervention effectiveness: SMS reminders

mHealth is a newer tool in the field of public health so research and evidence of its effectiveness as a platform for public health interventions is growing rapidly. Of the evaluations conducted, few have been conducted on mHealth interventions in low and middle-income countries [60,65]. SMS reminders are one mHealth method applied and tested for effectiveness in changing behavior [66]. An evaluation of a daily SMS job aid based on the National Malaria treatment guidelines concluded that the frequent SMS improved case management by 24% points at the end of the six-month intervention and 25% points six months after the end of the intervention [57]. The qualitative evaluation that complemented the quantitative study concluded that the frequent SMS motivated the CHW and created a sense of being watched since the HSAs were receiving frequent communications from their program [67].

Rationale for misclassification assessment and SMS job aid intervention

HSAs are potentially a good source of PNM data. Within their scope of work set by the Malawian Ministry of Health, HSAs are tasked to follow pregnancies and document births and deaths

in their Village Health Registers [68]. Each HSA is responsible for a catchment area covering an estimated 1,000 inhabitants and is required to live in the specified catchment area [52,53]. These are favorable requirements for the capturing of perinatal events, but literature on CHW has revealed the challenges of fluctuations in responsibilities and low motivation, which can greatly affect data quality [69-71].

HSA documentation of these events should be evaluated for accuracy given the numerous challenges in correct stillbirth and ENND classification. Moreover, the HSA scope of work is broad so data quality may be lacking if motivation and support are not sufficiently provided. Research shows that fluctuations in responsibilities, lack of supervision, and poor compensation weaken the quality of work conducted by community health workers, especially a project like RMM that requires motivation, engagement, and understanding for the continuous collection of complete and accurate PNM data [70,71]. These limitations could impact data quality criteria such as accuracy, reliability, timeliness, and data completeness (Table 3) [7,8,18,21-25]. However, with research showing the positive effect of various interventions on data quality, there is opportunity to improve and maintain good data quality in RMM if, in fact, the PNM data quality is not high [65,71,72].

A data quality SMS intervention was developed based on research evidence and a feasibility assessment among RMM HSAs. Evidence from health communications programs highlights the

25

importance of reinforcing messages through various means [60]. The SMS was sent to complement data quality criteria disseminated on a job aid and reviewed at the quarterly data review meetings. Although RMM HSAs are linked to a health facility, they work independently in the field. They have monthly supervision meetings but issues with supervisor retention and fluctuating fuel prices have resulted in infrequent supervision meetings. SMS cannot replace supervision meetings, but can potentially improve HSA motivation despite their independent fieldwork.

Although evaluations of mHealth projects in low-and middle-income countries is limited, there are some studies that highlight the role of mHealth as a motivator and reminder for data collectors which improves data quality criteria such as completeness, timeliness, accuracy, and reliability [57,67,73-75]. The success of these studies may lie in their consideration of socio-cultural-technical factors of health information systems in the design and implementation of the mHealth projects [76]. The study researchers considered various factors in the design and implementation of the intervention.

Conceptual framework

This model presents the pathway for the documentation of a complete pregnancy outcome and accurate perinatal mortality event (Figure 2). Event identification and recognition may depend on the characteristics of the event, and HSA characteristics, work planning, and materials.

The main association of interest was between the mHealth intervention and the documentation of a complete pregnancy outcome. All HSAs were allocated through cluster randomization to one of two mHealth treatment groups. We hypothesized that HSAs in the treatment group would improve pregnancy outcome completeness by 20% more than HSAs in the control group. SMS sent to the HSAs in the treatment group range from definitions of adverse events, reminders to collect data from in-migration, and follow-up on pregnancies. The frequency was intended to remind HSAs of their overall RMM documentation responsibilities in addition to the specific data quality guideline in the SMS to improve accuracy of documented perinatal events.

The first research objective that describes the classification errors looks at the final step of the model. Among pregnancies with documented outcomes, those with adverse outcomes— miscarriage, induced abortion, stillbirth, and ENND— have been selected for evaluation of the accuracy of classification. Although it is possible that pregnancies without outcomes reported by HSAs might have resulted in an adverse pregnancy outcome, we do not attempt to quantify the level of under-estimation in this dissertation.

Fig. 1. RMM project implementation timeline.

	2010												2011												2012												2013											
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
RMM Phase I																																																
RMM Phase II																																																
RMM training/Data review meeting (Balaka)																																																
RMM training/Data review meeting (Salima)																																																
Midline validation study- data collection																																																
Midline validation study- data analysis																																																
Situational analysis																																																
Endline validation study																																																

Fig. 2. Conceptual Framework.

RMM project

Completeness outcome

Accuracy outcome

Event → HSA characteristics / Vital event characteristics / RMM work planning and materials → mHealth intervention → Complete pregnancy outcome documentation → Accurate documentation of perinatal mortality event
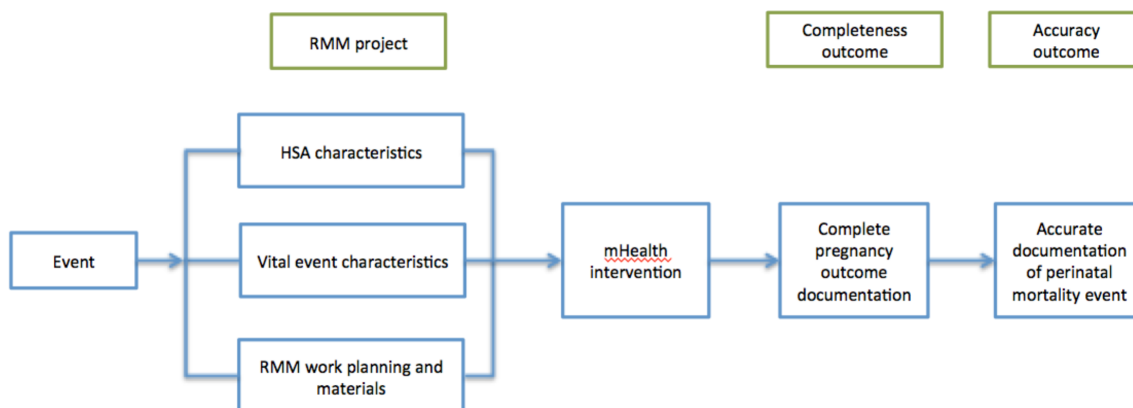
Table 1. Stillbirth terms.

Common term	ICD-10	ICD-10 definition[4]	Consideration for global comparison[3]
Stillbirth	Early fetal death	A fetus that died prior to or during labor weighing 500g or more, of 22 weeks gestation or more, or having a body length of 25 cm or more	Mainly used in countries with medical care capacity to support extremely early preterm births (<28 wks)
	Late fetal death	A fetus that died prior to or during labor weighing 1000g or more, or having a body length of 35cm or more, or of 28 weeks gestation or more	WHO recommended classification for PNM used by the DHS

Table 2. Comparison of certain PNM data collection methods.

	RMM	Pregnancy history	Full birth history, i.e. Demographic and Health Survey	Demographic Surveillance System
Strengths				
Community informant data collector	X			X
Continuous surveillance of pregnancies and outcomes	X			X
Established within the Malawian health system	X			
Follow-up conducted to confirm pregnancy loss and NND	X			X
Weaknesses				
Expensive	X	X	X	X
Infrequent		X	X	
Interviews by strangers on personal health topics including PNM		X	X	
Fluctuations in responsibility	X			

Table 3. Data quality criteria and considerations for PNM data collection.

Data quality		Considerations for PNM data collection	
Criteria	*Description*	*Data collection*	*Data provider*
Accuracy	*Data measure what they intend to measure*	*Differences in gestational age, birth weight, intentionality of loss, and/or signs of life used to define an event [18,21]*	*Linguistic discordance between biomedical and local terms [23,24]*
Reliability	*Consistency in capturing the same result*	*Various classification systems; change in terminology used; inconsistency in use of terminology [18,21]*	*Linguistic discordance between biomedical and local terms [23,24]; inconsistency in use of terminology*
Completeness	*Absence of missing data*	*Health facility data do not capture events that occur at home; Interviewer bias [18,21,22]*	*Cultural norms of hiding pregnancies, pregnancy losses, and neonatal deaths; Hiding negative outcomes at health facilities [24,25]*
Precision	The data include all the necessary details	Detailed data collection tools can improve precision but interviewer fatigue may result in poor data quality	Stillborn infants or ENND that occur soon after birth may be taken from the mother before she is able to see the newborn; Recall bias if the event occurred in the distant past [8]
Timeliness	The data are collected, analyzed, and disseminated efficiently and within a time period in which the data maintains value	A cumbersome data management system will result in data sharing delays [7]	Temporary migration of pregnant and peripartum women may delay the capture of the event
Integrity	The data are not modified or influenced by external sources	A data management cycle and robust database are maintained [7]	N/A

Table 4. Published PNM data from Malawi.

Source	Years	Location	Study design	Data collection method	Use of WHO definition of PNM	Total participants	Perinatal mortality rate
McDermott et al.[42]	1987–1990	Health facility enrollment and community surveillance	Prospective, population-based	Not stated	Yes	3,184 women	68.3/1000
McDermott et al.[43]	1987–1990	Health facility enrollment and community surveillance	Prospective, population-based	Questionnaires	Yes	3591 women enrolled	64.2/1000
McDermott et al.[44]	1987–1990	Health facility	Prospective, population-based	Not stated	Yes	2,063 women-singleton infant pairs	53.8/1000
Verhoeff et al.[45]	1993–1995	Hospital based	Longitudinal	Questionnaire	No	1523 enrolled women who delivered at hospital	35/1000
Kulmala et al.[46]	1995–1996	Health facility	Prospective cohort	Not stated	Uncertain	778 women	65/1000
van den Broek et al.[47]	Not stated	Community based	Cross-sectional survey	Questionnaire	No	2176 deliveries	30/1000
NSO & ORC Macro[48]	2000	Community based	Cross-sectional survey	Birth history and contraceptive calendar	Yes	12,634 pregnancies of 7 + months duration	45.9/1000

NSO & ORC Macro[49]	2004	Community based	Cross-sectional survey	Birth history and contraceptive calendar	Yes	10,939 pregnancies of 7 + months duration	34/1000
Metaferia et al. [50]	2004–2005	Hospital based	Prospective, observational	Health facility pre-tested data capture sheet	No	10,700 deliveries	79/1000
NSO & ORC Macro[11]	2010	Community based	Cross-sectional survey	Birth history and contraceptive calendar	Yes	20,013 pregnancies of 7+ months duration	40/1000
Colburn et al. [51]	2008–2010	Health facility clusters	Prospective, population-based	Community surveillance form	Yes	61,728 births	48/1000–56.2/1000

Table 5. Phase II incentives.

Phase II incentive category	Activity or material	Reason
Supplies	Carbon copy extraction form booklets	To improve efficiency in submission of replacement form if original form misplaced
	Village health registers	To meet HSA need for new VHRs
	New backpacks	To promote the carrying of VHRs during household visits
Supervision support	Quarterly Supervisor of the Quarter incentive	To incentivize regular supervision
	Supervisor checklist	To provide guidance and structure to supervision visits
HSA feedback and incentives	Quarterly HSA report cards	To provide feedback on documentation accuracy, timeliness, and completeness
	Quarterly HSA of the Quarter incentive	To incentivize complete and accurate documentation
	Regular data quality SMS	To remind HSAs of RMM work and reinforce documentation practices
Community engagement	Village Health Committee (VHC) training on RMM	To improve collaboration in sharing vital events data among HSAs and VHCs

Table 6. mHealth domains and applications.

Domain	Application
Education and awareness	*Text-to-Change* in Uganda: Education on HIV and promotion of testing and treatment[63]
Data collection	*Child Count* in the Millennium Villages Project in Malawi: CHW register children under-five[63]
Monitoring	*Mobilize*, a mobile phone application in South Africa for mobile CHW used to monitor MDR-TB patients[64]
CHW communication & training	Daily SMS reminders of National Malaria Treatment guidelines sent to CHW [57]
Disease surveillance & outbreak tracking	*RapidSMS* in Uganda: Health centers submit weekly reports of malaria case management, medication availability, and epidemiological reports[63]
Diagnostic and treatment support	IMCI job aids on PDAs to support CHW diagnostic and treatment management[63]

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Chapter 3 Methods

Study goal and objectives

The goal of these studies is to evaluate the implementation and outcomes of data quality interventions focusing on completeness of pregnancy outcome reporting and accuracy of adverse pregnancy outcome reporting by HSAs in Malawi.

Objective 1. To quantify and describe the patterns of classification error of induced abortions, miscarriages, stillbirths, and early neonatal deaths of HSA pregnancy outcome documentation using data editor verification as the verification method.

- **Specific objective 1.1:** To calculate the percent agreement of induced abortions, miscarriages, stillbirths, and early neonatal death of HSA documentation of pregnancy outcomes against the data editor verification method

- **Specific objective 1.2:** To conduct data quality checks on reported stillbirths and ENND by comparing against reference values

Objective 2. To evaluate the implementation of a data quality mHealth intervention.

- **Specific objective 2.1:** To describe the intervention design and implementation processes.

- **Specific objective 2.2:** To assess the intervention fidelity against the initial study design through summative measures evaluating study sample maintenance, short message service dose, and cost maintenance

Objective 3. To determine if the documentation of pregnancy outcomes on monthly data extraction forms is improved among HSAs in Malawi who receive frequent data quality SMS as compared to a control group of HSAs receiving basic motivational SMS.

- **Specific objective 3.1:** To determine if the documentation of pregnancy outcomes on monthly data extraction forms improves among HSAs in Malawi who receive data quality SMS messages on a regular basis as compared to a control group of HSAs receiving motivational SMS messages

- **Specific objective 3.2:** To determine if the documentation of pregnancy outcomes on monthly data extraction forms improves by treatment group between baseline and intervention periods

Intervention implementation timeline

The RMM project supported HSAs from January 2010 through December 2013, divided into phases one (January 2010-August 2012) and two (September 2012-December 2013) (Figure 3). During phase two RMM improvements, we implemented data quality improvement intervention in the last quarter of 2012, including some that allowed for an analysis to complete objective one. A data editor was hired and trained in adverse pregnancy outcome (APO) verification, conducted retrospectively for events reported prior to December 2012, and thereafter prospectively through the end of RMM in December 2013. We also trained RMM HSAs in improved APO classification during the September 2012 data review meetings and conducted APO documentation reviews in subsequent quarterly data review meetings.

The mHealth intervention implemented to complete objectives two and three was implemented from November 2012 through 2013. The intervention was piloted in November 2012 and the subsequent trial period was divided into two phases. We implemented phase one of the mHealth intervention from December 2012 through June 2013, and phase two from July 2013 through November 2013 (Figure 3).

Data sources

We used three data sources to conduct the study analyses (Table 7). The RMM data source consisted of three unlinked Census and Survey Processing System (CSPro) databases, one for each of the events tracked by HSAs in the Balaka and Salima districts from January 2010 through December 2013: pregnancies, live births, and all deaths excluding stillbirths [1]. The RMM HSA catchment areas cover an estimated population of 95,266 inhabitants in Salima and 116,186 inhabitants in Balaka. This database is one of two data sources used in the analysis of objective three.

The APO verification database is a Microsoft Excel database managed by the RMM data editor and includes data on adverse pregnancy outcomes and neonatal deaths reported by RMM HSAs. Events verified by the data editor had HSA and data editor classifications of events to conduct the analysis of percent agreement for objective one. This database was also a key database in the analysis of objective three.

Finally, we used the mHealth program management database to conduct objective two. This Microsoft Excel database includes program design and implementation components tracked by the mHealth field coordinator, including SMS content, schedule, interruptions, costs, and number of recipients. This database is the primary data source for the analysis of implementation of the data quality SMS intervention.

Analysis methods

Objective one evaluates the accuracy of adverse pregnancy outcome documentation by HSAs, using the data editor verification method as the gold standard. The primary analysis is the calculation of overall percent agreement and specific proportions of agreement by category. The secondary analysis presents results of data quality checks on reported stillbirths and ENND by comparing to other reported results.

The evaluation of the fidelity of implementation of the data quality SMS intervention was conducted using summary measures to evaluate implementation against intervention design. This study also included details on costs and cost tracking.

To conduct the analysis for objective three we matched reported pregnancies with reported outcomes (induced abortions, miscarriages, transfer-out/migration, stillbirth, live birth, disappear, and unmatched). We conducted the analysis in Stata 12 using a population-averaged panel data model with generalized estimating equations to analyze the effect of the mHealth

44

intervention on matched pregnancy documentation [2]. The model included clusters to account for the clustered design.

Ethical Considerations

The RMM project obtained ethical approval in the U.S. from the Institutional Review Board (IRB) at the Johns Hopkins University Bloomberg School of Public Health, and in Malawi from the National Health Sciences Research Committee. Approval letters are available upon request. The mHealth trial is registered as ISCTRN24785657.

Fig. 3. Intervention implementation timeline

	2010												2011												2012												2013											
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
RMM phase one																																																
RMM phase two																																																
RMM training/Data review meeting (Balaka)																																																
RMM training/Data review meeting (Salima)																																																
APO data quality training and review																																																
Prospective data editor verification process																																																
mHealth intervention pilot																																																
mHealth intervention phase one																																																
mHealth intervention phase two																																																

Table 7. Research methods and analysis plans

Topic	Objective	Data source(s)	Location	Timeline	Methods	Analysis
Research topic 1	Accuracy of adverse pregnancy outcome documentation	APO database	Balaka & Salima	January 2010–December 2013	Matching the classification of adverse pregnancy outcome reported by HSAs and verified by the data editor	Percent agreement
Research topic 2	Analysis of implementation	mHealth program management database	Balaka, Salima	November 2012–November 2013	Comparison of design against implementation	Tabulation and percent calculations of summative measures
Research topic 3	Completeness of pregnancy documentation	RMM and APO databases	Balaka, Salima	November 2012–November 2013	Matching reported pregnancies with outcomes	Population-averaged panel data model with generalized estimating equation

Chapter 3 References

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Chapter 4 Community-Based Documentation of Perinatal Mortality: Evaluating the Classification of Adverse Pregnancy Outcomes Captured by Health Surveillance Assistants before and after data quality process improvements

Abstract

Background

Global health agendas have accelerated progress in reducing under-five mortality, but reductions in neonatal mortality have been slower and now represent a greater percentage of under-five mortality. The post-Millennium Development Goals agenda has focused attention on early neonatal deaths (ENND) and stillbirths, but high quality data are lacking. We assessed the accuracy of adverse pregnancy outcomes (APOs)— induced abortions, miscarriages, stillbirths, and ENND— reported by Health Surveillance Assistants in two districts in Malawi between January 2010 and December 2013. We implemented data quality improvements and training from September to November 2011 and evaluate APO classification results pre- and post- training.

