mHealth and MNCH: State of the Evidence

Reviewing Evidence on the Use of mHealth to Improve Maternal, Newborn and Child Health: Trends, Gaps, Stakeholder Needs, and Opportunities for Future Research

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EXECUTIVE SUMMARY

The mHealth Alliance commissioned the study summarized in this Report to review the state of the evidence on the use of mHealth to improve maternal, newborn and child health (MNCH). The purpose of the study is to identify evidence trends, gaps, stakeholder needs and opportunities for research. The audience for this Report is intended to be the Evidence Working Group of the mHealth Alliance and any other stakeholders who are interested in issues around evidence and mHealth. The Evidence Working Group is a group of individuals working in the area of research and mHealth who have accepted invitations to work collectively to identify issues and promote the use of quality evidence around mHealth. This Report is intended to inform and assist the Evidence Working Group and other stakeholders in identifying research gaps and recommending research priorities to be advocated with stakeholders who influence the research agenda around mHealth.

The study was conducted in three parts: 1) a literature review of the currently available published studies examining the use of mHealth for MNCH; 2) a landscape scan of ongoing studies and evaluations of the use of mHealth for MNCH and; 3) interviews with 26 individual key informants who use evidence and represent various types of stakeholders involved in mHealth and MNCH (e.g., donor governments, researchers, implementers, etc.).

The identification of “gaps” in evidence includes a certain amount of subjectivity, and is dependent upon the perspective of the stakeholder and the standards or criteria that are employed to ascertain the “gaps”. For purposes of this study, “gap” categories include: 1) “rigor” in study designs; 2) type of MNCH intervention; 3) measurement indicators and; 4) crosscutting approaches that are heavily influenced by global health trends.

The review of the currently available literature and conversations with key informants, particularly those in the research community, indicated that there was a paucity of mHealth/MNCH studies which employed what researchers typically consider standard criteria for rigor and quality study designs including:

- Clear, full and transparent description of the study design, including limitations of the design and a justification for the choice of study design for the particular research questions;
- Randomization;
- Collection of baseline data;
- Comparison groups;
- Sufficient sample size;
- Having an underlying theory, drawing on past studies.
In terms of identifying gaps in types of MNCH interventions being studied, there are no generally accepted criteria to gauge gaps. The perspective of the stakeholder plays more of a role when compared to identifying gaps in study design (an area in which reference can be made to the research community’s generally accepted criteria and standards for assessing rigor).

The current body of evidence in mHealth and MNCH represented in peer-reviewed and grey literature tends to focus more on interventions aimed to decrease maternal mortality, particularly reminders for antenatal appointments, and less on interventions aimed to improve newborn and child health. Accordingly, most of the key informants who opined on content gaps in evidence indicated that the one MNCH area in which they did not see any evidence gaps was using mobile phones to improve access to antenatal services.

Although there are no generally accepted criteria to gauge gaps in types of MNCH interventions, there is some guidance from those who are tracking progress in achieving Millennium Development Goals 4 & 5. “Countdown to 2015” a multi-disciplinary, multi-institutional collaboration, tracks progress in the 75 countries where more than 95% of all maternal and child deaths occur, including the 49 lowest-income countries. If the gaps in MNCH coverage, as identified in Countdown to 2015, serve to inform evidence priorities for evaluating mHealth and MNCH, the following areas of lowest coverage along the MNCH continuum of care would warrant greater attention: 1) increasing contraception prevalence 2) intermittent prevention treatment of malaria in pregnant women, 3) PMTCT, 4) children sleeping under insecticide treated nets, 5) antibiotics for pneumonia and, 6) malaria treatment. Studies evaluating the impact of using mHealth to improve PMTCT results are patently absent in the current literature although there are numerous studies and projects using mHealth for PMTCT that are either ongoing or have been recently completed and currently being written up for publication.

Key informants and authors of other literature reviews of mHealth and MNCH identified outcome measurements as its own separate gap category. Many of the key informants, particularly those affiliated with governments and NGOs noted a lack of mHealth studies using health outcomes as either primary or secondary measurement indicators. One of the most pressing needs expressed by the key informants was a desire for evidence showing that mHealth actually contributes to improving the health status of women and children. Most studies appearing in mHealth and MNCH literature used indicators such as feasibility, usability, acceptability, return visits and appointments (e.g., to antenatal clinics) offering no further evidence of how any of these measurements is linked to improved health.

Global health trends and the subjective needs of particular stakeholders dictate the identification of gaps in crosscutting approaches. The trend in global health toward: 1) strengthening health systems to provide quality care; 2) scaling up health programs by integrating health interventions into holistic packages to reach more people; 3) sustaining health programs; 4) understanding how to implement evidence-based interventions and; 5) analyzing the underlying social determinants for accessing quality health services has led to stakeholders, particularly governments, expressing a need for evidence on how mHealth contributes to:

- Strengthened health and community systems;
• Scale-up and integration of health services;
• Sustainability and financing;
• Implementation science and;
• Reduction of health inequities due to social and economic marginalization.

An emerging trend gleaned from the literature review, landscape scan and key informant interviews indicates that gaps in terms of rigor, intervention type, measurement indicators, and even crosscutting approaches, is closing. The frequency of studies using more rigorous methodologies including randomized control trials and detailed study protocols is increasing. More rigorous study designs are being used to evaluate the use of mHealth along MNCH continuum of care identified under “Countdown to 2015”, including those MNCH interventions for which coverage is lacking such as PMTCT and a number of areas in newborn and child health.

The landscape scan revealed that more studies are using health outcome indicators as primary or secondary measurement units. These health outcome indicators include maternal mortality and morbidity, child mortality and morbidity and, child nutrition indicators such as weight for height (wasting) and exclusive breastfeeding. Lastly, more researchers are attempting to tackle crosscutting approaches in study designs. They are starting to examine how to evaluate mHealth from the perspectives of strengthening systems, scaling-up and reducing inequities by incorporating systems analysis, cost-effectiveness studies and to a lesser degree, social analysis, into study designs.

These trends toward closing the gaps in the evidence, however, are gradually emerging and therefore are not yet standards routinely reflected in studies. If evidence gaps are to close, the stakeholders who use evidence, particularly those who influence the research agenda, ought to advocate, promote, mandate and ultimately fund activities that would close the gaps. There are numerous studies and projects in mHealth and MNCH generating evidence that is not reflected in the literature or in other ways widely shared with the global health community. Greater efforts should be made to identify, capture and disseminate that evidence. Lastly, the technical and research communities that have been primarily driving the mHealth agenda ought to frame the evidence in a language using lexicon that resonates with the global health community, paying particular attention to the global health trends that have become priorities to the major donors.
## LIST OF ACRONYMS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>BSE</td>
<td>Breast Self Examination</td>
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<tr>
<td>EID</td>
<td>Early Infant Diagnosis</td>
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<tr>
<td>GSMA</td>
<td>GSM Association</td>
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<td>ICT</td>
<td>Information and Communication Technologies</td>
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<td>IMCI</td>
<td>Integrated Management of Childhood Infections</td>
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<td>LMIC</td>
<td>Lower and Middle Income Countries</td>
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<td>MAMA</td>
<td>Mobile Alliance for Maternal Action</td>
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<td>MNCH</td>
<td>Maternal, Newborn and Child Health</td>
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<tr>
<td>NGO</td>
<td>Non-Governmental Organization</td>
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<tr>
<td>NIH</td>
<td>National Institutes of Health</td>
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<td>NTD</td>
<td>Neglected Tropical Diseases</td>
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<td>PHI</td>
<td>Public Health Institute</td>
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<tr>
<td>PMTCT</td>
<td>Prevention of Mother-to-Child Transmission (of HIV)</td>
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<td>SMS</td>
<td>Short Messaging Service</td>
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<td>USAID</td>
<td>United Stated Agency for International Development</td>
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<td>WHO</td>
<td>World Health Organization</td>
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BACKGROUND

Mobile technology, particularly, mobile telecommunication technology, is increasingly becoming an important tool in global health programs. Excitement about the potential of what has become known as “mHealth”1 centers especially on how mobile technology can be applied in lower and middle income countries (LMIC) where people have traditionally had limited access to health services because of geographic distance to services, social marginalization, inadequate skilled medical personnel or a lack of financial resources - or, very often, a combination of all of the above.

In accordance with its mission and strategy, the mHealth Alliance (the “Alliance”) has commissioned this Report to present the findings of a needs assessment and gaps analysis of the current state of the evidence in mHealth, using maternal, newborn and child health (MNCH) as a use case.2 The intent for the Needs Assessment and Gaps Analysis summarized in this Report is to identify gaps in the evidence base, advocate and promote others to undertake research to fill these knowledge gaps and build the evidence base for mHealth. The primary intended audience of this Report is the Alliance’s Evidence Working Group3 and other stakeholders who generate and use evidence.

Partly because the evidence base supporting mHealth is not yet developed and mature, the global health community has yet to fully realize the potential role that mHealth can play in improving health program results. Many interventions utilizing mHealth solutions remain in pilot form and opportunities to scaleup are few and limited. Moreover, the fragmented fashion in which many of these initiatives have been designed has contributed to challenges when integrating into existing health systems. A 2011 internal study commissioned by the mHealth Alliance (the “Alliance”) identified the lack of rigorous evidence linking mHealth solutions to improved health and demonstrated cost-effectiveness as a primary hindrance to coalescing more wide-scale support for mHealth. The multi-disciplinary nature of mHealth, involving specialists in various areas from the health and technology worlds has been a driver for the splintered nature of the evidence in mHealth, and arguably for the varying levels of rigor found in the evidence base today.

Some within the development and global health communities have even identified mHealth as a priority area for research to better understand its role, if any, for improving results in global health programs.4 Accordingly, generating quality evidence through methodologically rigorous research has emerged as a priority for the mHealth community.5

The evidence base for supporting mHealth as a component of global health programs is just beginning to grow within the last few years as more researchers evaluate mHealth and increasingly use more rigorous research methodologies such as randomization, collecting baseline data and studying comparing groups. The term “rigor” can have many meanings, depending upon who is using the term. For purposes of this Report, the following factors contribute to a “rigorous” study: 1) clearly and fully documenting the study design being used, including the limitations and rationale for using the particular study design for the particular research question; 2) using comparison groups (paying attention to the components being compared); 3) collecting baseline information; 4) being theory-based, drawing on past studies; 5) including a certain sample size; 4) transparently disclosing all results, including undesired, unexpected
and negative outcomes that contradict the original hypothesis for the study. Preferably, the studies are published in peer-reviewed journals.

While rigorous study methodologies contribute to the “quality” of the evidence, the purpose of this report is not to assess “quality”. Gauging “quality” can be a subjective exercise and dependent upon the stakeholder who is using the evidence, and the perspective of that stakeholder. What might be quality evidence that sufficiently answers the questions of a needs-based clinician may not be quality evidence to a rights-based sociologist who wants to understand underlying social determinants.

Contributing toward and nurturing a more robust and relevant evidence base requires a process. The process involves understanding and clearly identifying several things, namely: 1) the current state of the evidence and specific gaps in that evidence base; 2) the various stakeholders who will use the evidence (and for what purpose) and; 3) the specific evidence needed by these stakeholders, reflecting trends in global health and the stakeholders’ position in the health system. These evidence needs may refer to: 1) types of study designs; 2) the particular area of health intervention being studied (e.g., antenatal care, PMTCT, emergency obstetric services), 3) crosscutting approaches (systems analysis) and, 4) desired outcome measurements (e.g., health impact, process measurements). Once the evidence gaps have been identified and the needs of the evidence stakeholders have been clarified, research efforts can be prioritized, focused and promoted.

