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# ACRONYM LIST

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<th>Full Form</th>
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<td>ANC</td>
<td>Antenatal Care</td>
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<td>CHW</td>
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<tr>
<td>ERC</td>
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<td>M&amp;E</td>
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<tr>
<td>MCH</td>
<td>Maternal and Child Health</td>
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<tr>
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<tr>
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<td>Ministry of Health</td>
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<tr>
<td>MWN</td>
<td>Mobile WACH NEO</td>
</tr>
<tr>
<td>MW</td>
<td>Mobile WACH (Mobile Solutions for Women’s, Adolescent’s and Child Health)</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
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<tr>
<td>SMS</td>
<td>Short message service</td>
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<tr>
<td>SOP</td>
<td>Standard operating procedure</td>
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<tr>
<td>UoN</td>
<td>University of Nairobi</td>
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<td>WHO</td>
<td>World Health Organization</td>
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</table>
1) **TITLE:** Mobile WACh NEO: Communication Empowering Mothers and Newborns

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4) FUNDING AGENCY
Funding type: Grant
Name of Funding agency: USAID
Principal Investigator on Proposal: Jennifer Unger
Proposal Identification Number: AID-OAA-F-16-00026
Title of Proposal: “Mobile WACH NEO: Communication Empowering Mothers and Newborns”
Dates: 07/2016-06/2018

5) ABSTRACT
An estimated 6.3 million children die before the age of 5, 44% in the neonatal period.\textsuperscript{1} Approximately 75\% of those neonates (NEOs) die in the first week of life.\textsuperscript{2} The Kenyan neonatal mortality rate has remained stagnant at 26.8 per 1,000 live births contributing to 60\% of infant mortality.\textsuperscript{3} In sub-Saharan Africa, where more than half of global maternal and child deaths occur, unmet need for family planning (FP) exceeds 30\%.\textsuperscript{4} In Kenya, only 50\% of the total potential demand for FP is being met by the use of effective methods of FP.\textsuperscript{3} Data from modeling studies suggest that if the unmet need for FP could be eliminated, an estimated 1.1 million infant and 80,000 maternal deaths could be averted.\textsuperscript{5} High coverage of effective interventions, such as facility delivery, early neonatal evaluations and FP, is essential to end preventable deaths. mHealth technologies have been identified as a potentially effective strategy to improve maternal and neonatal outcomes by supporting scale up of evidence base interventions. When used appropriately, mHealth can catalyze, support and monitor health improvements at scale. Despite the growing evidence for mHealth, robust research on cost effectiveness, scalability and sustainability are still lacking and it is not clear if these technologies are able to address human resource constraints.

We developed a human-computer hybrid communication system, Mobile WACH: Mobile Solutions for Women’s and Children’s Health (MW) that engages mothers using short message service (SMS) to increase demand for care, and has demonstrated promise for improving outcomes of both mothers and infants. Mobile WACH NEO (MWN) is an adaptation of this system focused on the period close to delivery when risk to mothers and infants is highest, bringing a virtual healthcare worker into homes to support preparation for labor, early postpartum and neonatal care, and FP. Our plan is simple: remotely connect women to a care provider during the most dangerous period for themselves and their babies and provide tailored support in 3 strategic domains which have the greatest impact on maternal and child health (MCH): facility delivery planning, clinical assessment of NEOs and the postpartum mother, and contraceptive decision support. Improved identification and management of neonates with
potentially life-threatening illness is critically needed to significantly reduce neonatal mortality. Although there is evidence that women and their families actively and enthusiastically engage in this type of SMS communication and that it may improve maternal and child outcomes, in order to be considered a “success,” MW needs to be assessed and designed for scale and sustainability.

This Saving Lives at Birth Award enables systematic determination of the “infrastructure” needed for scaling up and sustaining the MWN project. The award will address the scalability and sustainability of the MW model with three targeted interwoven strategies:

1) Development of a Business Plan for MW
2) Road map and buy-in for integration of MWN platform within the Kenya MOH maternal, neonatal, and child health (MNCH) and e/mHealth strategies
3) MWN Demonstration Project which will allow for testing MWN in a real life clinic environment, outside of the resource intensive research study environments, and enable costing analysis for the project.