Methods and Findings

We assessed the percent agreement of HSA-reported APOs using the data editor classification as the verification source. We calculated percent agreement for all verified events by training period and disaggregated by district. The data editor verified 71% of the 573 reported adverse pregnancy outcomes. Correct classification of stillbirths and ENND was high in both districts in both training periods. Classification of early

pregnancy loss was poor in the pre-training period and improved in the post-training period, although results were still poor. HSAs continued to misclassify induced abortions and miscarriages as stillbirths and ENND in the post-training period despite the training and continuing education. The characteristics of the reported stillbirths and ENND were consistent with characteristics from population-based studies.

Conclusions

HSAs improved classification in the post-training period, but still under-reported and misclassified APOs despite the additional training and continuous education. Given the improvements in classification, the classification training demonstrates potential if results are regularly assessed and training is tailored to address data quality improvements. These results also demonstrate the need to include early pregnancy loss in perinatal misclassification assessments. The mobile-based verification shows promise as a method to verify event classification in community-based reporting of APOs in low-income countries. Further studies should be conducted to validate results given the advantage of applying phone-based verification in projects with limited human and financial resources.

Background

Global health agendas, such as the Millennium Development Goals (MDG) and Global Strategy for Women's and Children's Health, have focused attention and resources on child mortality as well as other key global health issues to accelerate progress [1]. During the MDG assessment period under-five mortality declined 53% from baseline estimates, yet many countries failed to reach their 2015 under-five mortality rate targets [2]. Neonatal mortality rates declined at a slower rate during the MDG assessment period and now comprise a larger proportion of under-five mortality. In fact, neonatal mortality rates are projected to grow from 45% to 52% of under-five deaths from 2015 to 2030 if annual rates of reduction remain constant [2]. With 77% of neonatal deaths occurring during the first week of life, the post-MDG agenda needs to place greater attention on reducing neonatal death with a particular focus on early-neonatal mortality [3]. However, focusing on neonatal deaths alone excludes the 2.7 million stillbirths that occur annually [4,5]. Frequently aggregated as perinatal mortality, stillbirths and ENND share some causes but also sufficient differences to merit disaggregation.

Policy makers and program planners need timely, high quality data to assess and respond to the burden of disease. In low-income countries where stillbirth and ENND rates are high, data quality is limited by completeness and accuracy [6-8]. Currently, 75% of neonatal and child mortality data are collected from surveys, a method that may under-report ENND where newborns

who die soon after birth are not recognized as being born or ever existing [9-14] The reliance on surveys already greatly impacts the availability of stillbirth data, because most surveys employ birth histories that exclude capture of pregnancy loss.

The use of the contraceptive calendar in the Demographic and Health Surveys allows for the capture of stillbirth data, although under-reporting is evident [8,15]. Moreover, the phrasing of the Demographic and Health Surveys stillbirth question also asks about the reporting of induced abortions, events that are often culturally and legally taboo, and can lead to under-reporting if women associate stillbirths with induced abortions [9,16-18]. Cultural norms also pressure women in many settings to hide stillbirths, because of a fear of sorcery affecting the woman's fertility or the survival of future children [19].

Health facility data are another potential source of ENND and stillbirth data, although this method fails to collect complete data because an estimated one-third of births occur at home [20,21]. Furthermore, researchers have found that health care providers who participate in a birth resulting in ENND or stillbirths may be reluctant to document the event to avoid blame [22].

Even when stillbirths and ENND are reported, the accuracy of the event classification is still a concern. Researchers in Jamaica, Malawi, and South Africa have found that the various classification criteria for stillbirth and lack of clarity in ENND and stillbirth differences result in ENND and stillbirth

misclassification [7,23,24]. In Tanzania, linguistic discord between biomedical and local terms resulted in misclassification of stillbirths and other adverse pregnancy outcomes (APOs) [19]. Tolhurst has also documented misclassification of APOs in Malawi, although it was based on differing definitions of the same term in the local language [25]. If misreported as the other perinatal event, stillbirths and ENND can erroneously inflate stillbirth and ENND rates. In low-income countries, a stillbirth: ENND ratio of 1.2 is used as a benchmark to assess the extent and direction of misclassification [26]. Misclassification bias can be mitigated when stillbirth and ENND are aggregated as perinatal mortality, although this approach is discouraged given the differences in stillbirths and ENND etiology and interventions [27].

The methodological challenges in stillbirth and ENND data collection can potentially be improved through changes in data collection strategies. These challenges, along with challenges in the collection of data on overall under-five mortality were considered in the development and implementation of the Rapid Mortality Monitoring (RMM) project, a collaboration between the Johns Hopkins Institute for International Programs and the Malawi National Statistical Office (NSO). From January 2010 through December 2013, the Institute for International Programs and the NSO implemented the RMM project in two districts using trained Health Surveillance Assistants (HSAs) as the data collectors. [28,29]. Developed to test the accuracy and completeness of

under-five mortality reported by HSAs, the RMM project also presented an opportunity to evaluate the accuracy of stillbirth and ENND classification, because HSAs reported all adverse pregnancy outcomes and vital events, including maternal mortality.

HSAs monitor an average population of 1000 people and are responsible for maintaining a government-issued Village Health Register where they routinely record pregnancies, births, deaths, and other information including antenatal care visits, immunization status of children, growth monitoring, and water and sanitation [30]. Each HSA has an assigned supervisor, who maintains regular communication and conducts regular meetings in the field or at the health facility to support HSAs with their tasks. Currently, HSAs are required to have a minimum of 10 years of education, and to complete successfully a 12-week long training course designed and supported by the Malawi Ministry of Health [31]. HSA training facilitators refer to induced abortions, miscarriages, stillbirths, and neonatal deaths in the standard HSA training course, but are not instructed to review definitions and classification differences of these events [32].

The primary objective of this study is to quantify and describe the misclassification of HSA-reported APOS- induced abortions, miscarriages, stillbirths, and ENND- using a phone-based verification method as the verification source. We quantified correct and incorrect classification for two 2-year periods: Jan 2010-Dec 2011, pre-APO training and Jan 2012-Dec

2013, post-APO training. As a secondary objective, we conducted data quality checks on reported stillbirths and ENND by comparing them to other reported results. Although the focus of the misclassification interest is on stillbirths and ENND, I include all reported APOs in order to evaluate and describe potential misclassifications relative to stillbirths and ENNDs.

Methods

Study population and design

The community-level RMM project was implemented in the Balaka and Salima districts of Malawi from January 2010 to December 2013. Details of the project design, implementation, and validation results are described elsewhere [28,29]. In September 2011 we conducted a data management assessment of the RMM project and subsequently implemented improvements to enhance efficiency in data editing and data quality of adverse event documentation. We hired and trained a data editor to focus solely on supporting the data quality process, a job previously managed by the RMM coordinator at the NSO. We created a detailed list of APO classifications and data editing guidelines to systematize data editing and the verification of APOs (Appendix A). We trained HSAs in the APO classifications at the quarterly data review meeting held in the fourth quarter of 2011 and reviewed the guidelines at each subsequent quarterly meeting.

During the period of improvements in 2011, the data editor conducted retrospective verification of events submitted from January 2010 through November 2011. Starting in December 2011,

the data editor conducted prospective verification of APOs, verifying events during the monthly data editing process.

Training

In September 2011 we trained the editor in a structured method of editing extraction forms and verifying APOs though phone calls. We supervised the data editing and verification process after initial training, and semi-annually for the remainder of the project. We maintained daily contact with the data editor to discuss and resolve data quality concerns. At the 2011 fourth quarter data review meeting and each subsequent quarterly meeting, the data editor reviewed the APO classification criteria. He also presented examples of correctly and incorrectly classified HSA-reported APOs from the previous quarter to reinforce RMM classification criteria. The NSO data management team also created a job aid with the APO classification criteria to distribute at the 2011 fourth quarter meeting and all subsequent quarterly data review meetings to replace any potentially misplaced, damaged, or lost job aids.

Data collection

HSAs identified pregnancies, births, and deaths within their catchment areas and recorded the information in their village health register. For the RMM project, HSAs reviewed the events recorded in their registers at the end of each month, and extracted them onto an RMM form. Supervisors reviewed the completed RMM forms and submitted them to the NSO data management team during monthly field visits. Additional details of the data

collection, supervision, and data cleaning process are published
elsewhere [29].

Event Verification

In December 2011, the APO verification process became a
component of the data editing process. The data editor flagged
all extraction forms with documented induced abortions,
miscarriages, stillbirths, early neonatal deaths, maternal
deaths, crossed out or noticeably erased events, and events noted
as *disappear*. The data editor contacted HSAs by phone during
weekday work hours to verify the events and document in the APO
verification database. The latter included both HSA-reported and
NSO-verified classification of all verified events. Additional
details of the verification process and documentation are
discussed in Appendix B [25].

Data sources

The misclassification analysis includes data from the RMM
database and the APO verification database. With the RMM project
focus on U5M, we designed the RMM database in CSPro to capture
details on pregnancies, live births, and deaths, excluding
variables classifying pregnancy loss [33]. When we strengthened
the data quality process, we created the APO database to compile
all adverse events- induced abortions, miscarriages, stillbirths,
and ENND. ENND were documented in both databases. The APO
database is an Microsoft Excel database managed by the RMM data
editor that includes all APOs reported by the HSAs to the NSO.
This spreadsheet was reviewed on a monthly basis by an IIP

57

researcher who conducted periodic event audits during field visits to ensure complete and accurate documentation of APOs. The RMM database was reconciled and cleaned on a monthly basis.

Event matching and statistical analysis

For the primary outcome, we only analyzed HSA-reported induced abortions, miscarriages, stillbirths, and early neonatal deaths confirmed by the data editor verification method. We matched the HSA-reported event with the data editor-confirmed event in Stata [34]. We calculated percent agreement for all RMM HSAs by training period and disaggregated by district. We calculated percent misclassification by using the HSA-reported misclassified events as the numerator and the data editor verified events as the denominator. We conducted this analysis using events confirmed in each district and calculated the difference to quantify percentage point differences to reflect changes between training periods.

For the secondary outcome, we assessed all stillbirths and ENNDs, confirmed and unconfirmed. Among these perinatal events, we used the data editor classification for a confirmed event. For unconfirmed events, we used the HSA-reported classification. We conducted descriptive and quantitative data quality checks of confirmed and unconfirmed stillbirths and ENND. We calculated stillbirths, ENND, and perinatal mortality rates for the four-year project period.

Ethical review

We obtained ethical approval in the U.S. from the

Institutional Review Board (IRB) at the Johns Hopkins University Bloomberg School of Public Health, and in Malawi from the National Health Sciences Research Committee. Approval letters are available upon request.

Results

HSAs in the RMM project covered an estimated population of 203,741 inhabitants and reported 16,130 births that resulted in 489 perinatal deaths (Table 8). HSAs reported 573 adverse pregnancy outcomes, among which the majority of events were classified as ENND (46.8%) or stillbirths (38.4%). Less than 15% of events were classified as miscarriages (11.2%) or induced abortions (3.7%). HSAs in both districts reported a comparable percentage of induced abortions and miscarriages. HSAs in Salima reported similar percentages of stillbirths and ENNDs, whereas HSAs in Balaka reported almost 20% more ENND than stillbirths (41.8% and 43.1% versus 33% and 52.4%).

Among the 573 reported APOs, the data editor confirmed 71.4% events, 50.7% of events reported by Balaka HSAs and 85% of events reported by Salima HSAs (Table 9). The data editor confirmed most induced abortions, miscarriages, and stillbirths reported by Salima HSAs (90%, 90.5%, and 98,6%, respectively). In comparison, the data editor confirmed approximately half of the induced abortions, miscarriages, and stillbirths reported by Balaka HSAs (54.5%, 54.5%, and 61.3%, respectively).

A total of 268 ENND were captured in the RMM death dataset, but only 67.9% (n=182) were processed in the verification system.

The NSO data editor failed to flag and process 32.1% (n=86) ENND reported by HSAs. The NSO data editor confirmed 57.8% of the 268 ENND captured in the RMM project, 69.8% of all ENND reported by Salima HSAs and only 42.9% of all ENND reported by Balaka HSAs.

In both periods, HSAs classified induced abortions and miscarriages poorly (pre-training: 20.8% and 26.9%; post-training: 40% and 56.5%) (Table 10). Though percent agreement only reached 40% in the post-training period, HSAs improved documentation of induced abortion with notably fewer indued abortions misclassified as stillbirths (n=8 versus n=1) or ENND (n=2 versus n=0) (Appendix C). HSAs continued to misclassify miscarriages as stillbirths and ENND in the post-training period.

HSAs classified stillbirths and ENND well in the pre-training period (89.1% and 87.5%) and improved to excellent classification in the post-training period (100% and 95.7%). Overall, HSAs improved classification of APOs between periods, from 67.7% percent agreement in the pre-training period to 87% in the post-training period. Salima HSAs improved classification between periods (62.5% and 85.9%), unlike Balaka HSAs who worsened (96% and 88.9%) though results are high in both periods.

HSAs improved classification of all events, with the exception of induced abortions misclassified as miscarriages (+24.2%); miscarriages misclassified as induced abortions (+2.7%), and miscarriages misclassified as ENNDs (+1%) (Table 11). The greatest improvement was noted in the misclassification of stillbirths as induced abortions or miscarriages. Post-training HSA misclassified 6.7% of induced abortions as

60

stillbirth, down from 33.3% pre-training. Similarly, post-training HSAs misclassified 28.3% of miscarriages as stillbirths, down from 53.8%. Post-training, all stillbirths were classified correctly (n=100). HSAs misclassified ENND only as stillbirth in the post-training period.

Table 12 presents maternal, birth, and death characteristics of reported stillbirths and ENND. Distribution of maternal age is similar in both events with a majority of stillbirths and ENND occurring in women aged 20-39. Stillbirths and ENND have comparable average gestational age of 8.4 months. Most stillbirths and ENND occurred in a health facility or hospital with approximately 25% occurring at home or with a TBA. Similarly, the place of death of most ENND was a health institution followed by home (53%; 35%). Of the 49 reported maternal deaths, six (12.2%) occurred with a stillbirth and none were reported with an ENND. HSAs reported more ENND as a multiple birth compared to stillbirths (25.4% versus 3.2%).

Most reported ENND occurred during the first two days of life (Figure 4). Approximately 50% of deaths occurred on the day of birth followed by 20% on day one. Overall this trend was demonstrated each year with the exception of 2013 when approximately the same number of deaths occurred on days one and two (Figure 5).

Among all reported ENND, we calculated a sex ratio at birth of 117, 125 in Salima and 109 in Balaka (Table 13). The stillbirth:ENND ratio in each district was lower than the ratio benchmark of 1.2. The ENND rate was similar in both districts

with a combined result of 16.5/1000. The stillbirth rate was lower in Balaka than in Salima (10.6 versus 15.8, respectively). The combined stillbirth rate was 13.5 per 1000 live and stillbirths.

Discussion

Results show that HSAs were capable of correctly classifying most stillbirths and ENND in the pre-training period and improved in the post-training period with additional training, job aids, and continuing education provided through the RMM project. During both periods, HSAs did not perform well in the classification of induced abortions and miscarriages, with implications for stillbirth and perinatal mortality estimates. In the post-training period, HSAs misclassified a significant number of miscarriages as stillbirths, thereby inflating the stillbirth and perinatal mortality rates if left unverified. Based on the calculation of stillbirth, ENND, and PNM rate estimates, HSAs under-reported both events and would not be a source of complete and accurate stillbirth and ENND data, even with the improved RMM data quality supports.

Literature quantifying misclassification of APOs is limited, especially in the context of low-income countries, and presents a range of misclassification patterns. In a comparison of a full pregnancy history survey against Matlab demographic and surveillance site data, Espeut found 9.4% of stillbirths misclassified as induced abortions and 3.2% of induced abortions misclassified as stillbirths in the pregnancy history [35]. In

Malawi, Koffi et al. found 16% of neonatal deaths captured in a full birth history were, in fact, stillbirths [36]. In a study conducted in northern California, Goldhaber similarly found fetal deaths misclassified as induced abortions [37]. Even after training, we found HSAs misclassified a large percentage of miscarriages as stillbirths. These results demonstrate a need to include miscarriage and induced abortion classification in any program supporting improved stillbirth and ENND data quality and classification.

Evaluation of the stillbirth:ENND ratio has been used to demonstrate misclassification of stillbirths and early neonatal deaths [15,38]. In health care settings, providers misclassify stillbirths and ENNDs intentionally or due to poor clarity in stillbirth classification given the multiple classification systems (8,13,14,21). Researchers found providers in Algeria and Jamaica intentionally misclassifying ENND as stillbirths if they were not present at the birth or to avoid having families manage the administrative formalities of death registration [24,39]. HSAs do not assist or participate in births and would not feel this pressure to intentionally misclassify an event. Our study estimates of stillbirth, ENND, and perinatal mortality rates demonstrate an overall under-reporting of these events. These results are consistent with the under-reporting of under-five mortality despite the incentives and supports provided to HSAs and their supervisors throughout the RMM project [28,29].

If misclassification of stillbirths and ENND is limited to these events, the use of reporting perinatal mortality rather than the disaggregated events is a method of mitigating misclassification error [8,20,41]. Given our results, the use of perinatal mortality would include misclassification error, stemming from misclassified early pregnancy loss. Moreover, there are sufficient differences in the causes of stillbirth and ENND to necessitate disaggregation of PNM as stillbirth and ENND for program planning [27]. Efforts should be made to collect accurate, event-specific data, which is currently limited by retrospective data collection methods, social norms, and induced abortion laws (9,12,16,24]

A significant limitation to this study is the reliance on phone-based communication for the data editor verification method. ICD-10 diagnoses from a trained health care provider or through verbal autopsy are recommended methods of event classification, but can potentially include misclassification error [7,24,42]. The NSO data management team established regular phone communication at the start of RMM with HSAs, so the verification method, constrained by human and financial resource limitations, was developed as an extension of the already established communication method. The data editor was not a trained health care professional, but received a thorough training, regular supervision, and daily phone support to improve accuracy in event verification. We intentionally designed the verification method with semi-structured questions and a well-

trained data editor to allow a discussion about the event, revealing the necessary detail for classification without guiding the HSA. Because the study was also limited by the use of events reported by women to the HSAs, we created this semi-structured narrative to facilitate event verification. The stillbirth and ENND characteristics match those of large population-based studies, reflecting an effective method of stillbirth and ENND classification verification despite the limitation of a phone-based method [36,43]. Studies triangulating phone-verified APO classification with a validated source, such as hospital or verbal autopsy diagnosis, should be conducted to validate event classification, namely the early pregnancy losses, as they were not included in the data quality assessment. If validated, phone-based verification has the potential to improve data quality constrained by human resource and financial constraints.