The findings of this Report should not be deemed conclusive or dogma. Just as assessing “quality” is a subjective exercise depending upon the perspective of the key informant being asked, identifying “gaps” in evidence can be just as subjective with different stakeholders with differing needs providing wildly varying answers for what they perceive as gaps. Accordingly, the intent of this Report is simply to provide an overview of the various evidence gaps and needs gleaned from the author’s objective, but non-academic review of the available literature and from the perspectives of different types of stakeholders working in different areas of the health ecosystem.

**Methodology**

The Needs Assessment and Gaps Analysis methodology for this Report was conducted in three parts:

1) Literature Review of existing published articles in the areas of mHealth and (some aspect of) maternal, newborn or child health;
2) Landscape Scan of current ongoing projects or programs evaluating mHealth (research) and some aspect of MNCH:
3) Key informant Interviews with individuals representing a convenience sample selected from different types of organizations involved in generating, supporting and/or using evidence relating to some aspect of mHealth and MNCH.
Based upon the scope of the Report and the limited available resources and capacity, these three methods for obtaining information should serve to partly counterbalance intrinsic biases and subjectivity and provide sufficient triangulation to identify trends, gaps, stakeholder needs and research opportunities. It should be noted, however, that the stakeholders’ subjectivity is a key and necessary component in identifying evidence gaps.

The findings in this Report is a just snapshot of the state of the evidence at the particular point of time this Report is being written. This Report may be viewed as a living document and because of the dynamic and evolving nature of using mHealth in MNCH, the observations noted herein will consistently change with the constantly evolving evidence base for mHealth and MNCH.

1. Literature Review

The literature review was not a systematic review conducted in accordance with Cochrane or Campbell process guidelines for systematic reviews. Although detailed and methodical, the literature review summarized in this report did not employ the standards typically used in literature reviews published in academic journals.

MNCH was selected as a use case because: 1) MNCH is one of the key health areas in which mHealth is used; 2) the Millennium Development Goals specifically emphasize MNCH in MDGs 4 &5 and implicitly in MDG 6 and; 3) several key initiatives of the mHealth Alliance have prioritized MNCH including the Mobile Alliance for Maternal Health (MAMA)\(^6\) and the Norwegian supported catalytic grant program to improve women and children’s health.\(^7\)

The scope of the search for MNCH was kept broad. “Maternal health” included, but was not necessarily limited to:

- Sexual and reproductive health
- Family planning
- Antenatal, perinatal, intrapartum and postnatal care
- Delivery (midwifery)
- Maternal depression (psychological issues)
- Maternal mortality
  - Hemorrhage
  - Hypertensive disorder
  - HIV
  - Sepsis/Infections
  - Abortion
  - Obstructed labor
  - Anemia
  - Ectopic pregnancy
  - PMTCT
“Newborn and child health” included all health conditions relating to neonates, newborns and children age five (5) and under. Adolescents were excluded unless they were part of an analysis of a health condition linked to a health event or situation occurring at the age of five (5) or under.


Literature and programs that examined the health consequences of the use of mobile phones by mothers on their children (which were extensive) and using phones to control childhood obesity were excluded. Articles with exclusive references to eHealth, internet and non-mobile forms of ICT were also excluded, as were articles that discussed mHealth without an explicit focus on some form of MNCH.

Literature and programs pertaining to general health conditions such as HIV, malaria, tuberculosis, diabetes etc. were excluded unless they explicitly targeted women and/or children age five and under.

Searches were limited to articles and programs published or occurring in 2009 to present based upon the assumption that the two literature reviews outlined below captured relevant research and studies published prior to 2009.

Because of limits placed on costs, full versions of published articles requiring payment were not accessed; in which case, information was retrieved from the articles’ abstracts.

The literature review of published articles for this Report involved the following steps:

• Review of published other Literature Reviews and Systematic Reviews of mHealth and any aspect of MNCH;
• Review of publication databases for both academic articles and grey literature addressing mHealth and any aspect of MNCH. Databases and websites searched included: Google Scholar, Mendeley; Cochrane Collaboration, Campbell Collaboration, 3IE, GSMA, PubMed and the World Health Organization Bulletin.
• Review of articles in knowledge management sites including: the mHealth Alliance’s “HUB”, K4Health, MobileActive.org and, the Royal Tropical Institute’s “mHealth in Low Resource Settings” knowledge portal.

Various search iterations in the various databases using the key words and terms identified above generated approximately 1760 articles and documents, of which the preponderance were duplicative or fell within one of the exclusion criteria.
2. Landscape Scan

The Landscape Scan of current ongoing projects included a review of the following:

• National Institute of Health’s (NIH) Clinical Studies database (www.ClinicalTrials.gov);
• National Institute of Health’s Project Reporter database (http://projectreporter.nih.gov/reporter.cfm);
• Various articles and inventories of projects and programs maintained by organizations, websites and listservs including the mHealth Alliance’s “HUB”, Johns Hopkins Global mHealth Initiative, K4Health.org, MobileActive.org; GSMA, ict4chw, Mobihealth.org;
• The 2012 Report and Inventory of all mHealth and eHealth projects around the world conducted for the Alliance by the Center for Innovation and Technology in Public Health (CITPH) at the Public Health Institute (PHI) and;
• Unpublished reports, inventories and descriptions provide by key informants interviewed.

3. Key informant Interviews

Telephone interviews were conducted during the period of April 2- May 10, 2012 with 26 individuals representing a convenience sample of stakeholders involved in some aspect of mHealth and MNCH and use evidence. The objective of the interviews was to inform the gaps analysis, as well as to understand who are the users of evidence and what the users are looking for in terms of evidence (e.g., types of studies, indicators, health intervention areas, etc.). These individuals represented organizations that included:

• NGOs/Implementers
• Researchers/Academic
• Governments (donors and LMIC)
• Private Sector
• Academic/research institutions
• Multinational organizations

While there may be a number other types of stakeholder (e.g., foundations), because of time and capacity issues, a non-random convenience sample was used in identifying key informants. However, an assumption underlying the study was that this particular convenience sample would not respond differently than a random sample from the same population. (For a comprehensive perspective of mHealth stakeholders, see “Appendix “C” – mHealth Ecosystem Stakeholders”).
Key informants fell into one of the following categories. Sometimes, a key informant “wore two hats” as both an implementer and researcher (which explains why the following numbers add up to more than 26):

- NGOs/Implementers: 9
- Researchers: 11
- Government: 7
  - Donor (5)
  - African (2)
- Private Sector: 5
- Networks/Associations: 3
- Multi-national organizations: 2

- All key informants had some experience in the area of both MNCH and mHealth.
- 17 Key informants were female (65%); 9 Key informants were male (35%).
- 14 Key informants were U.S.-based (54%).

Key informants were interviewed (one contributed by email) conducted either on the phone or through Skype. Leading questions were purposefully avoided. Respondents were asked open-ended questions, contextualized for the individual depending upon his or her organizational affiliation. These questions included (but were not necessarily limited to):

- What sources of information do you find the most credible for building your personal knowledge base (in the area of mHealth and MNCH)?
- What sorts of evidence do you use and what do you use the evidence for?
- In your opinion, from the perspective of your role in “X” organization, in what topic areas do you believe there is an adequate evidence base (in mHealth and MNCH)?
- From your perspective in “X” organization, what are the primary gaps in evidence and research efforts (in mHealth and MNCH) that should be prioritized for future research and evaluation efforts?

**LITERATURE REVIEW**

1. **Summary**

Although peer-reviewed journals and other literature are increasingly addressing the general topic of mHealth, the literature review of the current evidence revealed a limited number of articles evaluating mHealth in MNCH contexts. Yet, there appears to be a gradual increase in recent years in the number and quality of published studies. While the emerging body of evidence is still nascent, more research using rigorous study methodologies (e.g., randomization, comparison cohorts) to evaluate using mHealth across the MNCH continuum of care (which also includes reproductive health) is appearing in both academic and grey literature.
The use of mHealth to improve results in MNCH programs tends to focus on appointment reminders to increase access (demand) to antenatal and other maternal health clinic services, SMS messaging to improve health-seeking behaviors and, mobile phone applications for improving data collection (accuracy, reliability and completeness). There have been few published studies that report on the correlation of mHealth with health outcomes (e.g., morbidity, mortality, weight for height, etc.).

The literature review revealed a limited number of published studies evaluating mHealth as applied to MNCH. Of those studies that were published, few used rigorous research methodologies such as randomization and comparison cohorts. However, just within the last year (2011-2012), there appears to be an uptake in the number of studies evaluating mHealth applied to MNCH and a greater effort to use more rigorous research methodologies in studies.

The Literature Review findings can be broken down into the following two (2) parts:

1. Review of literature and systematic reviews previously published and,
2. Review of the results of a supplemental articles search. (Articles included both peer-reviewed and non-peer articles.

2. Literature and Systematic Reviews Previously Published

The literature search revealed there have been:

- Two (2) literature reviews, both published in 2011, which explicitly examined the published evidence for mHealth and some aspect of MNCH.\(^{10}\)
- One (1) Systematic Review conducted by Great Lakes University Kisumu and funded by the WHO, pending publication in 2012, that examines the effectiveness of mobile phone technology in improving maternal, neonatal and child health in middle and low-income countries.
- An unpublished student paper that included a literature review of studies on mHealth and MNCH published in 2002, 2009, 2010 and 2011.\(^{11}\) (The findings of this study mirror the findings of the two literature reviews and supplemental articles search outlined below and therefore will not be specifically discussed.)

There has also been a White Paper One (2010) that examined and synthesized mHealth literature, but did not exclusively nor explicitly focus on MNCH.\(^{12}\)

Tamrat Literature Review

Tigest Tamrat and Stan Kachnowski conducted a literature review published in 2011 providing a schematic overview of the outcomes, barriers and strategies for integrating mHealth with a focus on
improving prenatal and neonatal outcomes (hereinafter, “Tamrat”). Their search found 34 articles that fit their criteria about the use and limitations of mHealth for prenatal and neonatal healthcare access and delivery (i.e. the period from conception to 28 days following birth) along the stages of the continuum of care for MNCH as defined by the WHO.

Of the 34 articles that met the search criteria in the Tamrat literature review, 26 studies used a qualitative design methodology; 4 studies used a mixed qualitative and quantitative design and; 4 used a quantitative design.

The Tamrat literature review noted the escalation of the use of mHealth for child and maternal health, but not surprisingly, concluded that few studies have focused exclusively on mHealth’s use to improve prenatal and neonatal services. Tamrat identified key health areas for study of the use of mHealth in neonatal and prenatal health which included:

- Emergency medical responses
- Point-of-care-support
- Health promotion
- Data collection and management
- Economics

The Tamrat literature review made the following conclusions in each of the above categories based upon Tamrat’s interpretation of the evidence presented in the literature:

- **mHealth tools can help minimize time barriers and facilitate urgent care during obstetric referrals** - based upon interventions that i) trained traditional birth attendants to use protocols to recognize pregnancy complications and connected them with walkie talkies to health centers for emergency transport; ii) observed the correlation between family ownership of telephones with seeking emergency services during pregnancy-related complications; iii) furnishing traditional birth attendants and outreach workers trained to recognize obstetric complications with mobile phones to make appropriate emergency referrals and; iv) used 24-hour obstetric mobile-phone based helplines to mitigate the delays associated with obstetric deliveries.

- **Health systems can use mHealth to ameliorate human capacity issues** - based upon interventions that i) equipped midwives with mobile phones and phone credit to consult with specialists while providing obstetric support in remote locations and; ii) equipped community-based health workers to contact supervisors for consultation and timely referrals of emergency cases.