The verification method was also limited by its reliance on documented events. The data editor could only verify events documented as APOs or questionably documented, such as those noted as *disappear*, crossed out, or visibly erased. Twenty-eight HSAs (18%) did not report APOs, which is unlikely given the high fertility, U5M rate, and perinatal mortality in Malawi. The omission of APOs by these HSAs may bias our results positively if the lack of reporting is due to poor identification and classification of APOs. During the retrospective verification of events prior to December 2011, verification was limited by HSA turnover since HSAs could not verify events reported by other

HSAs. Even during prospective verification, the data editor failed to flag and verify all reported APOs. Future applications of APO verification should include continuous audit of data collectors and editors to identify the potential omission of events in the verification process during project implementation. Creating the APO verification task as a unique job would also potentially improve inclusion of all reported APOs in the verification process and field-based follow-up of HSAs reporting no APOs or with poor network communication during verification calls.

By design, a prospective, community-based approach is an ideal method of capturing APOs [9,12,15]. HSAs have a continuous community presence and support pregnant women and children through age five, yet they under-reported perinatal events and misclassified early losses although they received additional classification support through continuing education and job aids. Despite these results, we believe that this study demonstrates the potential of APO classification training and a phone verification method to improve data quality among community health workers.

Overall, classification improved between training periods and results highlighted areas in need of further improvement. Given the growing interest in accelerating reductions in ENND and stillbirths in the post-MDG agenda, further studies evaluating tailored classification training should be implemented to evaluate the completeness and accuracy of community-based APO

data. The similarity of stillbirth and ENND characteristics to population-based studies provide initial evidence in the proof of design of the phone-based verification method. This method should be validated given the increase in mobile applications in public health that function within human resource and financial constraints. Classification assessments of perinatal events should not be limited to ENND and stillbirths. Our results demonstrate the challenges in correct classification of APOs despite training support.

Conclusions

Malawi does not have a regular source of high quality perinatal mortality data. Given our results of the classification training and continuing education, HSAs cannot at this time be recommended as a reliable source of perinatal mortality data due to continuing under-reporting and APO misclassification. Classification training has the potential to improve APO accuracy and completeness, although further testing is needed to identify appropriate tailoring of training and support to improve accuracy and completeness results. The mobile-based verification method demonstrated promise as an effective method of improving classification accuracy. This method should be validated given the ubiquity of mobile phones; increase in mobile networks; and need for high quality data despite human and financial constraints. Until perinatal classification is consistently and accurately reported, misclassification assessments of perinatal events should include early pregnancy losses.

Acknowledgements

Chapter 4 Figures and Tables

Fig. 4. Cumulative proportion of ENND. Timing of ENND deaths over

7-day period

Cumulative proportion
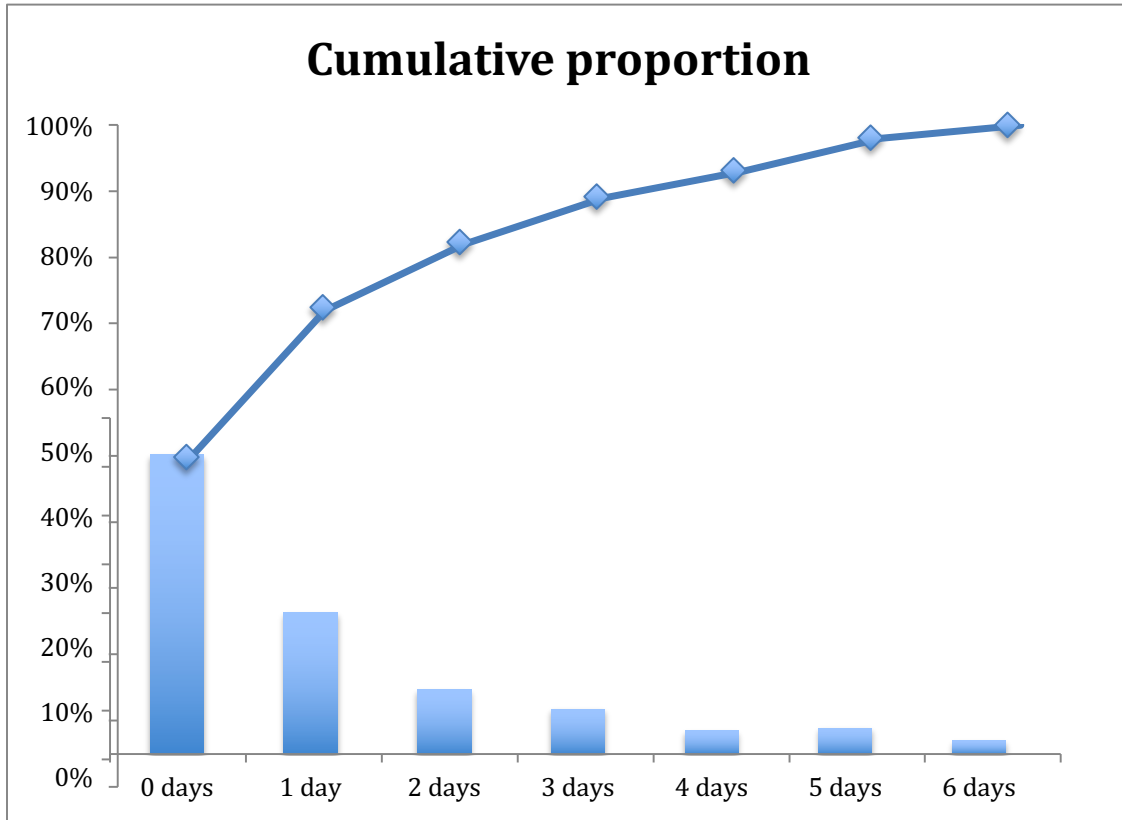
Fig. 5. Age at death. Timing of ENND deaths by year
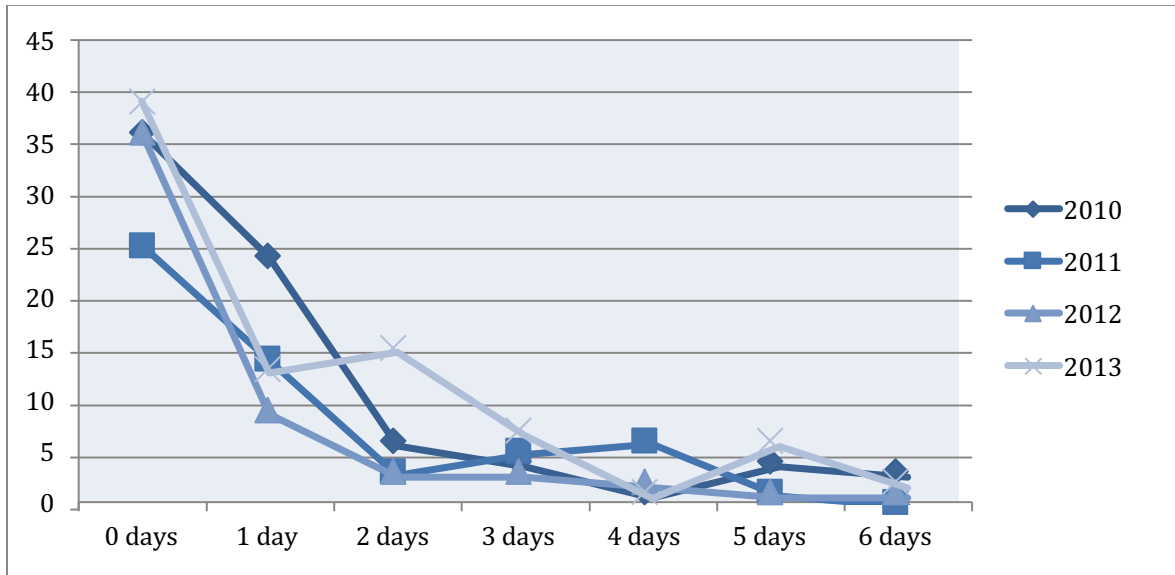
Table 8. Population characteristics.

	Balaka		Salima		Total	
HSA in RMM	79	49.7%	80	50.3%	159	100%
HSAs reporting APOs	*59*	*74.7%*	*72*	*90.0%*	*131*	*82.4%*
Estimated population	108,317		95,424		203,741	
Total births	7,034		9,034		16,130	
Total perinatal deaths	194		295		489	
Total under-five deaths	435		548		983	
Adverse pregnancy outcomes	227	100.0%	346	100.0%	573	100.0%
*Abortions**	*11*	*4.9%*	*10*	*2.9%*	*21*	*3.7%*
Miscarriage	*22*	*9.7%*	*42*	*12.1%*	*64*	*11.2%*
Stillbirth	*75*	*33.0%*	*145*	*41.8%*	*220*	*38.4%*
ENND	*119*	*52.4%*	*149*	*43.1%*	*268*	*46.8%*

Induced

Table 9. Adverse events confirmation in verification system.

	Balaka		Salima		Total	
Abortion*	11	4.8%	10	2.9%	21	3.7%
Unconfirmed	5	45.5%	1	10.0%	6	28.6%
Confirmed	6	54.5%	9	90.0%	15	71.4%
Miscarriage	22	9.7%	42	12.1%	64	11.2%
Unconfirmed	10	45.5%	4	9.5%	14	21.9%
Confirmed	12	54.5%	38	90.5%	50	78.1%
Stillbirth	75	33.0%	145	41.9%	220	38.4%
Unconfirmed	29	38.7%	2	1.4%	31	14.1%
Confirmed	46	61.3%	143	98.6%	189	85.9%
ENND	119	52.4%	149	43.1%	268	46.8%
Unconfirmed	18	15.1%	9	6.0%	27	10.1%
Confirmed	51	42.9%	104	69.8%	155	57.8%
Missed in verification system	50	42.0%	36	24.2%	86	32.1%
TOTAL	227	100%	346	100%	573	100%
Unconfirmed	62	27.3%	16	4.6%	78	13.6%
Confirmed	115	50.7%	294	85.0%	409	71.4%
Missed in verification system	50	22.0%	36	10.4%	86	15.0%

*Induced

Table 10. Percent agreement.

	Salima		Balaka		Total	
	Pre-training	Post-training	Pre-training	Post-training	Pre-training	Post-training
Abortion**	20.8%	0.0%	N/A*	66.7%	20.8%	40.0%
Miscarriage	25.0%	58.1%	50.0%	53.3%	26.9%	56.5%
Stillbirth	86.8%	100.0%	100.0%	100.0%	89.1%	100.0%
ENND	83.7%	93.1%	100.0%	100.0%	87.5%	95.7%
Documentation error	0.0%	N/A*	N/A*	N/A*	0.0%	N/A*
Total	62.5%	85.9%	96.0%	88.9%	67.7%	87.0%

Not applicable- no reported events
**Induced abortion*

Table 11. Percent misclassification: combined districts.

Type of misclassification	Pre-training	Post-training	Percentage point difference
Abortion*- NSO, other APO- HSA reporting*			
Abortion*- NSO, miscarriage- HSA	29.2%	53.3%	24.2%
Abortion*- NSO, stillbirth-HSA	33.3%	6.7%	-26.7%
Abortion*- NSO, ENND- HSA	8.3%	0.0%	-8.3%
Abortion*- NSO, documentation error- HSA	8.3%	0.0%	-8.3%
Miscarriage- NSO, other APO- HSA reporting			
Miscarriage- NSO, abortion*- HSA	3.8%	6.5%	2.7%
Miscarriage- NSO, stillbirth-HSA	53.8%	28.3%	-25.6%
Miscarriage- NSO, ENND- HSA	7.7%	8.7%	1.0%
Miscarriage- NSO, documentation error- HSA	7.7%	0.0%	-7.7%
Stillbirth- NSO, other APO- HSA reporting			
Stillbirth- NSO, abortion*- HSA	0.0%	0.0%	0.0%
Stillbirth- NSO, miscarriage-HSA	2.2%	0.0%	-2.2%
Stillbirth- NSO, ENND- HSA	4.3%	0.0%	-4.3%
Stillbirth- NSO, documentation error- HSA	4.3%	0.0%	-4.3%
ENND- NSO, any pregnancy loss- HSA reporting			
ENND- NSO, abortion*- HSA	0.0%	0.0%	0.0%
ENND- NSO, miscarriage-HSA	1.6%	0.0%	-1.6%
ENND- NSO, stillbirth- HSA	10.9%	4.3%	-6.6%
ENND- NSO, documentation error- HSA	0.0%	0.0%	0.0%

*Induced

Table 12. Stillbirth and ENND characteristics.

	Stillbirth		ENND		Total	
Maternal age (years)	**211**	**100%**	**129**	**100%**	**341**	**100%**
<20	38	18.0%	27	20.8%	65	19.1%
20-29	98	46.5%	56	43.4%	154	45.2%
30-39	67	31.8%	42	32.3%	109	32.0%
40+	8	3.8%	4	3.1%	12	3.5%
Gestational age (months)	8.4		8.3		8.35	
Maternal death (n=49)	6	12.2%	0	0%	6	12.2%
Multiple birth*	*n=220*		*n=268*		*n=488*	
	7	3.2%	57	21.3%	64	13.1%
Place of birth	**39**	**100%**	**220**	**100%**	**259**	**100%**
Home	9	23.1%	53	24.0%	62	23.9%
TBA	1	2.6%	10	4.5%	11	4.2%
Health facility	12	30.8%	78	35.3%	90	34.6%
Hospital	17	43.6%	79	35.9%	96	37.1%
Place of death			**260**	**100%**		
Home			91	35.0%		
Health facility			56	21.5%		
Hospital			82	31.5%		
Elsewhere			31	11.9%		

Table 13. Mortality estimates.

	Balaka	Salima	Total
ENND: Sex ratio at birth	125	109	117
Stillbirth: ENND ratio	0.63	0.97	0.82
Stillbirth rate*	10.6	15.8	13.5
Early neonatal death rate**	16.9	16.5	16.6
Perinatal mortality rate*	27.3	32.0	29.8

per 1000 births (live births and stillbirths)
**per 1000 live births

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Chapter 5. Analysis of implementation of a mHealth data quality intervention: measurement and description of intervention change

Abstract

Background

In Malawi, Health Surveillance Assistants (HSAs) play a critical role in linking community members to the health care system. Their scope of work set by the Ministry of Health is often broadened without a formal review and system-wide notification process, resulting in demotivation and fluctuations in responsibility. The Real-time Mortality Monitoring (RMM) project supported HSA tracking of pregnancies, and documentation of births and deaths- HSA tasks set by the Ministry of Health. We designed and implemented a mHealth intervention to support HSAs and test the effectiveness in improving data quality. In this study we describe the design and implementation processes, and present results on the fidelity of implementation.

Methods and findings

We describe the design and implementation processes of the mHealth intervention to support improved documentation of pregnancies and vital events, highlighting the technical considerations of the intervention design and project constraints. We assess fidelity of implementation against project design through four indicators and found that overall the project was implemented as designed with the exception of one intentional and one unintentional change. We increased SMS dose and sent 24%

more SMS than initially designed. Costs varied throughout the project from US$0.02 to US$0.05 per SMS without any changes in the Telecom provider or messaging platform.

Conclusions

This study presents various technical and operational considerations in the design and implementation of a SMS intervention in a resource limited setting. The intervention was successfully implemented with a majority of SMS sent as scheduled. We increased SMS dose to address HSA preferences and recommend that future mHealth intervention integrate formative research in the design process to improve fidelity of implementation. As designed, this intervention cannot be scaled up due to fluctuations in SMS costs. A comparable intervention should fix costs through a Telecom agreement to ensure sustainability. Despite technical and operational considerations, this intervention mostly achieved fidelity of implementation.

Background

Community health workers play a vital role in extending health services to communities, especially in low-and middle-income countries with poor health-seeking behaviors and challenges in accessing health care. Their unique placement as community members, residing near or in their catchment areas, allows them to bring health care promotion, prevention, treatment, and referral activities to the community [1-3]. For certain work, such as the tracking of pregnancies to identify and report pregnancy losses, it is preferable for CHWs to be responsible due to socio-cultural and health facility beliefs and practices limiting data quality [4,5].

This appeal to engage CHWs can be detrimental if too many additional tasks are added through programmatic changes and collaborations without consideration of the burden of increasing responsibilities. [6,7]. CHWs take on these additional tasks for intrinsic and extrinsic reasons, but may not be able to manage due to the heavy workload and fluctuations in responsibility [6]. As a result, CHWs may feel demotivated and may not meet expected performance and data quality standards. Research has found various motivators in job performance, including supervision, clarity in CHWs' role and responsibilities, incentives, good communication between CHWs and their associated health system, and regular trainings [8,9].

In Malawi, health-seeking behaviors among women are variable and health care access is limited. The 2010 DHS

estimated that 95% of women sought antenatal care services, although only 50% attended two to three visits and an estimated 48% of women attended their first visit at 4-5 months gestation [10]. An estimated 73% of women delivered in a health facility and only 43% had a postnatal checkup within two days of birth [10]. Among these women, 82% report at least one problem in accessing health care [10]. These results highlight the value of extending health care services to the community to potentially improve health practices and outcomes.

In Malawi, Health Surveillance Assistants (HSAs) are tasked with health promotion, prevention, and treatment activities in their catchment area of an estimated 1,000 inhabitants [11,12]. They maintain a Village Health Register (VHR) to document community health information, including pregnancies, births, and deaths. The Institute of International Programs (IIP) at the Johns Hopkins Bloomberg School of Public Health (JHSPH) collaborated with the Malawi National Statistical Organization to support HSA tracking of pregnancies, births, and deaths through additional training, incentives, and supervision- supports recognized as motivators in job performance. IIP and the NSO supported this project, titled Real-time Monitoring of Mortality (RMM), from January 2010 through December 2013. Details of the sampling methods, project, and annual U5M estimates using HSA-reported vital events are described in detail elsewhere [13,14].

Due to unfavorable results in U5M estimates at the midline in 2012, we provided additional supports to HSAs, including the

mHealth intervention, starting in November 2012 to improve monthly documentation of pregnancies, births, and deaths [13,14]. We implemented the mHealth intervention as a cluster randomized study to test whether HSAs in the treatment group with enhanced data quality messages demonstrated improved documentation of complete pregnancies, defined as a pregnancy with a documented outcome. The objective of this study is to describe the design and implementation processes and present results of the analysis of fidelity of implementation.

Methods

Design and implementation considerations

Intervention design

Noting the effectiveness of frequent, repeated SMS we designed the mHealth intervention as a basic motivational support for all RMM HSAs [15]. HSAs in the control group received a limited dose of support, receiving one of three basic motivational SMS twice a week during business hours. We randomized the sequence of the messages at the completion of the cycle, every 1.5 weeks, to limit avoidance of frequent notification, also called alert fatigue [16].