- **mHealth can support information for health promotion primarily through short-message service (SMS) to expecting mothers** - based upon interventions that i) used SMS to disseminate information pertaining to antenatal appointments and immunizations; ii) linked pregnant women with health services and skilled attendants for obstetric care; iii) improved emotional
health of pregnant women received SMS messages during the prenatal period\textsuperscript{24} and; iv) sent health education messages to pregnant women coinciding with the progression of pregnancy.\textsuperscript{25}

- **mHealth improves data collection and management** - based upon interventions that (i) linked health SMS health promotion programs to central health systems that contained records of pregnant women and their weekly progression\textsuperscript{26, 27, 28}; (ii) provided outreach workers in India with handheld computers to collect data on immunization records, prenatal care schedules and demographic information into a centralized health record systems that could be accessed by rural health providers\textsuperscript{29, 30} and; iii) provided frontline health workers with handheld devices to monitor and disseminate pregnancy, nutrition and immunization information to the nearest rural health centers.\textsuperscript{31}

- **While there are a number of articles being published on the economics and financial implications of mHealth, there are few published studies of the cost-effectiveness or demonstrating the value added economic benefits of integrating mHealth solutions.**\textsuperscript{32}

According to Tamrat, the strength of these study findings presented in this particular literature review is undermined by a number of factors, reflecting a lack of rigorous study methodologies including:

- “Logistical issues which may have compromised the study”;
- Failure to disclose in detail the research methodology;
- Not being published in peer review journals;
- Failure to report on comparison groups nor provide quantitative details on changes observed;
- Confounding factors which may have (negatively) influenced the results or;
- Lack of both an evaluation and conclusions based on qualitative evidence from programs “at similar locations”.

Further, Tamrat concluded that while some articles that fed into the conclusions appeared to use rigorous study methodology (mixed quantitative and qualitative), others were reports of nascent projects that had “not produced conclusive evidence on obtaining their objectives”.\textsuperscript{33} Other shortcomings identified by Tamrat included:

- While more rigorous study methodologies using quantitative analysis appeared to be used to demonstrate increased antenatal appointment and vaccinations, and improving emotional health, other data published were either preliminary or more of a descriptive overview.\textsuperscript{34}

- While a number of the studies demonstrated improvement in tasks relating to administrative functions (i.e. data management), increased access to health services and increased antenatal appointments and vaccinations, most of the studies did not translate such improvements into changes in health outcomes.\textsuperscript{35}
While articles are being published that describe financial obstacles to introducing mHealth, including financial implications for various stakeholders, there were no articles in the literature base meeting the search criteria actually presented conclusions from cost-efficiency studies.  

Noordam Literature Review

Another literature review conducted by a team led by Camielle Noordam (hereinafter “Noordam”), focused exclusively on maternal health service outcomes using mobile phones. Unlike Tamrat, Noordam did not indicate the number of articles meeting the search criteria nor did Noordam characterize or quantify research methodologies and study design.

Noordam primarily described various scientific and grey literature accounts of projects and concluded that there is “a need for robust evidence on evidence and impacts”, noting that there were few projects existing in the field yielding published evidence. Noordam found that most of the articles addressed the three phases of delay around maternal mortality.

Compared to Tamrat, who did more of an analysis of the strength of evidence to make conclusions regarding the use of mHealth, Noordam focused more upon describing the projects and studies found in the literature search.

Noordam described several early projects (Mali, Uganda, Malawi, Sierra Leone and Ghana) that used changes in maternal deaths as an outcome indicator for interventions that used radio systems (prior the wider use of mobile phones) to improve communications to reduce delays in getting pregnant women to a facility.

According to Noordam, the more recent projects that actually used what we call “mobile phones” targeted improving the capacity of health care workers by connecting them to skilled medical personnel. Outcomes for these projects included acceptability, usability and perceptions about changes in time efficiencies. Another project in Rwanda whose preliminary results were reported in The Lancet in 2010 used text messaging and a data exchange to coordinate communications among health workers, health centers and hospitals is measuring outcomes in terms of access to maternal health services and changes in mortality rates.

One article summarized by Noordam described a pilot project in Tanzania using forms and protocols meant support pregnant women before, during and after delivery. This article presented outcomes in terms of completed referrals and subjective perceptions of community health workers gleaned from “anecdotal evidence and focus groups” with regards issues such as duration of household visits and consistency of follow-ups. Other articles cited in the Noordam article were based on studies that were ongoing including an interesting study following 2500 women and the use of text messages containing health information and appointment reminders. Outcome indicators included
impact on quality of services, health seeking behavior and maternal morbidity and mortality.

Noordam identified a number of gaps in the literature pertaining particularly research in mHealth and maternal health. These gaps included:

- Lack of evidence-based studies focusing on the efficacy and effectiveness of interventions;
- Lack of studies focusing on interventions other than pilot interventions;
- Lack of baseline data;
- Lack of a control group;
- Lack of clear outcome indicators.  

Key gaps in content areas in the literature identified by Noordam include:

- Evidence for scaling-up;
- Analyses of the benefit of mHealth in ensuring timely delivery of medical equipment;
- Research on the use of mHealth to provide health education and improve access to reproductive health services;
- Evidence on the use of mHealth beyond life threatening situations, looking at other risk factors that would warrant accessing antenatal facilities, such as fistula, incontinence and infertility.

WHO supported Great Lakes University Kisumu Systematic Review: Preliminary Findings

The preliminary report of the yet unpublished WHO supported systematic review which is looking at the effectiveness of using mobile phone-based interventions to accelerate the there health MDGs in LMIC reported three (3) studies in the area of MNCH that met that reviews search criteria. Preliminary results of that systematic review do not include an analysis or conclusion regarding the evidence, but simply descriptions of published studies that the search yields. These studies include:

1. A study in Ghana evaluating the ability of TBA’s to use text messaging to correctly follow a protocol in reporting data for all births; All attendants followed the reporting protocol correctly, although with uncertain data integrity;

2. A study evaluating the effectiveness of two media (text messages and pamphlets) in imparting health education to mothers of preschool children. Text messaging was deemed more effective than pamphlets in improving knowledge, attitude and practices of mothers and;

3. A study in which monthly short text messages (SMS) were sent to remind them to carry out breast self-examination (BSE). That study reported both on the obstacles in following through with BSE (e.g., forgetfulness, too busy, anxiety) and that after the first two months of sending reminder the practice of BSE increased significantly (p<0.05). 30.2% by the sixth month.
report did not include the citations to the studies or with the exception of the Ghana study, where the studies were located except that they were conducted in LMIC.).

3. Supplemental Articles Search

To supplement the literature and systematic review referenced above that reported upon published articles through 2010, an additional search was conducted of the various databases for literature published during the period 2009 through 2012. Of approximately 1760 articles and documents screened, 38 articles and documents meeting the search criteria were retrieved from the search databases.

Of the 38 published articles during the period that met the search criteria, a snapshot of the study characteristics (some articles carrying more than one characteristic) included:

- 6 articles reported on a study that was designed as a randomized control trial;
- 10 articles reported on a study where there were no comparison groups;
- 2 articles reported on studies that used a case control study design;
- 11 articles were exclusively descriptive in nature (not reporting on a specific study) or research methodology not described;
- 9 articles reported studies that used exclusively interviews, focus group discussions or surveys (two of which included randomization);
- 3 articles presented study protocols.
- 1 article was a systematic review*

(* This systematic review actually did not meet the search criteria insofar as mHealth was not a focus of its analysis, but is being mentioned because the systematic review was: 1) conducted by leading global maternal health experts, 2) addressed key areas of maternal health and, 3) made an explicit recommendation to further examine the use of cell phones in maternal health programs).^51

The results of the supplemental articles search generally confirmed the conclusions presented in the literature reviews concerning the paucity of studies using rigorous study methodologies to evaluate mHealth in the context of MNCH, and the scarcity of studies using health outcomes as measurement indicators.

Fortunately, however, there is an emerging, albeit slowly, evidence base using more rigorous methodologies including randomization, baseline data, comparison cohorts (controls) and clearly documented study designs.
The plurality of the articles addressed using mHealth to assist mothers in accessing antenatal and/or postnatal care services. There were relatively few published studies addressing using mHealth to impact pediatric health.

As in most of the mHealth literature, in the MNCH realm, there is an emphasis on studies evaluating the technology itself in terms of usability, feasibility and acceptability. While there also appears to be a gradual emerging evidence base evaluating mHealth using health outcome measurements, a discernible portion of this emerging evidence base, as in the HIV realm, has not gone past using attendance and accessing health services (e.g., antenatal visits, vaccination appointments) as proxy measure for health outcomes.

Some of the key findings and MNCH intervention areas reported in the Supplemental Articles Search include:

- The plurality of the articles related to using mHealth to facilitate accessing antenatal and/or postnatal care services.\(^{52, 53, 54, 55, 56, 57}\)

- A significant number of articles analyzed using mHealth for data collection and management (e.g., by midwives, village health workers, village elders etc.) of information such as birth and death registration (maternal and neonatal), tracking maternal care, registration of pregnancies, nutrition surveillance and postpartum hemorrhage data.\(^{58, 59, 60, 61, 62, 63}\)

- There was a significant published protocol, Project Masihambisane from South Africa, which does not exclusively focus on evaluating the use of cell phones in data collection and management, but is important as part of the evidence base because it is a cluster randomized control trial evaluating a comprehensive integrated PMTCT program.\(^64\) The intervention involves using cell phones (Rapid SMS and existing cellular networks) for collecting routine information, completing questionnaires and remaining in contact with participants over time. The intervention involves working with peer mentors to improve quality of life outcomes and mental health of pregnant women living with HIV through antenatal and postnatal small group sessions and a clinic-based strategy to improve their health behaviors over time. Pregnant WLH (N = 1200) were randomly assigned by clinic (N = 8 clinics) to an intervention program, called Masihambisane (n = 4 clinics, n = 600 WLH) or a standard care PMTCT control condition (n = 4 clinics; n = 600 WLH). The study is ongoing and using a number of physical and mental health outcome indicators (relating to the overall intervention using peer mentors). The article made a preliminary conclusion that data collection with cellular phones are “innovative and effective” in low-resource setting.\(^65\)

- While a plurality the articles which report on studies presented findings in terms of usability, feasibility and acceptance as outcome measurements,\(^66, 67, 68, 69, 70, 71\) it appears that there may be a trend, although still nascent, for an increasing number of the published articles (albeit some of which are protocols) reporting on the impact of mHealth using health outcome measurements such as mortality\(^72\), vaccination coverage (although one is an ongoing study)\(^73\), “pregnancy outcomes”\(^74\), “maternal and infant outcomes”\(^75\), anxiety levels\(^76\)
HIV tests significantly shortened the times between sample collection and results notification implementation to 35.0 days post mean time to notification of a caregiver also fell significantly, from 66.8 days pre-reduction in turnaround time was statistically significant in 90% of the facilities (9 of 10). The mean time to notification of a caregiver also fell significantly, from 66.8 days pre-implementation to 35.0 days post-implementation. The study is ongoing in both Zambia and Malawi, but preliminary results from Zambia indicated that the texting of the results of infant HIV tests significantly shortened the times between sample collection and results notification.

- Two articles examined how mHealth may be utilized to reach marginalized or particularly vulnerable populations (displaced border populations and “vulnerable” prenatal and postnatal mothers) and several articles, while not research studies, addressed social determinants and constructs that serve as obstacles in using mHealth.

- At least three articles reported on findings connected with using mHealth to implement protocols in (1) data reporting and, (2) treatment and/or clinical services: (a) a randomized control trial in Kenya for pediatric malaria treatment with the primary outcome being correct pediatric treatment management; and (b) a qualitative study nested within a larger quantitative study in Tanzania around the Integrated Management of Childhood Illnesses (IMCI), examining user perception (using personal digital assistants) and provider adherence to IMCI protocols. While the data reporting and pediatric malaria studies indicated using mobile devices improved protocol adherence, the last study reported “widespread non-adherence” to the IMCI protocols, although there were positive perceptions of using the devices.

- One study published, but not in a peer reviewed academic publication, reported on a case study using mFinance to reimburse sexual and reproductive health vouchers in Madagascar. This is a descriptive case study looking at the implementation challenges in an ongoing project using mFinance to reimburse vouchers for sexual and reproductive health. The data used in this case study are drawn from Marie Stopes International online database that stores all voucher reimbursement claims, as well as all SMS data received and sent. The data were collected for a period of six months, starting from the implementation of the voucher project in February 2011 until the end of July 2011. Semi-structured interviews with several of the implementers’ team members and two social franchisees on the implementation process were used to construct and identify the programmatic lessons and recommendations.

- One article, published in the World Health Organization Bulletin, reported on the preliminary results of a UNICEF supported study of an intervention called Project Mwana in Zambia using mHealth (via a printer connected to a phone) to expedite the delivery of early infant diagnosis results (dry blood spot tests for HIV). Baseline data from a 19-month retrospective period was compared with a system over a 7 1/2 month period that delivered the test results automatically and directly from the processing laboratory to the health facility of sample origin via short message service (SMS) texts. Mean turnaround time for result notification to a health facility fell from 44.2 days pre-implementation to 26.7 days post-implementation. The reduction in turnaround time was statistically significant in 90% of the facilities (9 of 10). The mean time to notification of a caregiver also fell significantly, from 66.8 days pre-implementation to 35.0 days post-implementation. The study is ongoing in both Zambia and Malawi, but preliminary results from Zambia indicated that the texting of the results of infant HIV tests significantly shortened the times between sample collection and results notification.
to the relevant health facilities and caregivers. While inference can be made that the shortened turnaround time for the delivery of HIV results expedited HIV + infants beginning ARV treatment, preventing morbidity and mortality, there was not indication in the preliminary report that actual health outcome data from the expedited delivery of test results were being collected and evaluated.

LANDSCAPE SCAN

The Landscape Scan confirmed the existence of a trend to conduct more rigorous studies focusing on mHealth and MNCH compared to the body of evidence available in the currently available literature.

The mHealth Alliance contracted the Center for Innovation and Technology in Public Health at the Public Health Institute (PHI) to identify and collect information of all eHealth and mHealth projects on MNCH globally. At the request of the Alliance, PHI focused on thirteen (13) LMIC and conducted the study during the period between May 17, 2011 and January 31, 2012.

The PHI study identified 70 projects in MNCH in the 13 countries, both completed and ongoing. It also identified 160 projects in other health areas. Of the 70, 36 were in Africa, 27 in Asia, 7 in Latin America and 18 in “Other”. The author of the PHI report indicated that the “mHealth applications in the MNCH field are in the formative stage and preliminary evidence of their effectiveness and impact on health impacts is emerging.”

A search of the NIH’s website, ClinicalTrials.gov produced 106 studies using mobile phones, but only four met the search criteria for this Report.

Noting that taking a complete inventory of ongoing relevant studies is impractical for purposes of this Report, a notable number of illustrative studies were nonetheless identified that are currently ongoing that could bolster the evidence base in mHealth and MNCH and are included as Appendix “A” to this report.

A review of those illustrative studies and other studies discovered in the landscape scan revealed some clear trends in the shaping of the evidence around mHealth and MNCH. The most obvious trend is more studies using more rigorous study designs. There are a number of randomized control trials underway or recently completed. There are also quite a few studies being conducted that use comparison groups and other methodologies evidencing rigor such as the collection of baseline data, larger samplings and providing full descriptions of research protocols (and the justifications for the selection of study design). Notably, there is a discernable number of studies underway that are or will be using health outcomes as primary measurement indicators. The landscape scan did not yield any studies that clearly indicated the use a theoretical framework.
The mHealth studies that turned up in the landscape scan range across the maternal health continuum of care and the coverage gaps identified under “Countdown to 2015” (described in more detail below), including PMTCT and early infant diagnosis, as well as in numerous areas of newborn and child health including vaccinations, promoting breastfeeding and improved infant and young child nutrition, implementing IMCI protocols (integrated management of childhood illnesses), pediatric malaria treatment, pediatric antiretroviral adherence, family planning and other areas of sexual and reproductive health. Crosscutting areas being studied include scaling-up programs, cost-effectiveness, community health worker performance, supply chains and financing of MNCH interventions.

KEY INFORMANT INTERVIEWS

1. Sources of Evidence

Researchers and academics tended to access and rely directly upon studies in peer-reviewed academic journals more than their non-researcher counterparts. Other than the researchers, few key informants indicated that they regularly access peer-reviewed publications to learn of evidence underlying the use of mHealth in MNCH. These non-researcher key informants indicated that they rely more on a variety of evidence sources including:

- Program evaluations
- Conference presentations
- Conversations with colleagues
- Websites such as mobileactive.org
- Evidence summaries and information released by inter-agency task forces such as the Maternal Health Task Force, the Interagency Task Force for the Reduction of Maternal Mortality and the Inter-Agency Task Team for the Prevention of Mother-to-Child Transmission and,
- Technical guidelines and standards developed by organizations or government bodies such as the World Health Organization and PEPFAR.

The fact that a significant number of key informants do not routinely directly access peer-reviewed articles does not in any way undermine the significance of the peer-reviewed articles and the evidence they contribute. Probing the key informants revealed that most key informants working in MNCH ultimately rely on guidelines; standards and technical briefs prepared by the World Health Organization, inter-agency task forces and, government bodies such as PEPFAR. The evidence underlying the guidelines, standards and technical briefs are all rooted in the evidence contributed by peer-reviewed studies.
2. How Key informants Use Evidence

In addition to informing their own knowledge base, key informants’ needs generally depended upon the type of organization with which they were affiliated.

- Key informants affiliated with governments used evidence to decide what sorts of projects to support with funding and inform fellow policy makers, particularly colleagues working in global health and those working with budgets. Some viewed the evidence as informing the process for setting standards (in global health). Two of the government key informants indicated that they depend upon the researchers to inform them the gaps in research to be supported with funding.

- Key informants who were affiliated with research organizations (or were researchers with another type of organization) used evidence to inform their own studies, either for comparison cases in terms of methodology, design and outcome measurements or; to guide them in selecting areas for their own research. Some would use the evidence to advocate governments to fund certain types of interventions or research initiatives.

- Key informants affiliated with the private sector use evidence to make a business case to colleagues, inform marketing efforts, identify potential marketing trends and, in some cases, make decisions about funding support.

- Key informants who were implementers and/or affiliated NGOs value evidence as a guide more on how to deliver services, not so much on what sort of services to deliver. The types of services to deliver are more guided by international and national standards and, what donors want. Some implementers, particularly those affiliated with the large NGOs, use evidence for advocacy to governments and other donors (for innovations and social related issues).

- Key informants affiliated with multinational organizations used evidence to inform standards of practice and make recommendations to governments, and placed the most weight on the need to disseminate the evidence to the wider global community (health, technology, governments, etc.). The goal of dissemination is also a concern of the networks/associations, and one of the government (donor) key informants.

(See Appendix “B” for List of Key informants Interviewed)

3. Themes Raised by Key informants

Interview responses were informally coded according to theme and issue raised. Codes were grounded rather than a priori:
A. Randomized Controlled Trials (RCTs); Study Design

Generally, while the majority key informants (58%) acknowledged the value of RCTs to the evidence base for mHealth (and MNCH), a significant number of the key informants (26%) opined that in the field of mHealth (in MNCH contexts and otherwise), other types of studies could be just as valuable, and in many situations, more valuable than RCTs. The field of mHealth warrants different types of study designs depending upon the research question and the hypothesis being tested.

There was near universal consensus that there should be more studies using more rigorous research methodology (compared to descriptive studies), including using comparison groups (paying attention to the components being compared), collecting baseline information, and fully and transparently describing research methodology, limitations and negative results.

Those key informants who tended to place more emphasis on the use and value of RCTs tended to fall into the researcher category. Those who were more open to other methodologies, and placed equal value on qualitative studies were affiliated with implementing organizations and governments.

Below are some of the specific comments made regarding RCTs and study methodology:

- “People generally tend not to value different types of methodologies; most see a hierarchy of methodologies. RCTs are not always the best. (For example) RCTs are not good for understanding complex behavior patterns.” (Researcher)

- “Technology is outpacing the research paradigm”. By the time we complete (and publish) an RCT study, because of advances in technology, that study will be irrelevant. (2 Implementers, both Researchers). Most studies are required (by donors) to show results in a short window of time dictated by the length of the project. It often is impractical “to gather useful evidence at a pace that even remotely corresponds with how technology moves”. In response, one other key informant adamantly stated that while technology may have advanced, the underlying premises that the research evaluates remain steadfast.

- To be valuable research, the questions (being studied) must be clearly articulated. That is not always being done. (1 Government Key informant, 1 Researcher)

- We need more evidence isolating the role mHealth plays in order to determine attribution. (2 Government Key informants, 1 Researcher)

- “Mixed methods studies are the most critical: what works and the process supporting it”. (Government Key informant).
• “We need to invest in solid formative research to understand the target for an mHealth strategy.” (Researcher).

B. Health Outcome Indicators

A significant number of the key informants (42%) identified the need to evaluate mHealth (in MNCH and other health contexts) in terms of health outcomes, using health outcome measurements (e.g., morbidity, mortality, nutritional indicators). Every key informant affiliated with a government mentioned the need of the evidence to demonstrate that mHealth actually makes a difference in program outcomes (i.e. health). One key informant affiliated with an NGO implementer indicated that implementers do not necessarily need health outcome information, and that indicators such as exclusive breastfeeding rates, treatment adherence and vaccination coverage were sufficient proxies for changes in health status.

One key informant (implementer/NGO) commented that gathering health outcome information takes time to observe and is most often not practical in light of the project duration. However, there are certain health outcome indicators that can be observed within a relatively short time window such the child health indicators wasting (weight for height), which is indicative of acute malnutrition (but more expensive to measure) and underweight (chronic malnutrition), a more cost effective measurement to take but not always the best indicator of growth because it is most sensitive to change.

Many of the studies focus how mHealth might improve the performance of community health workers (CHWs), which is important to know (particularly for a Theory of Change). However, several key informants commented that studies ought to address how changes in CHW performance translate into changes in the health status of the population.

C. Cost-Effectiveness

39% of the Key informant raised the need for robust evidence demonstrating the cost-effectiveness of employing mHealth solutions. They stressed that understanding how mHealth contributes to efficiencies is particularly important in LMIC contexts because of weak health systems with low human resource capacities. Pressures attributable to recent global financial problems have caused advocates for foreign aid in health to be more accountable in justifying apportionments for budget apportionments. There is more pressure to produce evidence on “getting the biggest bang for their bucks” to justify every budget line item in foreign aid in health. One key informant opined that if researchers are not able to demonstrate that mHealth actually improves impact (compared to other current standards), they should be able to demonstrate that mHealth can achieve equal impact (compared to current standards). In this case, the case for mHealth would need to be justified by demonstrating efficiencies in both financial and opportunity costs.
D. Scaling Up Pilots and Generalizability of Findings

A significant issue raised by approximate 31% of the key informants, including all key informants affiliated with a government, is the lack of evidence demonstrating how mHealth interventions can go to scale and demonstrating impact at scale. These key informants noted that most mHealth studies are conducted as pilots, worrying that the results could not be generalizable to other contexts. One government key informant proposed that supplementing and replicating the same study in different contexts and settings. Also, one of the key informants noted that certain biases accompany pilots, particularly around acceptability. That key informant questioned whether the use of mobile phones would be just as acceptable to the general CHW population as it is to a small finite pilot group of CHWs who might have been “cherry-picked” and already predisposed to using mobile phones. One of the government key informants (donor) noted that the plethora of “small things” going on underscores the importance for promoting interoperability.