HSAs in the treatment group received an enhanced and more frequent dose of support, receiving one of 12 data quality and motivational SMS three times a week during business hours. We randomized this sequence every three weeks, at the end of its

cycle, to similarly avoid alert fatigue yet emphasize key messages through repetition.

SMS content development

During the design phase, we developed a list of possible SMS messages including treatment group SMS based on the RMM data quality guidelines reviewed with HSAs at each RMM quarterly review meeting (Table 14). Prior to testing, we modified the messages, dropping some punctuation and substituting words with acronyms, to meet the 160-character limit of SMS. In September 2012 we conducted content testing of the proposed SMS messages with purposively selected HSAs in Balaka and modified the SMS based on their feedback. The content development process concluded with the confirmation of three motivational SMS for the control group and 12 motivational and data quality SMS for the treatment group (Table 15).

System constraints

The intervention design was constrained by inconsistent internet connectivity at the NSO, limited technical capacity of NSO staff supporting the RMM project, and limited funding. Since we could not rely on consistent internet access at the NSO, we decided against using a message aggregator, requiring network connectivity and linked to a Swiss phone number, thereby requiring HSAs to pay international costs if they responded to messages. The RMM data management team demonstrated strong computer and mobile phone literacy but had no programming

capacity. We determined that the SMS platform should require skills comparable to those required for emailing.

Funding to support this intervention was limited as it was one of various interventions implemented in phase two of RMM from August 2012 to December 2013 to support HSAs. Necessary hardware, such as cellphones for each HSA and computers for the NSO staff, were already provided at the start of the RMM program. Costs to implement and support this intervention were limited to the SMS costs and any additional hardware required for the software selected.

Hardware and software selection

Due to these constraints, we selected Frontline SMS as the messaging platform, as it is an open source software application that can be used to manage SMS via cell phones or GSM modems for one or two-way messaging [17]. It can be used with various operating systems and the basic application of Frontline SMS version 2, suitable for the SMS intervention, required no customizing. Frontline SMS provides technical support through their virtual community forum and is considered manageable to those with emailing skills.

Basic Frontline SMS hardware requirements are limited to a computer with a USB port and a USB GSM modem with a local SIM. We purchased a Huawei E153 USB GSM modem and a local SIM card with a local number. This would allow HSAs to only be charged local SMS rates for responses sent to the number associated with the Frontline SMS platform.

Training

Two RMM data management team members at the NSO were selected as field coordinators to manage the intervention, alternating the responsibility each week. The lead mHealth researcher trained the field coordinators in the use and management of Frontline SMS and supervised initial pilot implementation.

Intervention implementation

We started the intervention with a three-week pilot period in November 2012 to identify and manage technical issues and HSA concerns of the new SMS intervention before full implementation (Figure 6). Two informational SMS were sent on the first day of the pilot with a brief explanation of the new supportive communication and methods to communicate with the NSO data management team (Table 16). The SMS program manager sent the scheduled SMS in the morning and documented sent messages, technical issues, costs, and any responses sent by HSAs.

During the RMM quarterly review meetings held in January, April, and May 2013, we met with randomly selected RMM HSAs in each intervention group to elucidate HSA feedback on technical issues, SMS frequency and content. HSAs in the both treatment groups expressed support of the intervention but requested more variety. Although HSAs in the treatment group also requested more variety, they similarly requested continued repetition of messages. We used HSA feedback from these discussions to modify the frequency and content of the SMS intervention in July 2013, 7 months after the start of the intervention.

Additional SMS were tested among purposively sampled RMM HSAs in Balaka and Salima prior to implementation. We expanded the list of intervention group SMS from 12 SMS to 24 to add more variation to the SMS although all messages were based on the RMM data quality guidelines (Appendix D). For the control group we added three new SMS and modified the three original SMS for a total of six SMS. We increased message frequency from three to five SMS a week for the intervention group and maintained SMS frequency at two SMS a week for the control group. Main changes to the SMS content include the use of *"NSO:"* to start the SMS as a way to immediately identify the information source. For SMS that did not meet the 160-character limit, we ended the SMS with *"Zikomo,"* thank you in the local language, Chichewa. Only a few treatment group SMS included *Zikomo* due to the length of the data quality message.

Two informational SMS were sent at the start of phase two and throughout both phases to HSAs joining the RMM project when replacing departing HSAs or moving to RMM catchment areas with prolonged HSA absence (Table 16). Originally designed as a two phase intervention— pilot and implementation— the intervention evolved into a four phase intervention— pilot, phase one, phase two, post-implementation— implemented without any scheduled interruptions from November 13, 2012 through January 17, 2014 (Figure 6).

Message tracking and data collection

We managed messages and tracked costs on a Microsoft Excel database which included program design and implementation components. The lead mHealth researcher added the randomized SMS schedule to the database prior to the start of the week. The field coordinator documented on a daily basis the SMS sent to the test, control, and intervention groups; technical issues encountered; responses received; and costs. Technical issues were also reported directly to the study researcher to address or seek resolution through Frontline SMS support.

We initially estimated that the field coordinator would spend an estimated 20 minutes sending the SMS. The Frontline SMS platform was kept active in the computer for the remainder of the day to receive response SMS or questions sent by HSAs. At the end of the day on which SMS were sent, the field coordinator calculated airtime costs by checking the remaining balance on the SIM card used in the GSM USB. The field coordinator tracked airtime by documenting the airtime amount charged on the SIM card the day the SMS were sent.

Statistical analysis

We evaluated fidelity of project implementation through four indicators measuring different components of intervention design: study population, SMS dose, and cost (Table 17). We measured all indicators against quantities from the initial project design with the exception of message transmission.

90

For sample maintenance and message dose indicators, we conducted tabulations by phase and calculated percent differences between results. We limited the cost assessment to airtime, a recurrent and variable cost. The RMM project already supported salaries of the data management team, project computers, and HSA mobile phones, so these inputs did not incur additional costs in the SMS intervention. The Frontline SMS open source software and limited support we requested during project implementation did not incur fees. The cost assessment excludes the fixed cost of the GSM USB modem and the potential work cost of data management staff participation on sending SMS, completing necessary documentation, and maintaining communication with the research fellow.

Ethical review

We obtained ethical approval in the U.S. from the Institutional Review Board (IRB) at the Johns Hopkins University Bloomberg School of Public Health, and in Malawi from the National Health Sciences Research Committee.

Results

During the mHealth intervention we sent 35,080 SMS, among which 31,927 were sent during phases one and two. The initial study design included 156 HSAs in 30 health facility clusters (15 intervention & 15 control). The intervention group included 76 HSAs and the control group included 80 HSAs. Over the course of the two-phases, the study encountered HSA turnover in 9 catchment areas, with most occurring in the control group (n=6) and during

phase I (n=8). The evaluation of sample maintenance reveals only a 6% change from the initial study population.

Based on the initial design, we estimated the number of test, control, and intervention SMS combined would total 461 per week. The evaluation of message dose reveals that 1% more SMS in phase one and 24% more SMS in phase two were sent than initially designed. An average of 467 SMS were sent weekly in phase one and 570 SMS were sent in phase two (Table 18). Once we randomized and scheduled the SMS as per the intervention protocol, we sent most test, study content, holiday, and introductory SMS without interruption. The evaluation of message transmission reveals that 99.3% of scheduled SMS in phase one and 97.5% of scheduled SMS in phase two were successfully sent. The unscheduled interruptions occurred due to technical issues with the Frontline SMS platform, lack of electricity for computer use, and budget processing delays that affected the purchase of airtime for SMS transmissions.

We experienced fluctuations in SMS pricing over the course of the study period (Figure 7). Reported in the design period as approximately US$0.03 per SMS, SMS costs actually started at an average of US$0.02 in the pilot period and increased to US$0.04 in phase one and US$0.05 in phase two. The evaluation of cost maintenance reveals substantial cost fluctuations throughout the intervention phases (Table 19). The cost of weekly SMS support per HSA increased from US$0.09 to US$0.11 from the pilot period to phase one. Due to the phase two modifications, which resulted

in an increased dose of SMS for the intervention group, phase two and the post-implementation phase are not compared with the pilot period and phase I. The cost of weekly SMS per HSA in phase two was approximately US$0.22 and actually decreased slightly to US$0.18 in the post-implementation phase.

Discussion

The implementation of this mHealth intervention required careful consideration of various contextual, financial, and technical components and demonstrates the complexity of designing a mHealth intervention in a limited resource setting. Overall the mHealth intervention was mostly implemented as designed, with the exception of two notable changes. We made an intentional change in message dose and managed unintentional changes in cost management. These changes added analysis considerations and would impact the potential scalability of the intervention, respectively.

We address the analysis considerations in our results, but cannot address a current research gap in quantifying effective doses and duration of SMS interventions due to the changes made in both treatment groups midway through the intervention [18,19]. Future mHealth applications should measure behavior change by SMS dose to determine if effective doses can be identified, similar to measuring the pharmacodynamics of medications.

Current mHealth research emphasizes the importance in formative research to assist in the development of the most

effective design for the recipients [20,21]. Recipients of
mHealth applications who engage in the design process can
contribute contextual considerations to potentially improve
intervention success [22-24]. We did not consider conducting
formal formative research to inform intervention design given our
experience with HSAs through RMM since January 2010.

The RMM project had already established SMS as a primary
communications method and the intervention content was based on
the data quality job aids distributed and reviewed at the RMM
quarterly review meeting. Additionally, we designed this
intervention based on evidence in the effectiveness of frequent,
repeated SMS as demonstrated by Zurovac et al. [15]. In a
subsequent publication published after the start of this
intervention, Zurovac et al. estimated spending 45% of total
mHealth intervention costs on formative research in SMS
development [19]. Clearly, the success of their intervention with
frequent, repeated SMS was heavily influenced by the substantial
investment in formative research to tailor the intervention to
the context and recipient needs.

A limitation to this study is modification of design midway
through the intervention period. We limited the engagement of
HSAs in the design process to the testing of SMS content, mainly
to confirm understanding of SMS with abbreviations and modified
punctuation to meet the 160-character limit. The mHealth
intervention was successful since it appeared to meet HSA needs
based on feedback and did not affect the design sufficiently to

impede a robust analysis. Little et al. highlight the importance of framing mHealth interventions at scale within a model of behavior change to ensure success and sustainability [24]. Taking this approach and supporting the design with formative research, future mHealth applications may achieve improved fidelity of implementation of an effective and sustainable intervention.

The intervention also had a technological limitation that may have affected cost estimates. Frontline SMS does not calculate airtime costs directly. Instead, we indirectly estimated costs by tabulating total airtime used on days when SMS were sent. It is possible that costs we estimated slightly imprecise costs. The mHealth field coordinator diligently tracked airtime availability prior to and after sending the bundle of SMS to best capture SMS costs. The variability of costs has important implications on the scalability of such an intervention since such variability would be difficult to sustain. At a small scale, the use of a USB GSM modem was acceptable and fit the budget and technical capacity of our staff. Comparable interventions designed at scale should consider establishing a Telecom agreement to ensure stable costs and facilitate sustainability.

Conclusions

mHealth applications are diverse and vary in complexity of design and implementation. This mHealth intervention had a relatively simple design yet required substantial consideration to identify an appropriate intervention within the capacity of the project. The design of the study was mainly limited to

evaluating the technical and operational components of the data quality SMS intervention. Future mHealth application should incorporate formative research as an integral component in mHealth intervention design to improve implementation fidelity and sustainability.

Acknowledgements

Chapter 5 Figures and Tables

Fig. 6. mHealth intervention design and implementation timeline.

	2012												2013											
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
RMM phase one	░	░	░	░	░	░	░	░																
RMM phase two									░	░	░	░	░	░	░	░	░	░	░	░	░	░	░	░
RMM quarterly review meeting- Salima									▓				▓			▓				▓				
RMM quarterly review meeting- Balaka									▓				▓				▓			▓				
SMS design phase								▒	▒	▒														
SMS pilot											▒													
SMS phase one												█	█	█	█	█	█	█						
SMS phase two																			█	█	█	█	█	
SMS post-implementation																								▒
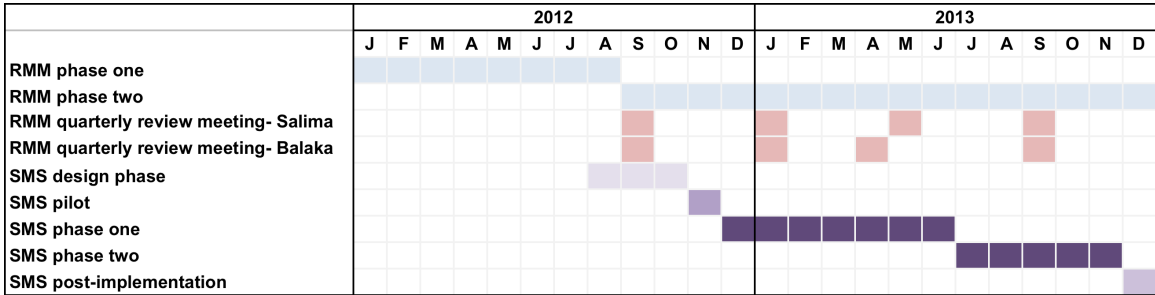
Fig. 7. Cost per SMS sent by week.
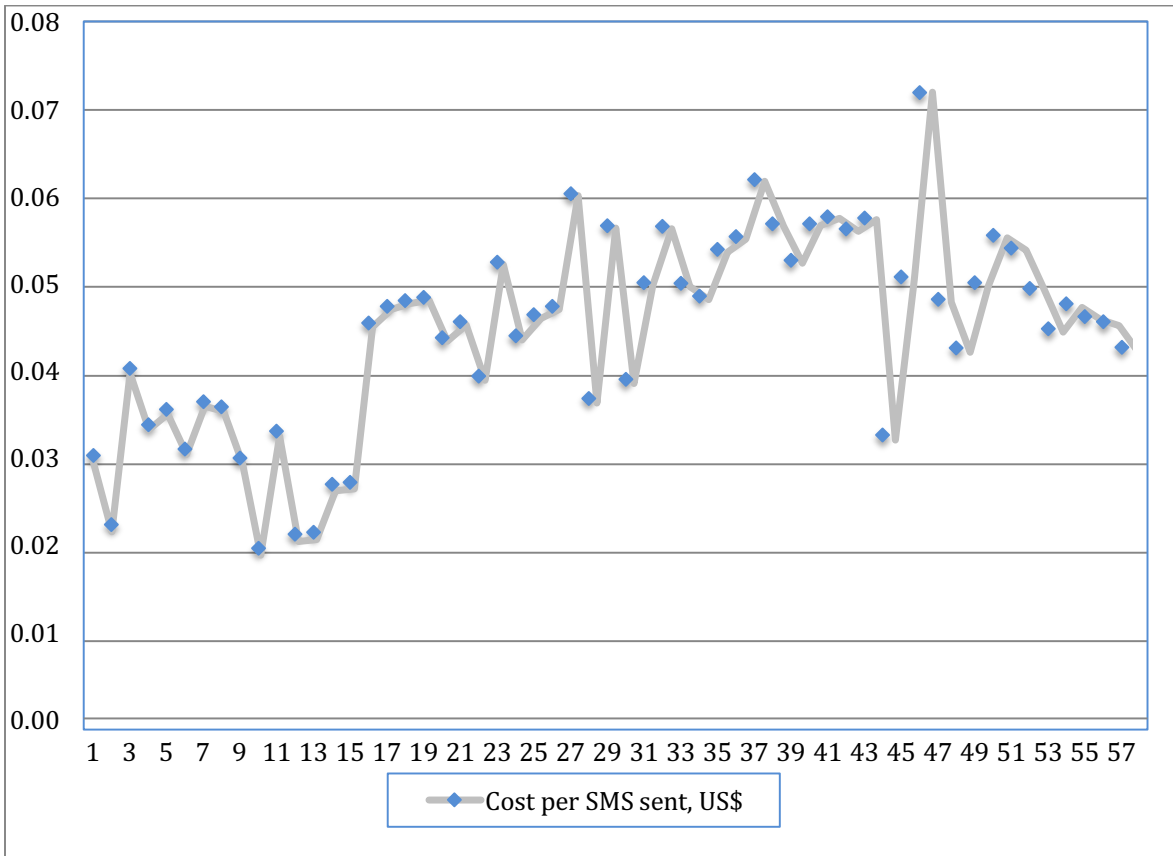
Table 14. Key messages from RMM data quality guidelines for HSAs.

Data quality topic	Key messages
Completeness	Submit forms every month
	Document all events— including all pregnancy outcomes
	New residents in the communities (transfer-ins) should be added to the Village Health Register and be included in the tracking of pregnancies and documentation of all vital events
	Meet regularly with the Village Health Committees in your catchment area to be notified of vital events
Accuracy	Each person has a unique code (twins, mom/baby, new community member)
	A complete code has 11-digits
	Abortions are the **intentional** death of a fetus during early months of pregnancy (**months 1-5**)
	Miscarriage is the **unintentional** death of a fetus at 1-6 months gestational age
	Stillbirth is the death of a fetus of 7+ months gestation. The dead newborn shows NO signs of life: breathing, movement, crying, etc.
	Newborn (7+ months) is born ALIVE: breathing, crying, movement, etc. Newborn dies at some point after delivery: within minutes, hours, or up to 28 days.

Table 15. SMS by treatment group.

SMS sent to Control Group	Sample of SMS sent to Treatment Group	
Good morning! The NSO thanks you for your efforts in RRT.	A woman is no longer pregnant but has no baby. Have you asked about abortion, miscarriage, NND, and stillbirth? Document these events in VHR & extraction forms!	Stillbirth, NND, and maternal deaths are difficult for families to discuss. Probe respectfully and include in VHR and extraction form. It is important!
Good Morning! Remember to complete your RMM work.	Ask the VHC about pregnancies, births, and deaths. They are a resource and support your RMM work.	You identified a death but didn't have your VHR? Remember to document the death in the VHR and extraction forms so that it counts.
Thank you for your contribution to RMM. Have a nice day!	A baby born alive but dies in one month is a NND. Document in birth & death tables. A baby born dead is a stillbirth. Document in pregnancy table with comment.	Add new households and transfer-ins in your VHR and give a unique ID. Their pregnancies, births, and deaths are included in RMM so document on extraction form.

Table 16. Introduction SMS

Phase one	Phase two
Hello this is the NSO! We are starting our SMS support project today. You will receive regular SMS from us to support your RMM work. Thanks for your work!	NSO: We continue to assess the regular SMS and have updated SMS based on your feedback. You will see new SMS to support your RMM work. Zikomo!
This SMS is from NSO SMS number. You can SMS if you have a question. To call or SMS Kingsley use his number XXXXXXXXX	This SMS is from NSO SMS number. You can SMS if you have a question. To call or SMS Kingsley use his number XXXXXXXXX

Table 17. Evaluation Indicators

	Evaluation question	Assessment	Comparison
Sample maintenance	To what extent did treatment groups change from initial sample?	Number of catchment areas with HSA turnover	Sample from initial study design
Message dose	Was the intervention implemented as specified in the initial study design?	Percent difference in the number of SMS sent per week by study phase	Message plan from initial study design
Message transmission	To what extent were doses of SMS sent to treatment groups as scheduled?	Percentage of SMS sent as per phase-specific schedule	Phase-specific SMS schedule
Cost maintenance	To what extent did costs meet budgeted costs in the initial design?	Total cost by phase and per HSA	Budgeted costs from initial study design

Table 18. Intervention characteristics by period.

	Phase I		Phase II		Combined	
Intervention period (wks)	30		27		57	
Average SMS sent per week	467	(371–508)	570	(281–849)	560	(281–84
Average cost per SMS	US$0.04	(0.02–0.06)	US$0.05	(0.03–0.07)	US$0.04	(0.02–0.07)
CA with HSA turnover	8	5.1%	1	0.6%	9	5.8%
Control	*6*	*7.5%*	*0*	*0%*	*6*	*7.5%*
Intervention	*2*	*2.6%*	*1*	*1.3%*	*3*	*3.9%*

Table 19. SMS totals and costs by phase.

	SMS scheduled	SMS sent		Total Cost*	Weekly HSA cost*
Pilot	1,926	1,926	(100%)	43.39	0.09
Phase I	14,003	13,911	(99.3%)	529.61	0.11
Phase II	18,487	18,016	(97.5%)	935.56	0.22
Post-Implementation	1,322	1,227	(92.8%)	56.48	0.18

Costs reported in USD

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Chapter 6 Evaluation of a mHealth data quality intervention to improve documentation of pregnancy outcomes by Health Surveillance Assistants in Malawi: a cluster randomized trial

Abstract

Background

While community health workers are being recognized as an integral work force with growing responsibilities, increased demands can potentially affect motivation and performance. The ubiquity of mobile phones, even in hard-to-reach communities, has facilitated the pursuit of novel approaches to support community health workers beyond traditional modes of supervision, job aids, in-service training, and material compensation. We tested whether supportive short message services (SMS) could improve reporting of pregnancies and pregnancy outcomes among community health workers (Health Surveillance Assistants, or HSAs) in Malawi.

Methods and Findings

We designed a set of one-way SMS that were sent to HSAs on a regular basis during a 12-month period. We tested the effectiveness of the cluster-randomized intervention in improving the complete documentation of a pregnancy. We defined complete documentation as a pregnancy for which a specific outcome was recorded. HSAs in the treatment group received motivational and data quality SMS. HSAs in the control group received only motivational SMS. During baseline and intervention periods, we matched reported pregnancies to reported outcomes to determine if

reporting of matched pregnancies differed between groups and by period. The trial is registered as ISCTRN24785657.

Conclusions

Study results show that the mHealth intervention improved the documentation of matched pregnancies in both the treatment (OR 1.31, 95% CI: 1.10-1.55, p<0.01) and control (OR 1.46, 95% CI: 1.11-1.91, p=0.01) groups relative to the baseline period, despite differences in SMS content between groups. The results should be interpreted with caution given that the study was underpowered. We did not find a statistically significant difference in matched pregnancy documentation between groups during the intervention period (OR 0.94, 95% CI: 0.63-1.38, p=0.74). mHealth applications have the potential to improve the tracking and data quality of pregnancies and pregnancy outcomes, particularly in low-resource settings.

Background

The field of global health has set ambitious goals, including the Millennium Development Goals and the recently defined Sustainable Development Goals [1]. These initiatives have catalyzed donor support and country engagement to make progress on education, health, and socio-economic development [2]. Shortages of skilled health workers and demanding scale-up agendas to meet targets have focused attention on the potential of community health workers (CHWs) to extend the reach of the formal health system [3]. Although CHWs are a heterogeneous group of health professionals globally, a common element is their presence within the community they serve. CHWs are gaining job responsibilities, recognition, and financial compensation due to skilled health worker shortages [4-7]. Their community presence has the potential to minimize access and utilization barriers by bringing health care services closer to the population they serve [3,8]. Reliance on CHWs for multiple responsibilities, however without commensurate consideration of appropriate support or compensation, can be demotivating and affect their performance [9, 10].

Researchers have demonstrated the importance of supervision and incentives to improve motivation and performance among CHWs [11-13]. Mobile technology for health, commonly called mHealth, is a growing field in public health that uses mobile technology for health care delivery, improving efficiency and data quality, minimizing bottlenecks, and supporting continuous education and

adherence [14-17]. mHealth applications are diverse and creative, although most fall within one of twelve domains: client education; point of care diagnostics; vital event tracking; data collection; electronic health records; decision support; provider communication; provider work planning; provider training; human resource management; supply chain management; and financial transactions [18]. mHealth applications are relatively new, so many mHealth projects to date have been implemented as pilots, and rigorous evaluations are only recently emerging [19-21]. Conclusions on effectiveness vary and research gaps remain, especially for rigorous quantitative evaluations, cost-effectiveness studies, and assessments focused on scaling up projects beyond the pilot stage [22,23].

The Institute for International Programs (IIP) at Johns Hopkins University and the Malawi National Statistical Office (NSO) collaborated to implement a community-based vital event documentation system ("Real-time Mortality Monitoring", RMM) using Health Surveillance Assistants (HSAs), government trained and paid CHWs with a scope of work set by the Malawi Ministry of Health [24]. We implemented the RMM project in two districts in Malawi from January 2010 through December 2013 to assess the completeness and accuracy of under-five mortality reporting by HSAs. Details of this study are described elsewhere [25-28].

An estimated 45% of under-five deaths occur in the neonatal period and many of these deaths are not reported due to cultural and social norms [29-31]. To promote HSA surveillance of pregnant

women and families with children, we designed RMM to include pregnancy tracking to facilitate the capture of neonatal deaths. To maintain motivation of HSAs and encourage high data quality, we provided incentives and supports. One such support was a mHealth intervention with two levels of intensity; these levels were randomly allocated within clusters to HSAs. We present results from this cluster randomized mHealth intervention designed as a job aid to improve the documentation of matched pregnancies. We defined matched pregnancy documentation as a recorded pregnancy with a matched outcome: induced abortion, miscarriage, stillbirth, live birth, or the out-migration of the pregnant mother.

Methods

Study population

We conducted the data quality mHealth intervention with the RMM project implemented in the Balaka and Salima districts of Malawi. The intervention period for the mHeath trial was from November 2012 to November 2013, and the intervention period for the RMM project was from January 2010 to December 2013. The districts in the RMM project were selected for their high under-five mortality, high fertility, ease of access for the study team, average population size relative to other districts in the country, and full coverage by HSAs deployed in the district. Each HSA in Malawi is assigned to a catchment area of approximately 1,000 inhabitants and its associated health facility, covering a

radius of eight kilometers except in district-defined hard-to-reach catchment areas [32]. We randomly selected 160 catchment areas: 80 from among 280 catchment areas in Balaka and 80 from among 355 catchment areas in Salima, Details of the randomization are presented elsewhere [25]. Among the selected catchment areas, the average number of HSAs affiliated with a health facility was 5.2 (range: 1 to 19). The selected HSAs were associated with a total of 30 health facilities. All HSAs assigned to RMM catchment areas were eligible for inclusion in the mHealth intervention.

Through the RMM project, HSAs received training on the documentation of pregnancies, births, and deaths, a task within the HSA scope of work set by the Ministry of Health [33]. At the start of the RMM project, HSAs and supervisors received a mobile phone to facilitate communication with RMM project staff for data editing calls and field visit notifications. Due to poor results in the midline assessment of under-five mortality reporting, we implemented phase two of the RMM project in September 2012 with additional incentives and data quality supports to improve HSA documentation of vital events.

Design

We designed the intervention as a mobile support for HSAs using one-way short message services (SMS) sent by the mHealth coordinator at the NSO to HSAs in the RMM project. The mHealth intervention had a three-week pilot phase and a twelve-month implementation phase divided into two phases. The study team modified the intervention after eight months of implementation to

incorporate feedback from the HSAs suggesting that the variety of SMS and their frequency should be increased (Figure 8). The intervention is described in two phases. Phase one ran for seven months between December 2012 and June 2013. Phase two ran for five months from July to November 2013. Throughout both phases, the treatment group received high-intensity SMS with motivational and data quality content based on the RMM data quality guidelines (Table 20). The control group received minimal-intensity SMS with basic motivational content. Appendix D presents all SMS sent to the control group and a selection of the SMS sent to the treatment group during each phase of the intervention [34].

For both periods, we pretested the SMS among purposively selected HSAs (only in Balaka for phase one SMS, in both districts for phase two SMS). To meet the 160-character limit of the SMS, established abbreviations were used and punctuation dropped in ways that pilot testing confirmed did not affect the HSAs' comprehension of the message. For both treatment and control groups, the SMS were randomized and scheduled as per the schedule. The repetition of SMS presented in a randomized sequence was done to reinforce important data quality messages in the treatment group yet avoid alert fatigue.

We selected Frontline SMS as the messaging platform because it is open source and fit the technical and management capacities of the IIP and NSO data management team [35]. Frontline SMS functions with a GSM wireless modem and SIM card for which we selected Airtel, one of the two leading telecom operators in

Malawi at the time of the study design. Because HSAs had Airtel SIM cards in their RMM-issued mobile phones, this allowed us to pay the lowest airtime costs.

Prior to the start of the intervention, the lead mHealth researcher trained two RMM data management team members at the NSO to serve as field coordinators for the study. During phase one, the two field coordinators alternated responsibility each week. During phase two, one coordinator retained lead responsibility and was supported by the other coordinator when conducting field visits. The lead mHealth researcher supervised the initial implementation of the intervention, maintained daily communication with the mHealth coordinators throughout the intervention, and assisted in resolving technical and logistical challenges.

At the September 2012 data review meetings of the RMM project, the NSO data management team introduced the mHealth intervention as a mobile support to HSAs and supervisors. We did not train HSAs in sending or reading SMS, because SMS were an established method of communication in the RMM project. At the start of the SMS pilot period and the second phase of the mHealth intervention, the field coordinator sent SMS with a brief description of the intervention expectations and schedule.

Prior to each scheduled transmission of SMS to HSAs, the field coordinator sent a test SMS to three NSO RMM team members to ensure proper functioning of the Frontline SMS platform. Once

receipt of the test SMS was confirmed by at least one of the recipients of the test SMS, the field coordinator sent the scheduled SMS. For HSAs with two phones, the field coordinator sent the same scheduled SMS to both numbers to increase the likelihood that the SMS was received. After the field coordinator sent the SMS, the Frontline SMS platform was kept open and the USB GSM modem was kept connected in the event that an HSA responded with a question or clarification.

Although the intervention was unidirectional, HSAs occasionally sent response SMS to the field coordinators. The field coordinator documented SMS communications and airtime costs each day SMS were sent and tallied totals at the end of the week (Table 20). Each week, the lead mHealth researcher and field coordinators communicated and confirmed the SMS schedule, the number of SMS that had been sent, responses received from HSAs, and weekly airtime costs, all of which were recorded in the SMS program management database in Microsoft Excel.

As per the scope of work set by the Malawi Ministry of Health, HSAs track pregnancies, births, and deaths using their Village Health Registers (VHRs). For the RMM project, we asked HSAs to extract these events monthly onto a RMM extraction form that was submitted to the NSO. Details of the data collection process are available elsewhere [25,27]. The data editor reviewed these forms and called HSAs who had reported an adverse event (induced abortion, miscarriage, stillbirth, maternal death, or neonatal death) to confirm the event and verify the outcome

classification.

The primary outcome measure was the improvement in matched pregnancy documentation between groups during the intervention period. Possible pregnancy outcomes included adverse events (induced abortion, miscarriage, stillbirth), live birth, and out-migration of the pregnant mother. The secondary outcome measures were the improvements in matched pregnancy documentation by group between baseline and intervention periods. We also evaluated changes in matched pregnancy documentation by HSA residency in their assigned catchment area.

Pregnancies and outcomes were matched using the six-digit HSA code and the woman's unique 11-digit ID. Matching results included three outcomes: (i) pregnancies matched to an outcome (ii) live births and adverse pregnancy outcomes without a pregnancy match (iii) pregnancies without a matched outcome. Only matched (i) and unmatched pregnancies (iii) were used to analyze the change in documentation of matched pregnancies, our primary and secondary outcome measures. We exclude unmatched outcomes (ii) from the analysis since they can be used to address a different research objective, the characteristics of women missed by HSAs during pregnancy.

Statistical analysis

We were restricted to the sample size of the RMM project, i.e. the number of pregnancies and outcomes that occurred within 160 randomly selected catchment areas of Balaka (n=80) and Salima (n=80) districts affiliated with thirty health facilities and 160

HSAs. We included only 156 of the 160 catchment areas in the randomization since four catchment areas did not have HSAs at the time of randomization (Figure 9). We randomized at the level of the cluster, health facilities (n=30). We did not use individual-level randomization to prevent contamination from HSA collaboration and interaction at their associated health facility.

We calculated the study power using published data from comparable studies conducted in Africa. We estimated that HSAs documented pregnancy outcomes for 70% of pregnancies at baseline, and HSAs in the control group would maintain this percentage during the intervention period [36]. We estimated HSAs in the treatment group would improve by 20% to document outcomes in 90% of the reported pregnancies [21]. Assuming a baseline prevalence of 70%, an effect size of 20%, a confidence level of 95%, an estimated intracluster correlation (ICC) of 0.3, inclusion of 30 clusters (15 control, 15 treatment), and a two-sided alpha of 0.05, we estimated a study power of 0.54, which falls short of the recommended power of 0.80 to reject the null hypothesis of no impact. This power estimate did not include pregnancy matching prevalence or ICC from baseline data, or factor variability in cluster size. Although we recalculated power using baseline data to reach a favorable estimate, we assume the study power of 0.54 given the study was designed with this estimate [37-39] (Appendix E).

To improve balance in treatment and control arms, we stratified by district and used a +/- 10% relative restriction to constrain on three variables: average catchment area population per HSA; total cluster population; and baseline timeliness of extraction form submission. The validity of the acceptable randomizations was checked by evaluating the number of times any two randomization units appeared in the same arm together [40]. From the list of 5,000 acceptable randomization schemes, one was randomly selected and a Bernoulli trial was used to determine the arm allocated to the intervention [41].

The data clerks performed double data entry in CSPro on edited forms [42]. Induced abortions, miscarriages, and stillbirths were recorded in an adverse outcomes database maintained by the data editor (doi: 10.7281/T1F769G3). HSA characteristics included in the mHealth intervention analysis were collected in August 2013 through the Village Health Register Verification assessment conducted for the RMM project. In catchment areas with HSA turnover, characteristics of the HSA interviewed for the assessment were used.

We did not conduct intention-to-treat analysis among HSAs who left RMM or transferred between RMM catchment areas, in order to minimize contamination in groups. HSAs who moved from a health facility cluster in one group to a health facility cluster in other treatment group received messages consistent with their new group. HSAs who transferred out of their RMM catchment area were instructed to stop submitting RMM extraction forms and were

dropped from the mHealth intervention. Their truncated data was included in the analysis. HSAs were masked to their treatment group allocation. It was not possible to mask the field coordinators to treatment group allocation since they were responsible for maintaining an updated contact list on Frontline SMS.

We used a population-averaged panel data model with generalized estimating equations to analyze the effect of the mHealth intervention on matched pregnancy documentation using Stata 12 [39]. The model assumed an independence working structure among observations. We specified a binomial distribution for the outcome variable and a logistic link between the outcome variable and predictor. We included clusters defined by health facility catchment area to account for the clustered design. Baseline and intervention data were included, so we specified an interaction effect between the intervention period and treatment group. We only considered explanatory variables that were not included in the constrained randomization. We evaluated district location and catchment area residence as explanatory variables, and only included HSA catchment area residence in the final model. We dropped unmatched pregnancies that would not have reached eight months' gestation in October 2013 or earlier. These unmatched pregnancies did not have full matching eligibility with the RMM dataset, because the dataset only included events through December 2013.

Ethical review

We obtained ethical approval in the U.S. from the Institutional Review Board (IRB) at the Johns Hopkins University Bloomberg School of Public Health, and in Malawi from the National Health Sciences Research Committee. We obtained a waiver of written consent from the IRB. Approval letters are available upon request.

Results

In the initial design, 76 HSAs affiliated with 15 health facilities were allocated to the treatment group and 80 HSAs affiliated with 15 health facilities were allocated to the control group (Figure 9). Two HSAs filled vacant catchment areas in the control group after randomization and were included in the study. Among the 158 HSAs linked to 30 health facilities in the RMM study, all HSAs participated in the mHealth intervention.

During the intervention, one HSA in the control group left the RMM project. Eight catchment areas experienced HSA turnover. One HSA replacement included the transfer of an HSA from a catchment area in the treatment group to a catchment area in the control group. The analysis was conducted with and without catchment areas with HSA changes. There were no substantive differences between the two sets of results, and the final analysis includes catchment areas with HSA changes during the intervention period.

Table 21 presents treatment and control group characteristics. HSA sex and catchment area population were used

118

to constrain the randomization. Baseline characteristics of HSAs are similar across groups, with only a small difference in the percentage of HSAs with large or small catchment areas. HSA reporting of matched pregnancies increased at the start of RMM phase two in September 2012, and was generally maintained over time. However, there was a jump in unmatched pregnancies at the end of the mHealth intervention (Figure 10). The monthly proportion of pregnancies that were matched increased in both groups during most of the mHealth intervention period (Figure 11). The proportion in both groups appears to decrease in September 2013, which coincides with the time-intensive preparations for the large endline survey conducted by the RMM data management team. During this period, the RMM data management team had limited day-to-day engagement with HSAs and RMM field members because they were preoccupied with preparations for the endline survey.

During the baseline and intervention periods, HSAs reported 7,407 matched pregnancies, of which 4,140 were reported in the intervention period (55.9%). Table 22 summarizes the number of events reported by group and the distribution of event types. Treatment group HSAs reported slightly more matched pregnancies at baseline than the control group (1,681 vs. 1,586). Both groups reported a similar percentage of live births among matched pregnancies in both periods. In the baseline period, the control group reported no induced abortions. The five induced abortions reported by the treatment group only accounted for 0.3% of its

reported events in the baseline period. Control group HSAs reported more out-migration than HSAs in the treatment group, with the difference increasing slightly in the intervention period (1.8% vs. 1.4% and 3% vs. 2.1%, respectively). Treatment group HSAs reported twice as many adverse pregnancy outcomes in the intervention period as the control group HSAs. The absolute number of events increased during the intervention period, but the overall distribution of events remained unchanged.