Most of the government key informants are looking for more program evaluations, studying what works in the field compared to the small pilot studies. One such key informant recommended establishing principles on how to contextualize and focus on targeting to subgroups. Another key informant recommended establishing criteria for scalability.

E. Systems Analysis

Related to the issue of generalizability of findings and taking activities to scale, Key informants identified the need to apply “systems analysis” in developing and analyzing the evidence base in MNCH. While key informants understood that this Report focused on MNCH as a “use case”, 20% of them, primarily government donors and researchers, emphasized the need to do systems research and be able to tie in what the evidence demonstrates about using mHealth in MNCH (and other areas such as HIV, TB, etc.) and apply that knowledge to how it impacts the health system. Those supporting tying mHealth/MNCH research with systems analysis worry about the risks of creating numerous parallel health systems when research efforts focus on use cases (e.g., MNCH) without integrating systems analysis. The increasing number of guidelines relating to integration of health services (e.g., PMTCT, nutrition, etc.) partly ameliorates these risks, but those key informants who advocated systems analysis nonetheless encouraged a more deliberate efforts to use a systems lens. Fortunately, mHealth/MNCH researchers and implementers are referring to the evidence being generated in the mHealth/HIV field (e.g., appointment reminders), marking one necessary step in applying a systems analysis approach. Specific comments about applying a systems approach included:

- “In the first generation (of mHealth research), the research will naturally be in siloes. We will gradually see a convergence of solutions and (simultaneously address multiple issues.” (Multinational Key informant)
• “We need (research) projects to think upstream and think systematically” (how to take all the small things being discovered at the project level and determine how it inform and feed into the higher level system). (Government donor)

F. Sharing and Dissemination of Evidence

A number of key informants were very vehement about saying there was a lot of evidence that has been or is currently being generated. There are numerous projects with research components that have demonstrated results that could add to the evidence base in mHealth and MNCH. These findings are not being adequately shared and disseminated to the wider communities working not only in mHealth, but also more importantly, to the larger global health community. Several reasons account for this including the reticence of health publications to publish academic studies focusing on mHealth. Some important points made by the Key informants included:

• The mHealth community appears to be a closed group and talks a lot to each other but it is unable or unwilling to reach out to the broader global health community. (3 Implementer Key informants)

• There is a need for more forums to bring together projects to share results with each other with an emphasis on promoting and sharing operational research and implementation research. (Government Key informant)

• There are a lot of rich examples of knowledge, but they are not being gathered, synthesized and used. The knowledge is not being captured in a quality manner (using a knowledge management vehicle) with a gatekeeper to monitor quality. (Government Key informant).

• We need to know what does not work in pilots and understand why they did not work. “Much of the bad stuff is being hidden”. (Researcher)

• The Researchers need to be able to translate research finding and evidence into a language that resonates with global health specialist, governments and policymakers.

• Relying on published peer-reviewed literature to establish an evidence base is not necessarily practical because it can take 4-5 years to publish: 3 years to do the research and 2 years to write and publish. (Implementer/Researcher)
G. Using Theoretical Frameworks and Theories of Change

A number of the researchers, joined by several of the implementers and government key informants, remarked that the quality of the evidence and its usefulness could be improved tying the evidence back to a theoretical model. One researcher stressed, “the best evidence refers back to a theoretical model”. For example, behavioral change theories should serve to inform mHealth activities aimed at CHWs to change their work patterns or, at mothers adopting behaviors to improve their health and wellbeing.

According to several of the key informants, there also needs to be a clear Theory of Change (similar to a results framework or logic model) that demonstrates the role that mHealth plays to achieve the desired results (1 Government Key informant, 2 Implementers, 2 Researchers). The Theory of Change should then guide the research questions and they types of evidence in terms of outcomes being generated.

H. Understanding Social and Cultural Determinants

Understanding how social and cultural dynamics affect using mHealth in MNCH and other health areas has been missing in much of the research according to at least 20% of the Key informants representing researchers, implementers and governments. One researcher remarked that, “we need to go further then sending messages to influence behaviors; we need to understand cultural and societal influences to change the behaviors (and using sound behavioral change theory) and use that understanding to frame the content and delivery of those messages.”

Applying a gender analysis lens to mHealth research, particularly when working with mothers, was identified as a gap by three of the Researchers. While mHealth is being used to afford pregnant women with access to health services, most of the research projects are not incorporating the research using a gender framework to understand at a deeper level the gender power dynamics that permeate all aspects of life in many LMIC, including the how mobile phones are used and how decisions are made (regarding accessing health care).

Issues of reducing inequities and health disparities were noted by several of the Key informants. One of the great promises of mHealth is its potential to reach people who traditionally have not had access to health services not only because of geographic isolation and poverty, but also because of social and cultural marginalization based upon prejudices and stigma. The mHealth field has not yet scratched the surface in generating evidence in how mHealth can be used to reduce inequities and health disparities in these populations, as well as populations that have been marginalized by geography and poverty.
DISCUSSION OF GAPS AND RESEARCH OPPORTUNITIES

Evidence gaps can fall into four (4) categories: 1) “rigor” in study designs; 2) type of MNCH intervention being studied; 3) measurement indicators and; 4) crosscutting approaches that are heavily influenced by global health trends. Identifying gaps generally involves a certain level of subjectivity and depends upon the perspective of the person being asked.

The following framework was developed as a tool to identify the evidence gaps in mHealth and MNCH for purposes of this Report.
1. Rigor in Study Design

Assessing methodological rigor in study design, which is directly related to the quality of evidence, can be a subjective exercise although the research community generally employs certain standards when assessing “rigor” and the quality of evidence. “Quality” of evidence generally pertains to the rigor of the methodology employed, referring to the scientific process encompassing all aspects of study design: regarding the match between the methods and questions, selection of subjects, measurement of outcomes, and protection against systematic bias, nonsystematic bias, and inferential error (Boaz & Ashby, 2003; Lohr, 2004; Shavelson & Towne, 2002).

From the perspective of researchers, rigor criteria for published studies would include: having a baseline; posing appropriate questions; selection of the appropriate research methodology for the question being investigated, and justifying that methodology; having a clear theory of change; sufficient size and description of comparison groups; controlling for biases and confounding; being peer reviewed; and no apparent conflicts of interests among the investigators.

The authors of the two literature reviews described earlier opined that the evidence base for using mHealth in the sphere of MNCH lacked quality, primarily because many of the studies: 1) did not have intervention and control groups for comparison; 2) did not have baselines; 3) were conducted as part of a pilot intervention (rather than a scalable program); 4) used small samplings for analysis; 5) did not sufficiently control for other biases and/or confounding; 6) did not adequately attribute changes observed (to mHealth) and/or; 7) were primarily descriptive in nature.

Using properly conducted cluster randomized control trials (RCTs) (the so-called “gold standard” in research) is often justification for characterizing the mHealth evidence base in MNCH as having the highest quality. However, as a number of the key informants pointed out during the key informant interviews, RCTs are not always necessary or even appropriate depending upon the research question being studied.

The Supplemental Articles Search conducted for the Report revealed the significant majority of the available published articles on mHealth and MNCH were descriptive in nature or simply reported the results of surveys and/or interviews with participants. Less than one-third of the articles reported on studies using experimental design, and often those studies were conducted with pilots and low “n” values in sample size. Only one published study had a clearly articulated theoretical framework.

Survey to Assess Evaluation Rigor

Several researchers recently conducted an evaluation in the form of a survey of mHealth project managers to assess the evaluation rigor of mHealth projects (across health areas). The purpose of the survey was to “better understand from the mHealth project managers their intentions and practices regarding monitoring, evaluation and impact assessment.” The unpublished study looked at 69 mHealth projects from 29 countries. 69% of the mHealth projects reported to be addressing MNCH. The investigators used an 8-point scale to assess the evaluation rigor each project. Top scores had to have comparison groups, randomization, adequate sample size, and other “quality markers”. Using the 8-point scale, less than ¼ (22.6%) reported strong evaluation rigor (6-8) and less than ½ (47.3%) of the
projects did not meet the minimum threshold of 4 (on the 8 point scale). Of the projects (all health areas) having a focus on evaluation, 60% reported using non-experimental designs; 19% reported using a quasi-experimental design and; 21% reported using an experimental design. The most common data collections approach was cross-sectional. Less common study designs were case-control and step-wedge. Less than ½ (47%) included a comparison group; 43% used randomization and 37% calculated sample size for power. The unpublished report summarized it findings by stating:

“A common feature of many mHealth projects is a general failure to address critical evaluation questions with rigor”.

2. Types of MNCH Interventions

It first must be said that “gaps” is probably an inappropriate word because of its negative connotation. Because the field of mHealth is still nascent, and because the evidence base is understandably still in the early stages of evolving, areas identified as “gaps” are actually opportunities for programmers and researchers to explore in the future.

Areas of mHealth with a More Established Evidence Base: Challenging Preliminary Findings?

The identification of gaps should best begin with identifying those areas in mHealth and MNCH which have been researched to a certain degree and for which the research has generated consistent findings. The preponderance of the literature in mHealth and MNCH has focused on: usability, feasibility and acceptance of mHealth; the use of mHealth in the area of data collection and management (not limited to MNCH); the use of mHealth for appointment reminders (e.g., antenatal visits); and the use of mHealth to improve access to emergency obstetric care by reducing the so-called “Three Delays” in accessing skilled delivery care. Those studies focusing on the Three Delays primarily focused on the first two delays namely: i) the delay in deciding to seek appropriate medical help for an obstetric emergency and, ii) the delay in reaching skilled birth attendants.

The PHI study concluded that the research in these focus areas has generated preliminary (emphasis added) evidence supporting the contention that mHealth contributed to the following outcomes:

- Improved compliance with scheduled follow-up appointments;
- Improved service utilization;
- High levels of trust; user satisfaction with services;
- Improved rates of delivery in the presence of skilled birth attendants.

There have also been findings in a few studies that participants “receive a strong psychological benefit” from the use of mobile phones.
A few key informants who were interviewed for this Report agreed with the conclusions of the PHI study and additionally noted a substantial evidence base supporting the role of mHealth in improving data collection and management.

Yet, some of the conclusions regarding having sufficient evidence to make generalizable statements regarding the role of mHealth may be challenged. While there may be preliminary evidence of outcomes attributable to mHealth, many of those studies were conducted using pilot programs, the findings of which are not necessarily generalizable to different contexts.

For example, there are a number of people working in the mHealth and MNCH fields who believe that the evidence, although promising, is still insufficient to make any conclusive generalizable statements about user acceptability. One key informant worried that the findings of user acceptability (using community health workers) generated from pilot interventions are not generalizable to scaled-up interventions that involve a greater number and range of users in terms of ages and experience. There is a risk that a larger pool of community health workers selected from a larger segment of society would not be as predisposed to using mobile phones in their work as the limited number of community health workers in pilot projects who may have been selected because of their willingness to be part of the study.

*Which MNCH interventions areas should be prioritized in the mHealth research agenda?*

**MNCH Continuum of Care and MDGs 4 and 5.**

Because of the nascent nature of the evidence base for mHealth in the area of MNCH, studies of all interventions along the MNCH “Continuum of Care” with the goal of improving maternal newborn and child health are certainly warranted. As duly mentioned in the Literature Reviews outlined above, the significant proportion of published studies evaluating mHealth in the area of MNCH focus on how mHealth can contribute to reducing the “Three Delays” for pregnant women accessing skilled delivery care.

Most Key informants interviewed were reticent about prioritizing specific MNCH interventions for research with the exception of PMTCT.

A few of the Key informants suggested that the ideal focus areas for research would be the MNCH areas prioritized by donors and the global health community. These interventions would be those areas in which the global health community have identified as “gaps” and/or those areas that are responsible the greatest proportion of maternal, neonate and child mortality.
A significant proportion of the global health community has prioritized achieving the health-related Millennium Development Goals (MDGs) by 2015, specifically MDG 4, 5, and 6. Goals 4 and 5 refer to reducing child mortality and improving maternal health. Global health experts who are tracking progress toward achieving MDG 4 and 5 as part of “Countdown to 2015” have identified the interventions along the MNCH continuum that contribute the most to MDGs 4 and 5. They have also identified obstacles to implementing those interventions. Much of the momentum behind mHealth...
emanates from its potential to improve health interventions that are not being effectively implemented. Those health interventions are identified as coverage gaps in “Countdown to 2015”.

Using “Countdown to 2015” as a standard to identify the most important interventions that contribute to MNCH and where there are gaps in coverage of those interventions, an argument can be made that the following MNCH gaps areas be prioritized for mHealth research and evaluation:

- Prevention-of-mother-to child transmission of HIV (PMTCT);
- Intermittent preventive treatment of malaria for pregnant women;
- Increasing contraceptive prevalence;
- Increasing postnatal follow-up visits for mothers;
- Intervention improving the nutritional status of children, particularly early initiation of breastfeeding and exclusive breastfeeding;
- Children sleeping under mosquito nets;
- Antibiotics for childhood pneumonia;
- Pediatric malaria treatment; and
- Pediatric diarrheal treatment.¹⁰⁷

While the literature review and landscape indicated studies looking at the role of mHealth in a number of these MNCH intervention areas, PMTCT coverage stands out as one of the most significant gaps. Insofar as the prevention of mother-to-child transmission or “PMTCT” (of HIV) is a priority health area not only under the MDGs, but also a priority area for under the President’s Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS Tuberculosis and Malaria (“Global Fund”), researchers who recently completed a systematic review of the literature addressing mHealth used for HIV interventions were surprised to discover that there were no completed studies published in any peer-reviewed journals focusing on how mHealth can improve results in PMTCT programs.¹⁰⁸ There was one study on how mHealth can improve treatment adherence looking of HIV+ patients that included PMTCT patients, but that study did not include an analysis of the impact upon those women based on their status as pregnant women.¹⁰⁹
Other Promising Areas for Study in the area mHealth and MNCH

Mental Health

There is an increasing and robust body of evidence describing the strong correlation between maternal depression and its impact on both maternal health and early childhood health outcomes, particularly in developing countries.\textsuperscript{110} There is also an increasing body of evidence indicating a correlation between the use of mobile phones and feelings of well-being or a sense of community.\textsuperscript{111,112,113} This correlation arguably justifies continuing research evaluating how using mobile phones may contribute to improving the mental health of mothers, affording them a greater sense of community particularly in stressful environments with extreme poverty, HIV and other diseases.
3. Measurement Indicators

Outcome Indicators as a Measure of Quality

The selection of primary outcome indicators is one of the key factors influencing study quality in the view of a substantial portion of the global health community. The literature review of current published studies in the field of mHealth and MNCH revealed a slowly emerging, albeit nascent, body of research in mHealth using maternal and child health outcomes as a measurement indicator. Yet, overall there is still a paucity of peer reviewed published mHealth studies in the MNCH area that used health outcomes as primary measurement indicators. A significant number of studies in the published literature instead used proxy or intermediate results indicators for clinical and health outcomes such as access to antenatal clinics and access to skilled birth attendants. In the area of child health, the literature search revealed no published studies that went beyond using returning for vaccinations appointments as the primary outcome measurement. There were no peer-reviewed published studies using, for example, reduction of morbidity or child nutrition indicators (e.g., weight for height) as outcome measurements.

A few key informants disagreed that indicators such keeping antenatal appointments and return immunization visits cannot be used to infer better health outcomes. The studies using treatment adherence that included pregnant women as clients were not classified as MNCH interventions insofar as pregnant women were included in the studies because of their HIV status and not according to their status as pregnant women.114

Fortunately, the landscape scan revealed an increasing number of current mHealth studies (and protocols) in the MNCH which are measuring the impact of mHealth in terms of clinical and health outcomes.

A few of the key informants interviews confirmed the perception that if mHealth in MNCH is going to attract significant funding, donors are expecting the research to increasingly show how mHealth contributes to clinical outcomes and health impact.115 While the concept of measuring the impact of mHealth in terms of MNCH clinical and health outcomes is an ideal goal, one of the Key informants duly noted that measuring clinical and health outcomes often takes significantly longer (and requires significantly more resources) than using proxy measures such as measuring return visits to a health facility. With the field of mHealth rapidly evolving in a way that technologies and approaches become obsolete rather quickly, the practicality of conducting studies that require longer amounts of time to gauge health impacts must be weighed against pressures to demonstrate results quickly and the limitations of available funding to support longer-term studies.

The absence of any rigorous studies using cost-efficiency indicators as primary outcome measurements was just as glaring, particularly from the viewpoint of government key informants. A few of the key informants speculated that mHealth is not necessarily going to generate evidence of substantial differences in outcomes and impacts when compared to standards of care that do not involve mHealth. There is a likelihood that in many instances, research will show that mHealth contributes to comparable outcomes and impact as current standards of care that do use mHealth. In these cases, in order to make
the case to the donors (and implementers) justifying using mHealth solutions, it is important to demonstrate the cost efficiencies afforded by mHealth, in terms of both financial and opportunity costs.

4. Crosscutting Approaches

Global health trends and the subjective needs of particular stakeholders dictate the identification of gaps in crosscutting approaches. The trend in global health toward: 1) strengthening health systems to provide quality care; 2) integrating health interventions into holistic packages to reach more people; 3) achieving sustainability; 4) understanding how to implement evidenced-based interventions and; 5) analyzing the underlying social determinants for accessing quality health services and led to stakeholders, particularly governments, looking for evidence on how mHealth contributes to:

- Strengthening health and community systems;
- Scaling up and integrating health services;
- Sustainability and financing;
- Implementation science and;
- Reducing health inequities due to social and economic marginalization.

Framing mHealth and MNCH Research in Terms of Health and Community Systems Strengthening; Value Chain Analysis

Priority areas that are receiving a lot of attention in the world of global health (all areas, not just MNCH) are *health system strengthening*[^16][^17][^18] and *community system strengthening*.[^19] Related to systems analysis (and cost-efficiency studies) is the use of Michael Porter’s value chain analysis in understanding how to add value to health systems.[^120] [^121]

There are few recent published studies (or known ongoing research) that evaluate mHealth and MNCH from the perspective of contributing to health and community systems strengthening.[^122] [^123] Global health experts, including major international donors like the World Health Organization, U.S. Government, the Global Fund to Fight AIDS, Tuberculosis and Malaria and DfID have been pondering how the programs and interventions they support with funding contribute to health systems and community systems strengthening.[^124] The World Health Organization (WHO) framework for health systems strengthening lays out six building blocks[^125]:

- Service delivery
- Health workforce
- Information systems
- Medical products, vaccines and technologies
- Financing
- Leadership and governance.
The Global Fund’s core components of community systems include:

- Enabling environments and advocacy – including community engagement and advocacy for improving the policy, legal and governance environments, and affecting the social determinants of health.
- Community networks, linkages, partnerships and coordination – enabling effective activities, service delivery and advocacy, maximizing resources and impacts, and coordinated, collaborative working relationships.
- Resources and capacity building – including human resources with appropriate personal, technical and organizational capacities, financing (including operational and core funding) and material resources (infrastructure, information and essential medical and other commodities and technologies).
- Community activities and service delivery – accessible to all who need them, evidence-informed and based on community assessment of resources and needs.
- Organizational and leadership strengthening – including management, accountability and leadership for organizations and community systems.
- Monitoring and evaluation and planning – including M&E systems, situation assessment, evidence building and research, learning, planning and knowledge management.

In scanning the WHO’s 6 building blocks and the Global Fund’s Community Systems core components, it is easy to see how mHealth can contribute to each building block and core component, whether it is in the area of MNCH or in any other health area.

There have been a number of studies, although not necessarily categorized as MNCH studies that demonstrate the impact of mHealth in improving community health worker performance.\(^{126}\)

Research and evidence of mHealth in the context of MNCH interventions, if framed in terms of how mHealth in MNCH interventions contribute to both health systems strengthening and community systems strengthening or, adding value to a health system, would certainly warrant prioritization from the perspective of many global health experts, particularly those affiliates with international institutions and major global health funders like WHO, the Global Fund and the U.S. Government.

**Integrating Health Services**

As global health moves toward the integration of various maternal and child health interventions as a strategy for scaling-up health services, guidelines for such integration are being issued. Key examples include: i) Integrated Management of Childhood Illnesses (IMCI);\(^ {127}\) ii) PEPFAR’s Technical Guidance for Integrating Prevention of Mother-to-Child Transmission of HIV Interventions with Maternal, Newborn, and Child Health Services\(^ {128}\) and; iii) the Essential Package for Young Vulnerable Children and their Caregivers Affected by HIV and AIDS.\(^ {129}\) Organizations such as Dimagi and D-Tree International have been spearheading the use of mobile applications like CommCare as decision support tools to aid community health workers with facilitating integrated health interventions with phone-based protocols.\(^ {130}\) While results have been mixed,\(^ {131}\) the use of mobile phones as decision support tools using
protocols to implement integrated health services, particularly in the area of MNCH, warrants further research.

**Sustainability and Financing**

Innovative means of financing for health interventions contribute to the sustainability of health programs. International donors, such as the U.S. government, are increasingly expecting that the interventions they support have developed plans for *sustainability*. A key component of sustainability plans is the identification of *financing mechanisms* that are not dependent upon donor funds. There is a lot of energy around employing mobile phone technology for payment and microfinance (e.g., “mFinance”, mPesa) systems. In maternal health in particular, there are a number of interventions, such as the Marie Stopes/SHOPS interventions, using of mobile phones for the reimbursement and use of vouchers and/or conditional cash transfers for the payment of health services related to MNCH.\(^{132,133}\)

With the proliferation of mobile technology in the mobile payment and mFinance arena, there does not appear to be an evidence base in either the published literature or the landscape scan explicitly linking and evaluating mFinance and mobile payments with mHealth outcomes (with the exception of the Marie Stopes/SHOPS evaluation which was not in a peer-reviewed journal). *The potential of linking mFinance with mHealth, particularly in the donor priority areas of performance-based (or results-based) financing and conditional cash transfers*, certainly warrants research and evaluation in terms of how (or if) the linkage of the two mobile technology areas contribute to the sustainability of programs.

**Implementation Science**

Studying how to implement guidelines and research findings around appropriate health Interventions fits within the field of “implementation science”, an area that has been receiving quite a bit of attention and support from global health actors such as PEPFAR.\(^{134}\) “Implementation science” (or research) has been defined as “the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of health care.”\(^{135}\)

Researchers are beginning to use implementation science to evaluate how mHealth can be applied improving the quality of health services. Topics studied within the implementation science framework include using mHealth to increase the skill levels of health workers using clinical practice guidelines or protocols.\(^{136,137}\) Framing research of the role mHealth may play in improving MNCH as “implementation science” may be a strategy for presenting mHealth evidence in a language that would resonate with the global health community, particularly those stakeholders who need evidence of not only “what” to do but also “how” to do it.
Reducing Health Inequities

Addressing the social determinants of health and how social marginalization leads to health inequities has become a priority topic in the global health community. The literature review revealed an emerging evidence base on how mHealth may be utilized as a tool for working with marginalized or particularly vulnerable populations. Some of the grey literature addressed the social determinants and constructs that serve as obstacles in using mHealth. In the field of MNCH and mHealth, gender power dynamics that contribute to inequities are being addressed by initiatives such as GSMA’s mWomen Program.