Table 23 summarizes the analysis of the primary and secondary outcomes. The intervention did not result in statistically significant improvements in matched pregnancies between groups during the intervention period (OR 0.94, 95% CI: 0.63-1.38, p=0.74). However, we found statistically significant differences by groups between baseline and intervention periods. HSAs in the control group reported 46% more matched pregnancies during the intervention period as compared to the baseline period (95% CI: 1.11-1.91, p=0.01). HSAs in the treatment group reported 31% more matched pregnancies during the intervention period as compared to the baseline period (95% CI: 1.10-1.55, p<0.01). We noted statistically significant differences in matched pregnancy documentation by catchment area residency. HSAs who do not reside in their catchment area are 28% more likely to match pregnancies than HSAs who reside in the catchment area (95% CI: 0.54-0.96, p=0.03).

Discussion

This mHealth intervention, designed and analyzed at the cluster level, led to an improvement in HSA documentation of matched pregnancies in each group between baseline and intervention periods. However, we did not find a statistically significant difference in matched pregnancy documentation between groups during the intervention period. Overall documentation of pregnancies and outcomes improved during the intervention period, with notable increases in the documentation of out-migration and adverse pregnancy outcomes.

A range of factors can influence CHW performance, but translating these factors to mobile applications is novel and results vary [20,43]. Researchers evaluating timeliness of reporting by CHWs have found that it can be improved with reminders by phone or SMS [17,44]. DeRenzi et al. found that supervisor follow-up via an SMS reminder system was associated with improved timeliness. SMS reminders alone did not improve timeliness. Our study was limited to SMS sent only to HSAs, without the inclusion of supervisors, who had higher rates of turnover in RMM than HSAs. The results of Derenzi et al. are notable in light of research on the importance of supervision on CHW motivation, which is a strong influence on performance [9,13,17]. Furthermore, they demonstrate that the design of a mHealth intervention can influence effectiveness. We pre-tested the SMS and made deliberate changes to the initial design of the SMS intervention based on HSA feedback for more variety of SMS

content and increased frequency. Robust formative research elaborating recipient perceptions of SMS intervention design and feedback mechanisms may facilitate the design and implementation of an effective mHealth intervention specific to the needs of the SMS recipients [45,46].

The improvements in the control group were not expected based on research showing no effect with simple, repetitive SMS [47]. We tailored the high-intensity intervention SMS to match the data quality guidelines of the RMM project since research has shown improved efficacy of tailored and personalized SMS [48]. Qualitative studies have found that mHealth interventions have had an unintended motivational and empowering effect on CHWs [45,49]. Additionally de Tolley et al. found statistically significant improvements with motivational SMS, though not with informational SMS sent to improve uptake of HIV counseling and testing [50]. These results may explain the statistically significant improvement in the documentation of matched pregnancies among control group HSAs in the intervention period compared to the baseline period. Qualitative assessments with multiple evaluation points to capture motivation levels and perceptions of mHealth content and frequency should be conducted to explain such unexpected results. Future mHealth research should be multidimensional, using qualitative research to complement and explain quantitative results [20].

The increase in the documentation of induced abortions, miscarriages, and stillbirths is noteworthy, because these events

are difficult to capture in low-income countries [30,51]. Haws et al. found that women in Tanzania did not share pregnancy loss or neonatal death with their community [31]. Research in South Africa and Ghana found that women hide pregnancies to protect against witchcraft [52,53]. Given this level of discretion, CHWs may be in a strong position to document these hard-to-capture events, given their presence in the community and their role as service providers. The increase in documented adverse pregnancy outcomes during the intervention period by both groups, and notably the treatment group receiving data quality SMS about these sensitive events, warrants further attention.

In a study conducted among HSAs in the Mwanza district of Malawi, Kok & Muula found that HSAs identified transportation challenges as one of the main work dissatisfiers [54]. Transportation challenges have also been identified as a contextual factor that can impact CHW performance [55]. Our results counter performance results from other studies. We found that HSAs who do not reside in their catchment area are more likely to document matched pregnancies than HSAs who reside in their catchment area. Catchment area residence is only one metric to assess HSA presence. It does not consider distance of the residence from catchment area or HSA time spent in the catchment area, variables that might be more indicative of community presence. Further research should be conducted to evaluate CHW community presence and the best metrics for assessment.

A major limitation to the study is limited power of the study due to a restricted study population. However, this design allowed for a pre-post intervention design with complete baseline data. This also allowed calculation of three ICC coefficients that can be used by researchers designing clustered studies. Another limitation is the change in design of the intervention midway through the trial to increase the dose of SMS in the treatment group from three SMS a week to five. We made this decision with great consideration. We agreed that the modest increase in SMS frequency in the intervention group responded to the needs of the HSAs. The change in intervention may have introduced bias for assessing the intervention effect. We expect the bias to be positive relative to phase I results and negative for phase II results in the treatment group assuming the increased dose improved matched pregnancy documentation. We did not measure the effect of the change due to the underpowered study design and absence of notable differences between phases in both treatment groups. This further highlights the importance of qualitative assessments in complementing quantitative results to elucidate HSA perceptions on the effect of any form of SMS modifications [20,45].

The Frontline SMS system did provide confirmation that SMS were sent though the cellular network, but we did not have confirmation from HSAs that the message was received, read, and understood, or about the delay between the arrival of the SMS and its reading. This required the assumption that a SMS confirmed by

Frontline was received and read by the HSA in a timely manner. A bidirectional SMS intervention would have allowed us to confirm receipt and quantify delays, but the intervention would no longer be a reminder system and require a higher level of engagement from the field coordinator at the NSO and from the HSAs. If this intervention is reconsidered for HSAs in Malawi, researchers should consider pilot testing a bidirectional system to determine its feasibility and acceptability given the more interactive design.

This intervention was not designed to be scaled up as implemented through the RMM project. New investments would be required to maintain the intervention and to scale it up. This pilot study is an example of the *"pilotitis"* that is plaguing mHealth interventions, but also generated important information that can be used to develop an improved design prior to scale-up [56].

The ubiquity of mobile phones and growing access to mobile networks in hard-to-reach areas makes mHealth a very attractive tool, especially in low-income countries. Our results reveal that regularly scheduled SMS with basic motivational messages, both with and without data quality content, can improve performance of CHWs in the documentation of pregnancy outcomes. The study was underpowered so results should be interpreted with caution. These results are still important given the growing interest in mHealth applications and respond to calls for their rigorous evaluation

[57]. Researchers, program planners, and policy makers stand to benefit from sharing results from mHealth applications.

Conclusions

We observed measurable improvements in the documentation of matched pregnancy outcomes associated with regular, unidirectional SMS of two intensity levels sent to CHWs in rural Malawi. Improvements were noted in each group regardless of whether or not the motivational SMS additionally included content explicitly related to data quality. The study was underpowered so results should be interpreted with caution. We did not find a difference in the documentation of matched pregnancies between groups during the intervention period. The effect of continuous guidance and support to CHWs via SMS on the data quality of pregnancy outcomes should be further investigated using randomized field studies. In particular, further research is needed to exploit the motivational effect of SMS communications, their content, and frequency. We believe that mHealth tools have the potential to improve the tracking of pregnancies and the documentation of pregnancy outcomes, particularly in low-resource settings.

Acknowledgements

Chapter 6 Figures and Tables

Fig. 8. SMS timeline. Timeline of RMM project and SMS

implementation from January 2010 through December 2013.

	2010	2011	2012	2013
	J F M A M J J A S O N D	J F M A M J J A S O N D	J F M A M J J A S O N D	J F M A M J J A S O N D
RMM phase one				
RMM phase two				
SMS pilot period				
SMS phase one				
SMS phase two				

Fig. 9. Trial profile. Profile of trial clusters at randomization, intervention, and analysis periods.

CONTROL

30 health facilities
156 HSAs

TREATMENT

RANDOMIZATION

15 health facility clusters
80 HSAs

15 health facility clusters
76 HSAs

2 HSAs added
to vacant CA*

15 health facility clusters
82 HSAs
5 CA* with HSA replacement
1 HSA dropout

1 HSA
transfer

15 health facility clusters
76 HSAs
3 CA* with HSA replacement

INTERVENTION

Phase one:
2 SMS per week

Phase one:
3 SMS per week

Phase two:
2 SMS per week

Phase two:
5 SMS per week

ANALYSIS

15 health facilities
1,993 baseline pregnancies
2,473 intervention pregnancies
81 HSAs in analysis

15 health facilities
2,084 baseline pregnancies
2,406 intervention pregnancies
76 HSAs in analysis

*catchment areas

129

Fig. 10. Matched and unmatched pregnancies by group. Number of matched and unmatched pregnancies by group during SMS baseline and intervention periods from December 2011 through November 2013.
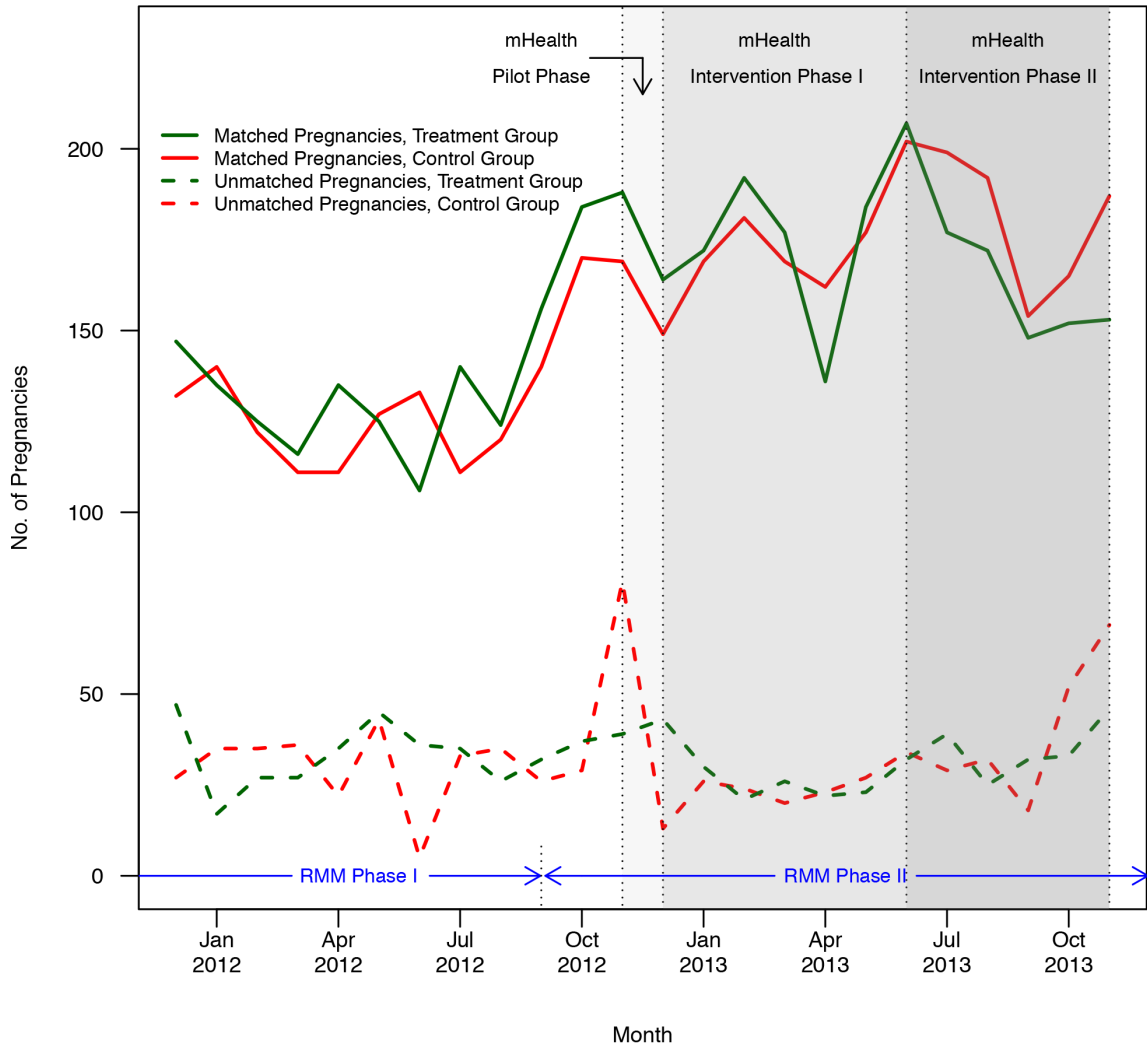
Fig. 11. Proportion of matched pregnancies by group. Proportion of matched pregnancies by group during SMS baseline and intervention periods from December 2011 through November 2013.

Table 20. SMS intervention two-phase schedule.

	Phase one	Phase two
Time period	12/2012–6/2013	7/2013–11/2013
Weeks	34	26
Total SMS sent		
Control group	2 SMS/week	2 SMS/week
Treatment group	3 SMS/week	5 SMS/week
SMS content		
Control group	Motivation	Motivation
Treatment group	Data quality and motivation	Data quality and motivation
SMS message variety		
Control group	3 unique messages	6 unique messages
Treatment group	12 unique messages	24 unique messages
Average weekly airtime US$	$19.00	$30.22
Total airtime US$	$646.11	$785.70

Table 21. HSA characteristics by group.

	Control		Treatment		Total	
	n	**%**	**n**	**%**	**n**	**%**
Health facilities *(n=30)*						
Balaka	6	40%	7	47%	13	43%
Salima	9	60%	8	53%	17	57%
HSAs working on RMM *(n=158)*						
Female	25	30%	26	34%	51	32%
Male	57	70%	50	66%	107	68%
Catchment area posting: *(n=157)*						
HSA does not reside in CA*	43	53%	41	54%	84	54%
HSA does reside in CA*	38	47%	35	46%	73	46%
Catchment area size: *(n=158)*						
<900 inhabitants	11	13%	4	5%	15	9%
900–1100 inhabitants	19	23%	20	26%	39	25%
1101–1400 inhabitants	26	32%	33	43%	59	37%
≥1400 inhabitants	26	32%	19	25%	45	28%

*catchment area

Table 22. Matching results by intervention periods and groups.

	Control		Treatment		Total	
	n	**%**	**n**	**%**	**n**	**%**
All documented events						
Unmatched pregnancies	774	15.1%	775	14.3%	1,549	14.7%
Unmatched outcomes	673	13.1%	946	17.4%	1,619	15.3%
Matched pregnancies	3,692	71.8%	3,715	68.3%	7,407	70.0%
Total	5,322	100.0%	5,612	100.0%	10,575	100.0%
Outcomes of matched pregnancies						
Baseline period						
Out-migration of pregnant woman	28	1.8%	24	1.4%	52	1.6%
Abortion*	0	0.0%	5	0.3%	5	0.2%
Miscarriage	8	0.5%	7	0.4%	15	0.5%
Stillbirth	20	1.3%	28	1.7%	48	1.5%
Live birth	1,530	96.5%	1,617	96.2%	3,147	96.3%
Total	1,586	100.0%	1,681	100.0%	3,267	100.0%
Intervention period						
Out-migration of pregnant woman	64	3.0%	43	2.1%	107	2.6%
Abortion*	3	0.1%	7	0.3%	10	0.2%
Miscarriage	12	0.6%	21	1.0%	33	0.8%
Stillbirth	36	1.7%	58	2.9%	94	2.3%
Live birth	1,991	94.5%	1,905	93.7%	3,896	94.1%
Total	2,106	100.0%	2,034	100.0%	4,140	100.0%

*Induced

Table 23. Odds ratio by intervention periods and groups.

	Odds Ratio	95% CI	p value
Primary outcome			
Control group-intervention period	*reference*		
Treatment group-intervention period	0.94	0.63 to 1.38	0.74
Secondary outcomes			
Control group- baseline period	*reference*		
Control group- intervention period	1.46	1.11 to 1.91	0.01
Treatment group- baseline period	*reference*		
Treatment group-intervention period	1.31	1.10 to 1.55	<0.01
Catchment area residency			
Does not reside in catchment area	*reference*		
Resides in catchment area	0.72	0.54 to 0.96	0.03

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Chapter 7 Conclusions

Each year, an estimated 4.7 million stillbirths and ENND occur with most occurring in low and middle-income countries [1-3]. In Malawi, where a majority of women report limitations to accessing care and demonstrate variability in health seeking behaviors for perinatal care, a perinatal death occurs in 40 per 1000 births [4]. These estimates from the 2010 DHS are the main source of SB and ENND data in Malawi since health facilities do not capture complete data on these events [4,5]. This data source is far from ideal given its decennial frequency and the potential for under-reporting these hidden events [6,7].

In theory, HSAs are in an ideal position to capture pregnancy outcomes given their work in tracking pregnancies and documenting births and deaths [8,9]. This was the motivation behind supporting HSAs through RMM to test the accuracy and completeness of HSA-reported vital events. Despite the regular data review meetings, additional supervision, and adverse pregnancy outcome classification training we conducted through RMM, we found that HSAs under-reported under-five deaths and perinatal deaths, the latter presented in chapter four [10,11]. Therefore, HSAs are currently not a good source of stillbirths and ENND data.

However, we strongly believe that HSAs have the potential to be a good source of stillbirth and ENND data if supported with appropriate interventions given the data quality improvements noted in chapters four and six. In the latter, we found that HSAs

in both treatment groups improved documentation of complete pregnancies (pregnancies matched to outcomes) through regular SMS support [12]. This result is notable for perinatal mortality documentation given the socio-cultural behavior of hiding perinatal losses and the recommendation to capture these events through pregnancy tracking [7-9].

In chapter four, we found that HSAs demonstrated excellent classification of stillbirths and ENND through the support of classification training. We identified continued misclassification of miscarriage as perinatal losses and induced abortions and stillbirths after implementation of the training, but noted improvements in classification between training periods.

From these data quality support activities, we have identified three key messages for policymakers in Malawi and other low-resource settings that pertain to the collection of high-quality perinatal mortality and broader topics in our work, the engagement of CHWs and implementation of mHealth applications.

Key Messages

Conduct annual review of community health worker responsibilities

Community health workers are garnering attention for their role in bringing services to communities, but the growing responsibilities have led to fluctuations in responsibility, affecting motivation and performance [13]. To ensure that CHWs

are well supported to conduct their work, we recommend that the Ministry of Health, or other agency responsible for their management, maintain a coordination, assessment, and communication process to annually renew the description of CHW responsibilities.

The coordination of activities is important given the dynamic evolution of CHW roles with the implementation and completion of programs and projects. To minimize redundancy in data collection and facilitate task-management, the MOH should maintain a centralized coordination role by carefully reviewing proposed CHW activities for integration in the job description and evaluating the continued inclusion of current tasks. As an example, RMM was designed with this strategy in mind and reinforced the task of pregnancy tracking and vital events documentation established within the MOH-issued scope of work [10-11].