Despite the global consensus around the role that social determinants play in contributing to health inequities and the emerging attention in the literature to how mHealth can influence social determinants, the evidence base for using mHealth to reduce health inequities is still nascent. In light of the recognized role that social and economic marginalization play in accessing health services, the lack of a strong evidence base analyzing how mHealth might impact health inequities should be considered a gap warranting further research.

CONCLUSION

The evidence base for using mHealth to improve MNCH interventions in terms of health impact and cost-effectiveness is still nascent. Research using pilot studies, process or proxy indicators for health and, less methodologically rigorous study designs are natural precursors for more rigorous studies using health and cost-effectiveness outcome indicators and more labor, time and cost-intensive research designs such as RCTs. All research, so long as there is transparent disclosure of limitations and results, adds to the evidence base. A number of research advocates propose that common metrics and quality standards regarding what is good research be developed to assist the larger community in understanding and using evidence. Efforts should be made to encourage sharing of results through an easily accessible knowledge management platform with quality controls to filter out information that do not meet quality standards. Research and evidence of the role that mHealth plays in other health fields such as HIV, behavioral change and neglected tropical diseases (NTDs) are valuable and should be evaluated as to how it may be integrated into the field of MNCH, particularly as the global health community prioritizes more integration and health systems strengthening.

“Gaps” in the evidence around mHealth and MNCH should be viewed as opportunities for future research. Because of the nascent nature of mHealth being used in the field of MNCH, all types of MNCH interventions present important areas to be studied. From a practical standpoint, those areas along the MNCH continuum that receive less service coverage, particularly pediatric health, warrant examination of how mHealth could increase their coverage and improve impact. Lastly, as the global community acknowledges the inherent inequities in health that exist throughout the world, mHealth presents a promising opportunity for increasing access to health services particularly to hard-to-reach people including not only those people isolated by geography, but also people who are marginalized by reason of gender, social, health and economic status.
• Improving Uptake of Early Infant Diagnosis of HIV for the Prevention of Mother-to-child Transmission of HIV

  (SMS4PMTCT) (underway in Kenya); as of June 29, 2012, enrolled 239 women out of a target of 388.\textsuperscript{140,141} The investigators are conducting a randomized controlled trial (RCT) to examine the effect of text messages sent to women enrolled in PMTCT programs on adherence to postpartum clinic visits and uptake of early infant diagnosis by DNA polymerase chain reaction (PCR). This study seeks to test the hypotheses that (a) text messages sent to women enrolled in PMTCT will improve their attendance at the postnatal clinic within the first 6-8 weeks after childbirth; and (b) text messages sent to women enrolled in PMTCT programs will increase uptake of DNA PCR HIV testing at 6-8 weeks among infants exposed to HIV. If proven superior to standard care, the proposed intervention can be easily scaled-up and integrated into existing healthcare systems in resource-limited settings. Primary outcome measures include: (i) proportion of women who attend postnatal clinic within 6-8 weeks postpartum (ii) proportion of infants tested for HIV by DNA PCR. Secondary outcome measures include: (i) infant adherence to antiretroviral prophylaxis; (ii) time to post-natal clinic return; (iii) maternal adherence to antiretroviral prophylaxis. The study includes sub-groups analyses: a) women on HAART vs. women not on HAART; b) women who knew status before pregnancy vs. women who learned status during pregnancy; c) women who share phones vs. women who own their own phones and; d) women in urban areas vs. women in rural areas.\textsuperscript{142} Findings from this study will provide randomized trial evidence to inform HIV prevention program planners and implementers. In addition, the study is conducting an exploratory analysis of the correlation between using SMS and impact on infant HIV status and infant feeding choices.\textsuperscript{143} This study will also provide further information on the feasibility of using mobile phone-based technology for public health interventions in resource-limited settings. (NIH supported project: University of Washington, University of California, San Francisco, Kenya Medical Research Institute).

  Project Mwana (Zambia and Malawi) – The intervention, supported by UNICEF, Boston University and the Clinton HIV/AIDS Initiative (CHAI) uses mHealth (via a printer connected to a phone) to expedite the delivery of early infant diagnosis results (dry blood spot tests for HIV).\textsuperscript{144} (See above under “Supplemental Articles Search”).
• **Pediatric Antiretroviral Therapy Adherence in Uganda.**

This observational study is assessing a wireless adherence monitoring device and mobile phone-based adherence data collection among caregivers of children under the age of ten years in Mbarara, Uganda. It involves both quantitative and qualitative measures of the feasibility and acceptability of these measures, as well as circumstances of adherence lapses and other individual and cultural factors affecting adherence. The qualitative data will be used to explore models of adherence behavior, which will likely include the child-caregiver dynamic, the child's mental and physical health, and social support mechanism. Primary outcome measures include: (i) distribution of adherence based on wireless adherence monitoring devices and interactive voice response (IVR) or short message service (SMS) self report by caregivers of HIV-infected children under ten years old in Mbarara, Uganda. Secondary outcome measures include: (i) feasibility and acceptability of wireless adherence measures and; (ii) model of adherence behavior.

• **Mobile Phones and Exclusive Breastfeeding** (at least two (2) studies)

  o Sponsored by the Lata Medical Research Foundation, Nagpur, the non-randomized case control efficacy and effectiveness study evaluated an intervention is using cell phones for lactational counseling to address malnutrition in pregnancy and other disorders of breast and lactation associated with childbirth. The objectives of the interventions are to improve exclusive breastfeeding, antenatal visits and the timely introduction of solid foods (complementary feeding). The primary outcome measure is changes in the percentage of women exclusively breastfeeding (breast milk and no other foods or milk based liquids) their infants at 24 weeks. The secondary outcome measure is growth through 6 months of age - weight, length and head circumference gains between birth and each immunization visit (at 6, 10 and 14 weeks), at 24 weeks and at 26 weeks for growth velocity.

  o Sponsored by the University of Toronto, this behavioral support intervention trial will investigate the potential to increase exclusive breastfeeding rates in an urban Kenyan community through peer mother support delivered either by cell phone or through group meetings. It will follow a cohort of more than 800 women attending antenatal care at a large public hospital, and compare indicators of breastfeeding and infant and maternal health between groups receiving one or other type of peer mother support. Study design included randomization, parallel assignments and double blinding.

• **Prevention of Mother-to-Child Transmission (of HIV)**

In addition to the EID studies (SMS4PMTCT in Kenya and Project Mwana in Zambia), there are several ongoing studies looking at how mobile phones can improve uptake of services and follow-up.
A study in Kenya sponsored by the University of Manitoba has the overall goal of assessing if mobile phones and SMS text messages can be used to help improve prevention of maternal to child transmission (PMTCT) of HIV services by strengthening health systems. The study is randomized and will include an intervention group and a control group. The primary outcome measure is increased nevirapine uptake in labor in pregnant HIV positive women from 60% to 70%. Secondary outcome measures include: i) HIV positive rates in infants born to mothers in the study; ii) number of antenatal care visits; iii) earlier identification and treatment of HIV positive infants and; iv) acceptability of SMS messages for PMTCT related care.

Cell-Life, partnering with the Empilweni PMTCT clinic in Johannesburg, has completed a randomized, controlled trial to assess whether SMS can be used to remind HIV+ mothers to keep appointments and bring their infants for HIV testing and, if needed, treatment. The object of the intervention was to reduce loss to follow-up of mothers delivering (and their infants) at Rahima Moosa hospital in Johannesburg. Preliminary results indicated that of the 323 mothers in the intervention (total 738 in the study), more than 90% who received the messages returned with their infants for testing. 78% who did not received texts brought their infants back for testing. In addition, the exit interviews have revealed that the participants in the intervention receive a “strong psychological benefit” from participating. The final results are currently being written up. Surprisingly, the final results of the trial did not indicate any statistically significant differences between the cohort and control groups. One possible explanation being considered for the difference between the mid-term and final results is that a strike of health workers midway into the trials may have confounded results.

- Project Masihambisane - (See Supplemental Articles Search, page 19).

The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) is conducting a comprehensive study in Kenya that is using a cluster randomized control trial design with 36 health facilities randomized to two arms (intervention and control) among 910 HIV-infected pregnant women to determine the effect of mobile phone technology on PMTCT completion from antenatal to six weeks postpartum. The study will examine the acceptability, effectiveness, and costing of implementing a PMTCT-focused mHealth strategy among HIV-infected pregnant women, health workers, and male partners. The tested intervention will engage women, health workers, and male partners in a multi-directional mobile communication network for PMTCT. Low-literacy SMS text messages and structured calls to reinforce key PMTCT messages, including provision of automated and manual reminders to encourage adherence to medical regimens, antenatal care use, skilled birth attendance, safe infant feeding, early identification of HIV in infants, and family planning will be introduced.
• **Maternal Mortality in India: Bihar Project (India Family Health Initiative)**

The $30 million comprehensive maternal mortality project in Bihar India supported by the Bill and Melinda Gates Foundation, uses mHealth as an integral part of the program. The program is conducting an RCT testing the hypothesis that frontline workers (FLWs) using ICT (mobile phone) enabled tools will have greater coverage and higher quality and timely interactions at multiple points in the family care continuum compared with FLWs using paper-based tools. Outcome measures include: i) Birth Preparedness Plan: % of mothers who have a transportation plan for normal delivery as well as for emergency; ii) Receipt of IFA tablet: % of mothers who received at least 90 IFA tablets during their last pregnancy; iii) Essential Newborn Care: % of newborn infants breastfed within one hour of delivery; iv) % of deliveries where clean cord practice was followed; v) initiation and age appropriate frequency of complementary feeding; vi) % of children receiving any cereal based complementary food from 6 month of their age; vii) % of children receiving age appropriate frequency of complementary feeding between 6-11 month of their age; viii) Family Planning: Adoption of modern method of contraception: % adopting a modern post-partum family planning method within 6 months of delivery; ix) Immunization: % children receiving DPT3 by 6 months. 153

• **Using CommCare to Implement Supervisory Management Techniques on ASHAs in India**

Dimagi is planning a randomized control trial assessing the use of CommCare to as a supervisory tool to improve community health workers (ASHAs) who work with pregnant women. The purpose of the study will be to compare performance outcomes (of the AHSAs) in terms of tracking pregnant women and births, % of enrolled women who attend all their antenatal visits and, the % of reported births receiving a visit (from an ASHA) within 48 hours, and clients' overall knowledge and practices related to pregnancy and newborn care. Because of the high associated survey costs, health outcome indicators such as maternal and neonatal morbidity and mortality will not be measured.

• **Txt4Baby (United States)**

A major randomized control trial that will reportedly include health outcome indicators. The intervention uses a free health text messaging service to help more pregnant women and new mothers get information about caring for their health and the health of their babies. Although conducted in the United States, according to several key informants, the results might have implications for health programs in LMIC.

• **MAMA (Mobile Alliance for Maternal Action)**

Testing accessibility, acceptability and effectiveness of Aponjon mobile phone based health information messages for behavior change for improved health care practices in Bangladesh, this proposed matched case-control research design has been proposed to test its effectiveness in
improvement in knowledge, attitude, healthy behavior practice and utilization of care for maternal and neonatal and child health. Will most likely include one health outcome indicator (e.g., child nutrition).

• **Using a mHealth Tool by Health Extension Workers in Ethiopia in carrying out maternal and child care responsibilities**

Supported by the World Bank, the randomized control study is rigorously testing (in a pilot) the impact of using the mHealth tool on the health outcomes with rural mothers and children, with the intention of scale up and collecting evidence for scale-up. The intervention addresses low level of complete antenatal care, unsafe deliveries, improving vaccination coverage and facilitating emergency referrals.