In Malawi, HSAs reported only receiving a job description at their initial training despite the continuous evolution of responsibilities [13,14]. This lack of clarity in the scope of tasks and responsibilities will naturally lead to fluctuations in responsibility. By receiving an updated job description annually, CHWs will have a clear understanding of their scope of work and the priorities as identified by the MOH. This has the potential of directly improving task management and indirectly bolstering performance through the recognition of their responsibilities within the health system [15].

This review, however, should not be limited to CHWs but also be shared with health facility staff, the head of village health committees, supervisors, and district health officers. In Malawi, district health officials and supervisors have expressed poor opinions of HSA performance along with limited awareness of their responsibilities [14]. A regular clarification of CHW responsibilities will reinforce the role of CHWs within the larger health system, potentially providing recognition of their work and further motivation [15].

Consider, design, and implement mHealth applications carefully

mHealth applications are considered very attractive given the increase in network coverage, growing ownership of phones in a range of socio-economic classes, and cost of implementation compared to other methods [16-18]. However, as we present in chapter five, mHealth applications require careful assessment of a variety considerations. We focused on technical and operational considerations, and overlooked the behavioral component, which subsequently required a change during the implementation period. Future mHealth applications should consider the assessment of behavioral, organizational, and technical requirements in the development of mHealth interventions using a framework such as the Performance of Routine Information Systems Management (PRISM) framework designed for routine health information system performance but appropriate in this context as well [19].

The behavioral assessment can be conducted as formative research in the design process to identify the most appropriate

intervention for recipients. In chapter six, we emphasize the importance of complementing quantitative assessments of mHealth interventions with qualitative research. Qualitative research in the implementation process can reveal insight on unintended results and provide further explanation for intended results.

Cost-effectiveness is a current research gap in mHealth and an important consideration when considering scalability [20]. As demonstrated in chapter five, we were capable of managing cost variations as a small scale throughout the intervention but we would have been challenged in attempting to scale up the intervention with such variability. We strongly recommend the careful consideration of cost management in the design phase of a mHealth intervention to facilitate potential scalability and sustainability of mHealth interventions.

Promote accurate documentation and consistent reporting of stillbirths and ENND

Blencowe et al. estimate that 40% of data used for global estimates of stillbirths do not use the WHO criteria [21]. This inconsistency in criterion applied greatly affects the assessment of the burden of stillbirths and comparability across countries and data collection methods [22,23]. We strongly recommend that policymakers and researchers follow WHO recommendations to promote classification consistency for trend analysis at a country and global level. Moreover, we strongly recommend that reports on stillbirths and ENND include a description of the

classification used to categorize the events given the variability in classification we present in chapter two.

Classification challenges are not limited to stillbirths. In chapter four we present the misclassification of early pregnancy outcomes with stillbirths and early neonatal deaths. In light of these results we strongly recommend that CHWs responsible for documenting vital events should be trained on clear definitions for all adverse pregnancy outcomes. Moreover, we recommend the inclusion of all adverse pregnancy outcomes—induced abortions, miscarriages, stillbirths, and ENND— for any data collection method focused on an adverse pregnancy loss. In chapter four, our classification intervention focused on stillbirths and ENND revealed misclassification errors with induced abortions and miscarriages that we would have overlooked had we limited our assessment to perinatal losses. Finally, the use of perinatal mortality, an aggregated indicator capturing late fetal deaths and ENND, should be avoided. There are sufficient differences in the causes of stillbirths and ENND to warrant disaggregation [24]. These documentation practices have the potential to greatly improve the accuracy of reported stillbirths and ENND.

Research implications

Results from our data quality interventions reveal the potential of using mobile technology in improving data quality among CHWs. Working in remote environments, CHWs may not have a support network in immediate proximity, but mobile technology has

the potential to create this link. Given the unexpected improvements in the control group, there is a need to conduct qualitative research concurrently with mHealth interventions to explain expected and unexpected results.

The unexpected results in the control group of our study raise potential research questions on the importance of SMS content and dosing for behavior change. Both treatment groups demonstrated improvements in pregnancy outcome documentation, despite differences in SMS content and dosing. These results present an opportunity to explore the effectiveness of SMS content in changing behavior. Additionally, the dose and duration of SMS interventions should be addressed to identify if such a dose is constant or dependent on the context and outcome.

Finally, we conducted the classification intervention using a phone-based verification method that has not yet been validated. This method has the potential to support improved data quality among CHWs yet cost substantially less than traditional supervision. It is not a substitute for supervision but can be used to support CHWs between supervision visits or for specific data quality concerns.

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Appendix A RMM APO classification criteria

Though ICD-10 is the preferred method to classify deaths, it requires a diagnosis by a trained physician for it to be considered medically certified. HSAs are not physicians and have limited clinical understanding, so training of on event classification is limited to basic concepts. Additionally, the classification is limited to the information provided to the HSAs.

HSAs receive gestational age quantified in months, which the mother calculates or had measured during antenatal care appointments. The APO classification criteria provided to HSAs to support event classification uses gestational age and descriptions of pregnancy or fetal output that mothers would be capable of describing (Table S1).

Table S1. RMM APO criteria.

Event	Definition
Abortion	Typically the **intentional** death of a fetus during early months of pregnancy **(months 1-5)**
Miscarriage	**Unintentional** death of fetus at **1-6 months** gestational age
Stillbirth	Death of fetus of 7+ months gestation. The dead newborn shows NO signs of life: breathing, movement, crying, etc
NND	Newborn (7+ months) is born ALIVE: breathing, crying, movement, etc. Newborn dies at some point after delivery: within minutes, hours, or up to 28 days.

Appendix B Verification process

In the RMM project, we standardized the data editing process from September 2011–November 2011 when we hired and trained a data editor, trained HSAs in the new data quality standards, and established a standard data editing and adverse pregnancy outcome process. The NSO data collector reviewed each RMM extraction form and flagged forms with any noted APO or documentation concerns, such as an erased or crossed out event, maternal death, or pregnancy described as *disappear*. The latter is not uncommon in Malawi where sorcery is believed to make a pregnancy disappear without bleeding or illness at any point in the three trimesters [25].

Once the data editor collected all the flagged forms, he called HSAs during business hours during the work week. The data editor initiated the discussion with an open-ended question asking the HSA to describe the event he had flagged on the extraction form (Figure S1). Once the HSA described the event, the data entry clerk went through a series of questions to verify the gestational age, presence and appearance of fetus or discharge, woman's intention of loss, and vital signs for fetal births to classify the event using the RMM APO classification criteria. For maternal deaths, the data editor asked the outcome of the pregnancy and initiated the verification process if the HSA described the birth as a potentially adverse event.

Fig. S1. Verification process: Semi-structured questions in adverse pregnancy outcome verification process
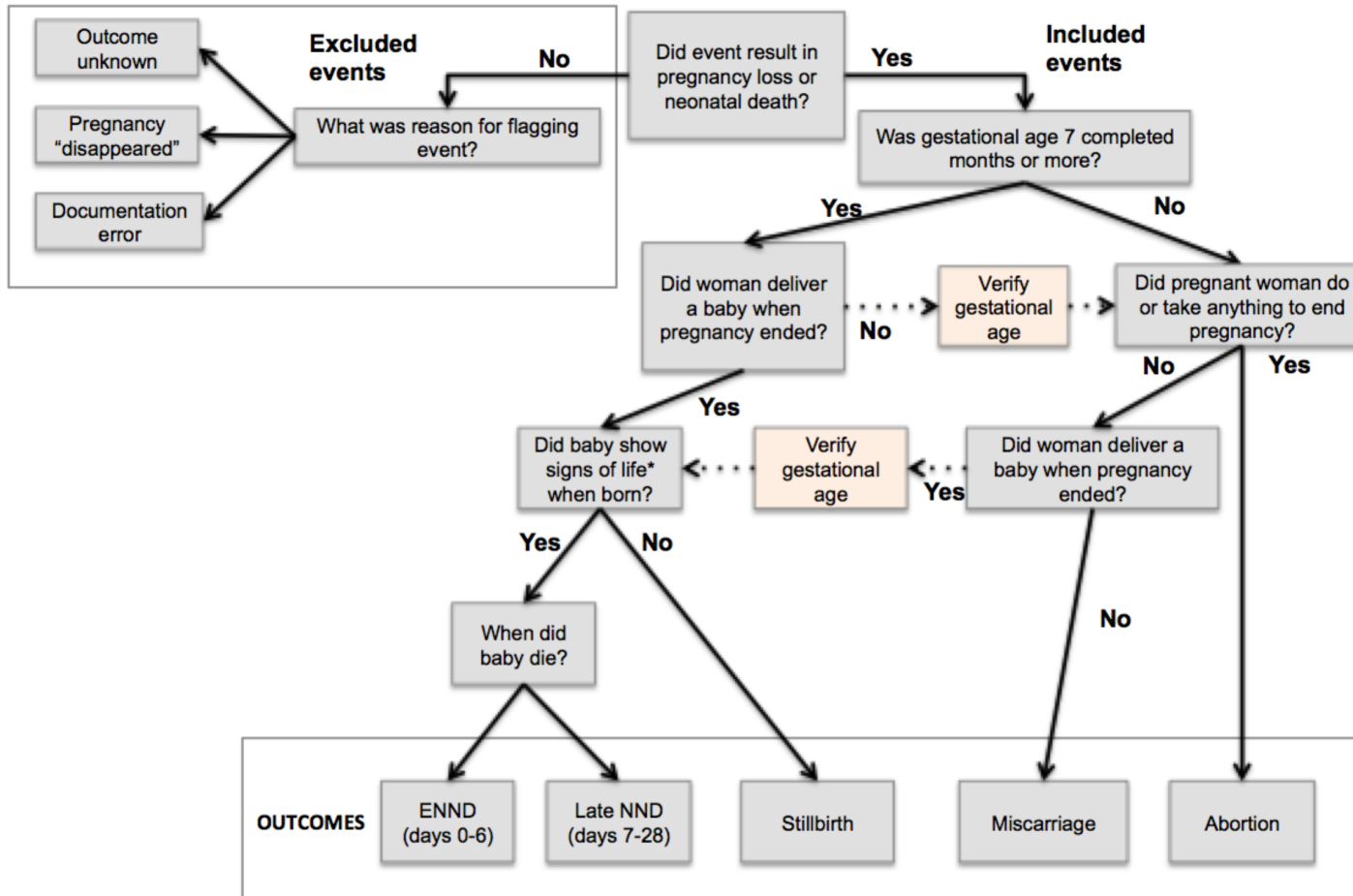
*Breathing, movement, crying

If, after multiple attempts, the data editor could not reach an HSA for event confirmation, he followed a sequence of steps to optimize verification of the event without affecting the monthly RMM data management process. Unconfirmed events were reported as such in the APO database for continued follow up. The data editor submitted the extraction forms with unconfirmed events to the data entry clerks for double data entry, reconciliation, and completion of monthly database cleaning.

For APOs requiring continued follow up, the data editor would contact the HSA's supervisor or neighboring HSA to assist in locating and scheduling a time to speak with the HSA. If the data editor could not locate the HSA through the HSA's colleagues, he would plan to visit the HSA in the field or during the data review meeting, whichever event occurred first. If the data editor confirmed an event that had been entered without confirmation, he would edit the form and resubmit to the data entry clerks to update the dataset. In instances when events could not be confirmed due to poor communication with HSA or HSA turnover, an event was accepted as the reported event but noted as unconfirmed.

The data editor maintained the APO database on which he recorded all HSA-reported APOs. He extracted the APOs from the extraction forms and single entered the HSA information, month and year of reporting, event, and details of the event in the database. Once the he completed the verification call, he single

entered the verified APO classification and noted the event as confirmed.

The data editor conducted retrospective verification of all APOs documented on extraction forms submitted prior to December 2011. The post-training verification period did not start until January 2011 since extraction forms reported events of the previous month. December 2011 events reported November 2011 events that might have been identified and documented by HSAs prior to the training. Thus, the post-training period started in January 2012.

Appendix C APO classification by district and training period

Tables S2 & S3 present classification results of all RMM HSAs by training period. HSAs reported more events post-training (253 versus 161) and improved percent agreement to 87%, up from 67.7%. Induced abortion and miscarriage classification was poor in the post-training period with percent agreement only reaching 50% and 58.5%, respectively. Among the 24 HSA-reported induced abortions in the pre-training period, 19 were misclassified as miscarriage, stillbirth, ENND, and documentation error. In the post-training period, HSAs misclassified induced abortions as miscarriage and stillbirth.

Tables S4 & S5 present pre-and post-training classification results among Salima HSAs. Percent agreement increased between periods from 62.5% to 85.9%, although induced abortion and miscarriage reporting remained poor. None of the HSA-reported induced abortions in the post-training period were classified as induced abortion by the data editor method. Salima HSAs improved miscarriage classification in the post-training period but continued to misclassify miscarriages as induced abortions, stillbirth, and ENND despite the training and classification support.

Tables S6 & S7 present Balaka pre-and post-training classification results. Balaka HSAs reported noticeably more APOs in the post-training period (n=90) compared to the pre-training period (n=25). Percent agreement worsened among Balaka HSAs but

that may be due to the increase in reported APOs. Balaka HSA percent agreement decreased from 96% in the pre-training period to 88.9% in the post-training period. Balaka HSAs did not report any induced abortions in the pre-training period. In the post-training period, Balaka HSAs reported 9 events and reached a percent agreement of 66.7%. Miscarriage classification did not improve between training periods with agreement increasing only slightly from 50% to 53.3%. Balaka HSAs misclassified

Table S2. Verification results: Pre-training, both districts combined.

		Abortion	Miscarriage	Stillbirth	ENND	Documentation error	TOTAL	Percent Agreement
HSA reporting	Abortion	5	7	8	2	2	24	20.8%
	Miscarriage	1	7	14	2	2	26	26.9%
	Stillbirth	0	1	41	2	2	46	89.1%
	ENND	0	1	7	56	0	64	87.5%
	Documentation error	0	0	1	0	0	1	0%
	TOTAL	6	16	71	62	6	161	67.7%

Table S3. Verification results: Post-training, both districts combined.

		Data editor validation method						
		Abortion	Miscarriage	Stillbirth	ENND	Documentation error	TOTAL	Percent Agreement
HSA reporting	Abortion	6	8	1	0	0	15	40.0%
	Miscarriage	3	26	13	4	0	46	56.5%
	Stillbirth	0	0	100	0	0	100	100.0%
	ENND	0	0	4	88	0	92	95.7%
	Documentation error	0	0	0	0	0	0	
	TOTAL	9	34	118	92	0	253	87.0%

Table S4. Verification results: Salima pre- training.

		Data editor validation method						
		Abortion	Miscarriage	Stillbirth	ENND	Documentation error	TOTAL	Percent Agreement
HSA reporting	Abortion	5	7	8	2	2	24	20.8%
	Miscarriage	1	6	13	2	2	24	25.0%
	Stillbirth	0	1	33	2	2	38	86.8%
	ENND	0	1	7	41	0	49	83.7%
	Documentation error	0	0	1	0	0	1	0%
	TOTAL	6	15	62	47	6	136	62.5%

Table S5. Verification results: Salima post- training.

		Data editor validation method						
		Abortion	Miscarriage	Stillbirth	ENND	Documentation error	TOTAL	Percent Agreement
HSA reporting	Abortion	0	5	1	0	0	6	0.0%
	Miscarriage	3	18	8	2	0	31	58.1%
	Stillbirth	0	0	68	0	0	68	100.0%
	ENND	0	0	4	54	0	58	93.1%
	Documentation error	0	0	0	0	0	0	
	TOTAL	3	23	81	56	0	163	85.9%

Table S6. Verification results: Balaka pre- training.

		Data editor validation method						
		Abortion	Miscarriage	Stillbirth	ENND	Documentation error	TOTAL	Percent Agreement
HSA reporting	Abortion	0	0	0	0	0	0	
	Miscarriage	0	1	1	0	0	2	50.0%
	Stillbirth	0	0	8	0	0	8	100.0%
	ENND	0	0	0	15	0	15	100.0%
	Documentation error	0	0	0	0	0	0	
	TOTAL	0	1	9	15	0	25	96.0%

Table S7. Verification results: Balaka post- training.

		Data editor validation method						
		Abortion	Miscarriage	Stillbirth	ENND	Documentation error	TOTAL	Percent Agreement
HSA reporting	Abortion	6	3	0	0	0	9	66.7%
	Miscarriage	0	8	5	2	0	15	53.3%
	Stillbirth	0	0	32	0	0	32	100.0%
	ENND	0	0	0	34	0	34	100.0%
	Documentation error	0	0	0	0	0	0	
	TOTAL	6	11	37	36	0	90	88.9%

miscarriages in the pre-training as stillbirth. In the post-training period, Balaka HSAs misclassified miscarriages as stillbirths and ENND. During both periods, Balaka HSAs reported all stillbirths and ENND correctly.

Appendix D Selection of SMS sent to RMM HSAs during phases one and two

In phase one, HSAs in the control group received one of three basic motivational SMS twice a week during work hours (Table S8). We randomized the sequence of the three SMS every 1.5 weeks to minimize alert fatigue, the avoidance of notifications such as SMS due to frequency [34].

Table S8. Control group SMS: motivational SMS in phases one and two.

Phase one SMS	Phase two SMS	
	Updated phase one SMS	New SMS
Good morning! The NSO[a] thanks you for your efforts in RMM.	NSO[a]: Good morning! The NSO thanks you for your efforts in RMM. Zikomo![b]	NSO[a]: HSAs[c] work very hard for RMM and the NSO recognizes your efforts. We appreciate your work! Zikomo![b]
Good Morning! Remember to complete your RMM work.	NSO[a]: Good Morning! Remember to complete your RMM work. Zikomo![b]	NSO[a]: HSAs[c] have many responsibilities and each is important. The NSO recognizes your efforts in RMM! Zikomo[b]
Thank you for your contribution to RMM. Have a nice day!	NSO[a]: Thank you for your contribution to RMM. Have a nice day!	NSO[a]: HSAs[c] are dedicated to improving community health. The NSO appreciates your work. Zikomo![b]

[a]*NSO – National Statistical Office*
[b]*Zikomo – Thank you in local language, Chichewa*
[c]*HSAs – Health Surveillance Assistants*

In phase one, HSAs in the treatment group received one of 12 data quality and motivational SMS three times a week during

work hours. A convenience sample of six SMS is included in Table S9. The sequence of these messages was randomized every four weeks to avoid alert fatigue, yet reinforce important data quality guidelines. The first and third SMS each week for the treatment group coincided with the first and second SMS each week for the control group. No SMS was sent to the control group when the treatment group received the second weekly SMS.

Table S9. Treatment group SMS: convenience sample of data quality and motivational SMS from phase one and improvements made for phase two.

	Phase one SMS	Phase one SMS
Data quality	A woman is no longer pregnant but has no baby. Have you asked about abortion, miscarriage, NND[a], and stillbirth? Document these events in VHR[b] & extraction forms[c]!	**NSO**[g]:A woman is no longer pregnant but has no baby. Have you asked about abortion, miscarriage, NND[a], and stillbirth? Write these events in VHR[b] & extraction forms[c]
	Ask the VHC[d] about pregnancies, births, and deaths. They are a resource and support your RMM work.	**NSO**[g]: Visit your VHC[d] often to ask about pregnancies, births, stillbirths, and deaths. They are very aware of community events and can help support your RMM work.
	A baby born alive but dies in one month is a NND[a]. Document in birth & death tables. A baby born dead is a stillbirth. Document in pregnancy table with comment.	**NSO**[g]: A baby born alive but dies in one month is a NND[a]. Document in birth & death tables. A baby born dead is a stillbirth. Write in pregnancy table with comment
	You identified a death but didn't have your VHR[b]? Remember to document the death in the VHR[b] and extraction forms so that it counts.	**NSO**[g]: You identified a death but didn't have your VHR[b]? Remember to write the death in the VHR[b] and extraction forms. Stillbirths, NNDs[a]– all deaths are important!
Motivational	Are you the HSA[e] of the quarter[f]? Find out at the January review meeting. Winners receive extra airtime.	**NSO**[g]: Are you the HSA[e] of the quarter[f]? The NSO[g] wants to recognize HSAs who excel in RMM. Find out at the January review meeting. Winners receive extra airtime.

Extraction forms for September 2012: Salima 77 out of 78. Balaka 69 out of 77. Good job Salima! HSAs[e], remember to complete and submit your forms on time.	**NSO**[g]: Extraction forms for September 2012: Salima 77 out of 78. Balaka 69 out of 77. Good job Salima! HSAs[e], remember to complete and submit your forms on time.

[a]*NND – Neonatal death*
[b]*VHR – Village Health Register*
[c]*Extraction forms are the monthly reporting forms for RMM reporting pregnancies, births, and deaths*
[d]*VHC – Village Health Committee*
[e]*HSAs – Health Surveillance Assistants*
[f]*HSA of the quarter– a RMM incentive of additional airtime provided at quarterly data review meetings to select HSAs meeting high data quality standards*
[g]*NSO – National Statistical Office*

Since the start of the mHealth intervention, HSAs in both groups asked for more variation in SMS content, though some HSAs in the treatment group recommended repeating SMS to emphasize important data quality issues. In response to this feedback we planned and implemented phase two. For the control group we modified the three phase one SMS and added three new SMS for a total of six SMS (Table S8). For the treatment group we modified the 12 phase one SMS and added 12 new SMS for a total of 24 SMS for phase two (Tables S9 & S10).

Table S10. Treatment group SMS: sample of new data quality SMS for phase two

New phase two data quality SMS	
NSO[a]: To address community needs you need to know the health of your community-pregnancies, births, stillbirths, & deaths. Document in VHR[b] and extraction forms!	**NSO**[a]: Catchment areas grow & shrink with births, migration and death. Document pregnancies, births, deaths in VHR[b] and extraction form to keep track!
NSO[a]: Dedicated HSAs[c] know their communities. Document pregnancies, births, stillbirths, and deaths in VHR[b] and extraction forms. Data helps with work planning!	**NSO**[a]:A family notified you of a maternal death.Did you ask about the baby? Is the baby alive? NND[d]? Stillbirth?Probe respectfully to identify and document for RMM
NSO[a]:A Family notified you of a newborn death. Probe respectfully to confirm stillbirth or NND[d]. Baby born alive but dies is a NND[d]. Baby born dead is a stillbirth	**NSO**[a]: Your VHCs[e] may identify pregnancies, births, deaths, and stillbirths that you had not identified. Work with your VHC[e] since they can support your work.

[a]*NSO – National Statistical Office*
[b]*VHR – Village Health Register*
[c] *HSAs – Health Surveillance Assistants*
[d]*NND – Neonatal death*
[e]*VHC – Village Health Committee*

We modified phase one SMS by starting the SMS with "*NSO:*" to notify the HSA of the information source immediately at the start of SMS. We ended the SMS with "*Zikomo,*" thank you in the local language, Chichewa, if the SMS was short enough to include the additional characters. Due to the 160-character limit, only a few treatment group SMS included *Zikomo*. We also increased the

frequency of weekly SMS in the treatment group from three SMS a
week to five SMS a week. We did not change the frequency of SMS
in the treatment group.

Appendix E Power and ICC estimates

Baseline data were not used in the design phase to calculate the intracluster correlation (ICC). We proposed an ICC of 0.3 for the calculation of the design effect. This was determined since HSAs work independently in the field yet are connected with HSA peers at the health facility. A level of homogeneity among HSAs in a cluster is probable, though it is not assumed to be high given the isolation in which HSAs work. We planned to check our assumption once we calculated ICC using baseline data.

In the recalculation of design effect and power, we used Stata 12 to calculate the ICC of matched pregnancies using baseline results of HSAs in all clusters [39]. We calculated an ICC of 0.015 (0.002-0.027), far smaller than the estimated ICC of 0.3 used in the design of the study (Table S11). Cluster size ranged from 1 to 19 HSAs per cluster with an average of 5.2 HSAs per cluster and 0.77 coefficient of variation of cluster sizes. We calculated a more favorable power calculation using baseline data but report the power of 0.54 as the study was designed with this power estimate [38].

Table S11. ICC calculations: Baseline and intervention periods.

	ICC	95% CI
Baseline	0.015	0.002–0.027
Intervention		
Treatment group	0.022	0.000–0.048
Control group	0.063	0.004–0.122

We also calculated the ICC of matched pregnancies during the intervention period, by treatment group. We calculated an ICC of 0.063 for the control group. The treatment group ICC was slightly lower during the intervention period at 0.022.

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study employing the FITT framework. Int J Med Inform 2009; 78: 39-52.

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study of terms, concepts, and survey questions. Calverton: ICF Macro; 2010.

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Curriculum Vitae

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EDUCATION

08/2009 – Present	**DOCTOR OF PUBLIC HEALTH:** INTERNATIONAL HEALTH *Johns Hopkins Bloomberg School of Public Health*
08/2009 – 08/2012	**NATIONAL LIBRARY OF MEDICINE PRE-DOCTORAL FELLOW:** Health Science Informatics *Johns Hopkins School of Medicine*
06/2008 – 05/2009	**MASTER OF PUBLIC HEALTH** *Johns Hopkins Bloomberg School of Public Health*
01/2003 – 05/2004	**BACHELOR OF SCIENCE:** Nursing *Georgetown University School of Nursing and Health Studies*
01/2003 – 05/2004	**CERTIFICATE IN INTERNATIONAL HEALTH** *Georgetown University School of Nursing and Health Studies*
09/1995 – 05/1999	**BACHELOR OF ARTS:** Psychology *Georgetown University*

AWARD AND DISTINCTIONS

2008 – 2009	**GLOBAL HEALTH SCHOLAR,** *Johns Hopkins Bloomberg School of Public Health*
2004	**MAGNA CUM LAUDE DISTINCTION IN NURSING/INTERNATIONAL HEALTH,** *Georgetown University School of Nursing and Health Studies*

INTERNATIONAL EXPERIENCE

09/2015– present	**CDC FOUNDATION:** Project Coordinator *Mumbai, India & Rabat, Morocco*

- Collaborate as technical advisor to support civil registration and vital statistic improvement activities for the Data for Health Initiative funded by Bloomberg Philanthropies and the Australian Government.
- Coordinate and lead project design and implementation of improved quality of cause of death data in Mumbai, including the training of 13,000 physicians and the transformation of the death certification coding structure.
- Design and support implementation of a verbal autopsy system integrated in the civil registration system for the identification of

cause of death of all deaths occurring outside facilities in Rabat.
- Conduct and report on initiative activities, including a baseline assessment, and monitoring and evaluation indicators.
- Facilitate coordination and communication for CDC civil registration and vital statistics team with initiative partners.

02/2010–
08/2015

INSTITUTE FOR INTERNATIONAL PROGRAMS: Research Fellow
Zomba, Malawi

- Coordinated and led project development, staff training, database design, data management, and data quality improvement activities on a community-based vital event documentation project.
- Developed instruments for various surveys on community health worker characteristics, work practices, documentation data quality, and motivation.
- Designed and implemented a mobile health intervention to improve data quality in vital event documentation.
- Assisted with data analysis and preparation of quantitative reports, publications, and presentations on vital event documentation and community health worker experiences and perceptions.
- Coordinated and led the completion of a donor report and publications presenting the design, methods, results, and key findings of the four-year project.

11/2010–
01/2011

WHO DEPARTMENT OF HEALTH STATISTICS AND INFORMATICS: Intern
Geneva, Switzerland

- Assisted with the research and editing of a report on the state of the world's health information systems titled, 'Country Health Information Systems: A review of current situation and trends.'
- Assessed the data availability, accessibility, and timeliness of Ministry of Health and National Statistical Office websites for low-income countries classified by the World Bank in 2011.

5/2009–
11/2010

INSTITUTE FOR INTERNATIONAL PROGRAMS: Research Fellow
Bamako, Mali

- Assisted with technical and operational issues in program management.
- Collaborated with in-country colleagues on the cleaning and analysis of formative research on vital event documentation in local communities

and the role of *Relais*, community health
workers.

- Supported the preparation of a qualitative
research report on current vital registration
systems and registration challenges in the
Segou Region

10/2009–
01/2010

JOHNS HOPKINS UNIVERSITY: Research Associate
Baltimore, Maryland

- Provided technical assistance in analyzing the
verification system of a $400 million results-
based financing project on maternal and child
health for a World Bank contract with the
Results-based Financing Team.
- Prepared a synthesis document for inclusion in
the World Bank publication, 'Verification at a
Glance.'

09/2006–
02/2007

PEACE CORPS RESPONSE: Clinical Technical Assistant
Kara, Togo at Association Espoir pour Demain-Lidaw

- Designed and implemented a medical record
system based on World Health Organization
recommendations, integrating home, hospital,
and clinic based psychosocial and medial
components of care into a comprehensive
assessment tool for adult and pediatric
patients living with HIV/AIDS.
- Trained eleven medical and psychosocial staff
to utilize, manage, and maintain a newly
implemented medical record system, highlighting
the importance of improved patient tracking and
the transition in focus from acute to chronic
care.
- Identified key indicators by which AED-Lidaw
can assess its services and report statistics
nationally and internationally

08/1999–
11/2001

PEACE CORPS: Health Education Volunteer
Wolonkotoba-Soni and Bamako, Mali

- Assisted in the establishment of a pharmacy,
design of an inventory system, and training of
a permanent pharmacist in basic computer skills
to manage the pharmaceutical inventory at the
main clinic in Mali caring for people living
with HIV/AIDS.
- Collaborated with *Association Feminine pour
l'Aide et le Soutien des Personnes Vivant avec
le VIH/SIDA*, Women's Association of Assistance
and Support for People living with HIV/AIDS, on
business and health promotion activities.
- Conducted a weekly radio show in Bambara and
French on various health topics, reaching an
estimated audience of half million villagers in
the Koulikoro region.

CLINICAL EXPERIENCE

06/2007 – 03/2009 **ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN:**
Philadelphia, PA
Pool Nurse (Emergency room and all inpatient units, including intensive care)

02/2007 – 05/2007 **ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN:**
Philadelphia, PA (via American Mobile Nursing)
Cardiac Care Unit

06/2006 – 09/2006 **UNIVERSITY OF CALIFORNIA MATTEL CHILDREN'S HOSPITAL:**
Los Angeles, CA (via American Mobile Nursing)
Pediatric Intensive Care Unit

08/2004 – 06/2006 **CHILDREN'S HOSPITAL OF PHILADELPHIA:** Philadelphia, PA
Cardiac Intensive Care Unit, Registered Nurse Level II
Pediatric Intensive Care Unit, Registered Nurse Level II

TEACHING EXPERIENCE

08/2010 – 05/2013 **LEAD TEACHING ASSISTANT:** Johns Hopkins Bloomberg School of Public Health, Extra departmental Distance Learning
Current Issues in Public Health

03/2013 – 05/2013 **TEACHING ASSISTANT:** Johns Hopkins Bloomberg School of Public Health, International Health
Large-Scale Effectiveness Evaluations of Health Programs

03/2012 – 05/2012 **TEACHING ASSISTANT:** Johns Hopkins Bloomberg School of Public Health, International Health Distance Learning
Large-Scale Effectiveness Evaluations of Health Programs

08/2009 – 05/2010 **TEACHING ASSISTANT:** Johns Hopkins Bloomberg School of Public Health, Extra departmental Distance Learning
Current Issues in Public Health

10/2009 – 12/2009 **TEACHING ASSISTANT:** Johns Hopkins Bloomberg School of Public Health, International Health Distance Learning
Health Information Systems

08/2009 – 10/2009 **TEACHING ASSISTANT:** Johns Hopkins Bloomberg School of Public Health, International Health
Quality Assurance Management Methods for Developing Countries

PUBLICATIONS

Mar 2016	**AMERICAN JOURNAL OF TROPICAL MEDICINE & HYGIENE: PUBLICATION**

- *Hazel E, Bryce J; IIP-JHU iCCM Evaluation Working Group.* On Bathwater, Babies, and Designing Programs for Impact: Evaluations of the Integrated Community Case Management Strategy in Burkina Faso, Ethiopia, and Malawi. Am J Trop Med Hyg. 2016; 94(3): 568-70.

Jan 2016	**PLoS MEDICINE: PUBLICATION**

- *Bryce J, Amouzou A, Victora CG, Jones G, Silva R, Hill K, et al.* "Real-Time" Monitoring of Under-Five Mortality: Lessons for Strengthened Vital Statistics Systems. PLoS Med 2016; 13(1): e1001904.

- *Bryce J, RMM Working Group.* "Real-Time" Monitoring of Under-Five Mortality: A Vision Tempered by Reality. PLoS Med 2016; 13(1): e1001912. doi: 10.1371/journal.pmed.1001912.

Jan 2016	**PLoS ONE: PUBLICATION**

- *Joos O, Silva R, Amouzou A, Moulton LH, Perin J, Bryce J, et al.* Evaluation of a mHealth Data Quality Intervention to Improve Documentation of Pregnancy Outcomes by Health Surveillance Assistants in Malawi: A Cluster Randomized Trial. PLoS One 2016; 11(1): e0145238.

- *Joos O, Amouzou A, Silva R, Banda B, Park L, Bryce J, et al.* Strengthening community-based vital events reporting for real-time monitoring of under-five mortality: Lessons learned from the Balaka and Salima districts in Malawi. PLoS One 2016; 11(1): e0138406.

- *Silva R, Amouzou A, Munos M, Marsh A, Hazel E, Victora C, et al.* Can Community Health Workers Report Accurately on Births and Deaths? Results of Field Assessments in Ethiopia, Malawi and Mali. PLoS One 2016; 11(1): e0144662.

Nov 2015	**PLoS ONE: PUBLICATION**

- *Munos MK, Koffi AK, Sangho H, Traoré MG, Diakité M, Silva R; et al.* Strengthening Community Networks for Vital Event Reporting: Community-Based Reporting of Vital Events in Rural Mali. PLoS One 2015; 10(11): e0132164.

Oct 2015	**SANTE PUBLIQUE: PUBLICATION**

- *Sangho H, Traore MG, Joos O, Keita HD, Keita AS, Munos M.* Recherche formative sur l'enregistrement d'evenements vitaux en

milieu communautaire au Mali. Revue Sante Publique 2015; 565–574.

May 2014	**PLoS One:** Publication
	• *Amouzou A, Banda B, Kachaka W, Joos O, Kanyuka M, Hill K, et al.* Monitoring Child Mortality through Community Health Worker Reporting of Births and Deaths in Malawi: Validation Against a Household Mortality Survey. PLoS One 2014; 9: e88939.
2011	**World Health Organization:** Technical Report *Geneva Switzerland*
	• Country health information systems: A review of the current situation and trends *WHO Department of Health Statistics and Informatics*
April 2011	**World Bank:** Technical Report *Washington, DC*
	• Verification at a Glance *Naimoli J & Vergeer P, Eds.*
Mar 2005	**Journal of Pediatric Oncology Nursing:** Publication
	• *Norton CK, Joos OH.* Caring for Catherine: a cry to support ethical activism. J Pediatr Oncol Nurs 2005; 22(2): 119–120.

PRESENTATIONS & POSTERS

May 2015	**Population Association of America:** Presentation and Poster *San Diego, California*
	• Challenges and Innovations in Using Community-Based Workers to Improve Vital Events Registration in Sub-Saharan Africa: Validation against Full Pregnancy Histories in Four Countries *Silva R, Amouzou A, Munos M, Jones G, Kidanu A, Arhinful D, Sangho H, Joos O, Koffi A, Bryce J (presentation)*
	• Community-based Documentation of Perinatal Mortality: Evaluating the Classification of Adverse Pregnancy Outcomes Captured by Health Surveillance Assistants *Joos O, Laija K, Mullany L (poster)*
Mar 2015	**Global Health and Innovation Conference:** Poster *New Haven, Connecticut*
	• Potential Contribution of Community Health Workers to Civil Registration and Vital Statistics: the case of Health Surveillance Assistants in Malawi *Joos O, Chimzimu M, Park L, Hazel E, Amouzou A*
Mar 2015	**Consortium of Universities for Global Health:** Poster *Boston, Massachussetts*
	• Evaluating Progress in Data Availability and Timeliness: A Scorecard Assessment of Ministry of Health and National Statistical Office Websites in

Low-income Countries *Joos O*

Aug 2013   **INT. UNION FOR THE SCIENTIFIC STUDY OF POPULATION:** Poster
Busan, Korea

- Monitoring Child Mortality through Community Health Worker Reporting of Births and Deaths: A Case Study of Community Health Surveillance Assistants in Malawi *Amouzou A, Banda B, Kachaka W, Joos O, Hill K, Bryce J*

Apr 2013   **POPULATION ASSOCIATION OF AMERICA:** Poster
New Orleans, Louisiana

- Monitoring Child Mortality through Community Health Worker Reporting of Births and Deaths: Case of Community Health Surveillance Assistants in Malawi *Banda B, Kackaka W, Amouzou A, Joos O, Bryce J*

PEER REVIEWS

Jan 2016   **JOURNAL OF THE AMERICAN MEDICAL INFORMATICS ASSOCIATION:** Reviewer

LANGUAGE SKILLS

English (native) ILR level 5 Native proficiency
Spanish (native) ILR level 3 Minimum professional proficiency
French ILR level 3 Minimum professional proficiency
German ILR level 2 Limited working proficiency
Bambara ILR level 1 Elementary proficiency