• **Johns Hopkins University (JHU)**

JHU, which has 49 ongoing mHealth studies/interventions in numerous health areas, is conducting studies in MNCH on: 1) using SMS reminders to improve immunization of children (along with cash transfers); 2) increasing communication between district hospitals and village CHWs in Malawi to report emergencies and supply needs. This mHealth intervention aims to provide CHWs with health information and encourage them to use the health information; 3) testing in integrated mobile phone based data system (mCare) in Bangladesh that links women and newborns to improve target delivery of care to high risk mothers and newborns, as well as enhancing the survival of pre-term neonates and growth restricted infants In resource poor settings.\(^{154}\)

• **Mobile Technology for Community Health (MoTeCH) Initiative\(^{155}\)**

MoTeCH is a program (rather than a pilot) to determine how to use mobile phones to increase the quantity and quality of prenatal and neonatal care in rural Ghana, with the goal of improving health outcomes for mothers and their newborns. MOTECH is comprised of two interrelated services. The “Mobile Midwife” application enables pregnant women and their families to receive SMS or pre-recorded voice messages on personal mobile phones that provide time-specific information about their pregnancy each week in their own language (99% have chosen voice). The messages continue through the first year of life for the newborn and reinforce well-child care practices and vaccination schedules. There is also a “Nurse Application” that enables Community Health Nurses to electronically record care given to patients and identify women and newborns in their area that are due for care. The two components are linked so that if a patient has missed treatment that is part of the defined care schedule, the Mobile Midwife service sends a message to remind the patient to go to the clinic for that particular service and the nurse is also informed that the patient is due for treatment. The MoTeCH initiative is supported by the Bill &
Melinda Gates Foundation, and collaborating with Grameen Foundation, Columbia University's Mailman School of Public Health and the Ghana Health Service.

• **Mobile for Reproductive Health** 156

In Kenya, PROGRESS has launched and is evaluating Mobile for Reproductive Health or m4RH, a new family planning information service delivered via text message. A similar evaluation will begin in Tanzania soon. PROGRESS is a five-year project funded by the U.S. Agency for International Development and implemented by Family Health International to improve family planning services among underserved populations. The goal of this project is to obtain evidence for whether mobile technology is an effective and acceptable means of providing family planning information. The m4RH project is designed to answer the following questions: (1) who can be reached with the m4RH family planning program? (2) What type of family planning information can successfully be delivered using the mobile platform? (3) What impact does the m4RH program have? (4) Is the program cost-effective and sustainable? (5) How feasible is it to evaluate this mobile phone program through the use of electronic data collection and monitoring? There are no indications that the research will be measuring health outcomes.

• **mMoney for Women with Fistula** 157

This project uses a combination of mobile banking, public information, and free treatment in order to give women access to fistula repair. Women can call a free hotline, and if money is needed for transport to a fistula unit this is transferred via M-PESA. The project commenced in 2010, and although research is planned, there is no information on the study design, methodology and primary outcome indicators.

• **mFinance to Reimburse Sexual and Reproductive Health Vouchers in Madagascar**

(see above under “Literature Review Findings”). Ongoing research is being conducted and will be presented at the 2012 GSMA-mHealth Alliance Mobile Health Summit in Cape Town in May-June 2012.

• **OASIS II Research Project: Evaluating MVG-Net**

The OASIS II Research Project in the Millennium Villages Project (MVP) is a study aiming to systematically assess the impact of the Millennium Villages Global Network (MVG-Net) and its components, including OpenMRS, ChildCount+ and other electronic service delivery systems in four* of the MVP sites, although implementation of MVG-Net is taking place across all MVP sites. The study applies a mixed methods approach. Key informant interviews comprise the qualitative component. The quantitative component focuses on tracking inputs and outputs as well as aggregated data generated through MVG-Net. Key areas that may be explored include the use of data, performance monitoring, human resources planning and budgeting, supply chain management, efficiency in service delivery, and quality of care on health interventions related
to MDGs 4, 5, and 6—such as pregnancy-related care; newborn health; diagnosis and treatment of children under 5; malaria, TB, and HIV/AIDS; respectively. Health-related indicators include: number of ante-natal care visits; immunization coverage; numbers of positive malaria tests; utilization of family planning techniques; exclusive breastfeeding, underweight children, and wasting (acute malnutrition), etc. 158

* The four MVP OASIS II Research Project Sites are: Bonsaaso, Ghana; Mbola, Tanzania; Mayange, Rwanda and Ruhiira, Uganda.

• **M-Afya Project** 159

A research project of Afya Research Africa, the M-Afya project is about a public-private partnership program to promote quality, timely utilization, and monitoring of focused ante-natal care and skilled delivery services through a network between health facilities and solar-powered community health kiosks (M-Afya kiosks) connected through mobile telephony. The kiosks are targeted at expectant mothers and are intended to facilitate the monitoring of clinical parameters that are important indicators of the progress and complications of pregnancy and delivery. Through mobile phone short messaging, the system incorporates a feedback system, and an educational and information advocacy service. The program also has a money saving scheme for expectant mothers, savings which are intended to earn interest as an incentive for attending all antenatal care sessions and for deliveries done in a health care facilities. This special money saving scheme for expectant mothers forms the basis of a business model that will help sustain the initiative beyond the initial funding. The successful implementation of this program is anchored on the improved mobile phone access by the Kenyan population. This program will first be initiated in the rural area of Thika district, an administrative region in Kenya, for an initial period of 2 years. Information about the study methodology, design and outcome indicates is unavailable.
### Appendix B: List of Key Informants Interviewed

<table>
<thead>
<tr>
<th>NAME</th>
<th>ORGANIZATION</th>
<th>LOCATION</th>
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<tbody>
<tr>
<td>Martin Were</td>
<td>Regenstrief Institute</td>
<td>Indianapolis/Kenya</td>
</tr>
<tr>
<td>Chaitali Sinha</td>
<td>IDRC</td>
<td>Ottawa</td>
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<tr>
<td>Garrett Mehl</td>
<td>WHO</td>
<td>Geneva</td>
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<tr>
<td>Sandhya Rao</td>
<td>USAID</td>
<td>Washington, DC</td>
</tr>
<tr>
<td>Alain Labrique</td>
<td>Johns Hopkins School of Public Health</td>
<td>Baltimore</td>
</tr>
<tr>
<td>Heather Cole-Lewis</td>
<td>Yale University, Columbia University</td>
<td>Hartford, CT, New York</td>
</tr>
<tr>
<td>Marc Mitchell</td>
<td>D-tree International, Harvard School of Public Health</td>
<td>Boston</td>
</tr>
<tr>
<td>Annette Ghee</td>
<td>World Vision</td>
<td>Seattle, Washington</td>
</tr>
<tr>
<td>Caricia Catalani</td>
<td>InSTEDD, Health Informatics Public Private Partnership (HIPPP)</td>
<td>Palo Alto, CA</td>
</tr>
<tr>
<td>Judy Gold (by email)</td>
<td>Marie Stopes International</td>
<td>London</td>
</tr>
<tr>
<td>Richard Gakuba</td>
<td>Government of Rwanda</td>
<td>Kigali, Rwanda</td>
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<tr>
<td>Craig Friderichs</td>
<td>GSMA</td>
<td>Cape Town, South Africa</td>
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<tr>
<td>Mwendwa Mwenesi</td>
<td>Government of Tanzania</td>
<td>Dar es Salaam, Tanzania</td>
</tr>
<tr>
<td>Camielle Noordam</td>
<td>UNICEF</td>
<td>New York</td>
</tr>
<tr>
<td>William Riley</td>
<td>National Institutes of Health</td>
<td>Bethesda, Maryland</td>
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<tr>
<td>Wendy Nilsen</td>
<td>National Institutes of Health</td>
<td>Bethesda, Maryland</td>
</tr>
<tr>
<td>Rachel Vreeman</td>
<td>AMPATH-Kenya, Indiana University School of Medicine</td>
<td>Indianapolis, Kenya</td>
</tr>
<tr>
<td>Anu Gupta</td>
<td>Johnson &amp; Johnson</td>
<td>New Jersey</td>
</tr>
<tr>
<td>Laura Raney</td>
<td>FHI 360, mHealth Working Group</td>
<td>Washington, D.C.</td>
</tr>
<tr>
<td>Dianne Sullivan</td>
<td>Vodafone</td>
<td>London</td>
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<tr>
<td>Christopher Grey</td>
<td>Pfizer</td>
<td>New York</td>
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<tr>
<td>Helga Fogstad</td>
<td>Government of Norway</td>
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APPENDIX “C”

mHealth Ecosystem Stakeholders

[Diagram showing the mHealth ecosystem with overlapping circles labeled Government, Health, Technology, mHealth applications, mHealth Service delivery, and Finance, each containing specific stakeholders like Legislators, Regulators, Medical supply chains, Patients, Software developers, Mobile operators, Handset makers, Banks, Insurance companies, Private investors, Philanthropists, Donors, Individual users/households.]
ENDNOTES

1 For purposes of a survey on mHealth published in 2011, the Global Observatory for eHealth at the World Health Organization defined “mHealth” as “medical and public health practice supported by mobile devices such as mobile phones, patient monitoring devices, personal digital assistants (PDAs) and other wireless devices. mHealth – New Horizons for Health through Mobile Technologies, Global Observatory for eHealth – Second Global Survey on eHealth, World Health Organization, 2011.

2 MNCH was selected as a “use case” for the Needs Assessment and Gaps Analysis primarily because of its prioritization in global health programming. Millennium Development Goals 4 and 5 directly reference maternal and child health and there are a number of major global health initiatives and campaigns targeting maternal and child health such as “Every Woman, Every Child”, “Global Plan towards the Elimination of New HIV Infections in Children by 2015 and Keeping their Mothers Alive” and “Every Child Deserves a Fifth Birthday”. In addition Millennium Development Goal 6 (combatting HIV, malaria and other Diseases) encompasses maternal and child health.

3 The evidence work of the Alliance is primarily performed through its Evidence Working Group, composed of technical and health specialists working in mHealth around the world, with an interest and expertise in research and evidence generation

4 The International Development Coordinating Group (IDCG) has identified “mHealth” as one of the priority issues amenable to a Campbell systematic review and recognizes it as an important topic in the broad field of international development. See http://www.campbellcollaboration.org/ID_Resources/Priority_Topics_in_International_Development.php, (accessed May 3, 2012).


6 See http://healthunbound.org/mama/


9 The "Continuum of Care" for reproductive, maternal, newborn and child health (RMNCH) includes integrated service delivery for mothers and children from pre-pregnancy to delivery, the immediate postnatal period, and childhood. Such care


Tamrat.


39 Noordam, C.


43 Tamrat.


46 Noordam, C.

47 Id.


49 Id.

50 Id.


87 Mitchell et al.


91 Id.

92 Id.


95 Id.

96 Id.

97 Id.

98 Id.

99 Id.

100 Id.

101 Id.


103 Cite to Noordam.

104 PHI. 24-26.

105 Id. 7.


107 Id.

108 Email correspondence from Caricia Catalani, April 2, 2012.


114 Email correspondence from Caricia Catalani, April 2, 2012.


Skype Conversation with Dr. Thomas Odeny, Fogarty International Research Fellow, Kisumu, Kenya, June 29, 2012.

Id.

Id.


Id.

Skype conversation with Katherine de Tolly, Cell-Life, Cape Town, South Africa, June 29, 2012.

Id.


158 Email Correspondence from Nadi Kaonga, June 25, 2012, summarizing the research protocol for the OASIS II Research Project evaluating MVG-Net.