These activities will take place in Nairobi and Western Kenya in partnership with current and planned partnerships with the Kenya MOH on the county and national levels, Kenya MOH e/mHealth Working Group, KNH, Safaricom (telecommunications provider), Villgro Kenya (mentorship, consultant), ITECH and other NGOs and academic institutions involved in current e/mHealth strategies in Kenya.

This protocol describes the demonstration project only, which is part of the larger Saving Lives at Birth project.

6) INTRODUCTION/BACKGROUND
mHealth projects for MNCH are being scaled but require sustainable approaches that actually improve maternal and neonatal outcomes. Here we present a plan to evaluate and design for scale an SMS project to support the health of neonates and postpartum mothers.

An unacceptable number of women and newborns die or experience significant morbidity in the time during and immediately after birth. The time of labor and delivery is when 46% of maternal deaths and 40% of all stillbirths and neonatal deaths occur and 73% of all neonatal deaths occur in the first week of life. Interventions aimed at this period of highest risk can save lives by connecting women and their babies to skilled birth attendants during labor and continued care in the immediate postnatal period. For example, a new Integrated Management of Childhood Illnesses approach incorporating the immediate neonatal period has good sensitivity for the diagnosis and referral of young infants with severe illness and for improving infant outcomes. In the original MW study, there was an infant mortality rate of approximately 60/1000 live births. Women sent SMS messages at greatest frequency around this most critical time and there was a protective trend in the two-way messaging group for infant mortality. Thus, we hypothesize that a two-way mHealth messaging program specifically targeting the neonatal period will improve mother-infant dyad communication with the health care system, improve maternal and neonatal outcomes, reduce costs, and ultimately be a scalable program model. Although we have previously demonstrated suggestions of efficacy to improve breast-feeding, FP and infant outcomes, this award enables a close examination of the MW approach as a sustainable business model with the potential for integration into standard care at a higher level.

The most distinctive component of MWN is the two-way communication with a trained nurse. Current SMS systems provide information and visit reminders but lack the capability to
**truly connect women to care.** MWN is designed specifically to meet the needs of women in the peripartum period, going beyond typical SMS messaging models to provide women with support needed at the most critical times. When urgent concerns arise, babies become ill, or women do not know the exact location of the hospital, one-way or push messages are not appropriate. If a woman has more than the expected amount of bleeding in the postpartum period or her baby struggles with feeding, a community health worker (CHW) may not show up that particular day, and if they do, they may only be able to refer her to a facility. Unlike other available products (Figure 1), each component of MWN leverages the power of two-way SMS communication to maximize the accessibility of higher-level health care workers to mothers, neonates and families, generating health benefits in a cost effective way through the ability of one nurse to provide support and tracking for many women at zero cost to the end-user.

There is evidence that home visits and assessments by CHWs can improve maternal and neonatal outcomes. However, feasibility in areas with shortages of CHWs is concerning. In addition, home visits are not ‘on-call’ and may miss critical periods when neonates become ill. The human-computer hybrid communication system of MWN provides efficiency gains over home visits, requiring less human capacity through computer level messaging automation and facilitated triage. Additionally, if a CHW is involved in the family’s care, this system augments her role, allowing for appropriate task shifting when a higher cadre of HW is required. MWN brings the skill set of a trained nurse into the home to provide remote primary and urgent care exactly when it is needed.

**The MW innovation is designed for maximal impact in areas with high neonatal morbidity and mortality, comparably high unmet need for FP, and in geographies where efforts are still needed to achieve full coverage for facility deliveries.** The best value will be achieved in poor, hard to reach communities with proliferating cell phone penetration and health care worker shortages. Sub-Saharan Africa in general, and Kenya in particular, meet the criteria for prioritization of this intervention given the stagnant neonatal mortality rate (26.8 per 1,000 live births), unmet need for FP (~50%), mobile phone penetration >80% and the World Health Organization’s (WHO) characterization of Kenya as a country facing an acute shortage of HWs. MWN addresses a critical gap in care between the last antenatal care (ANC) visit and the first (often delayed) postpartum visit when women are most at risk. This makes it adaptable to many different contexts in which care is not readily accessed during this crucial time period. Additionally, MWN and the entire suite of MW projects are designed specifically to reach women through mobile technology and to empower women with knowledge and support throughout their pregnancy.

**Conceptual Framework**
See Figure 2

![Figure 1: Comparison of current MCH SMS projects](image-url)
Assess the scalability and sustainability of the Mobile WACh model, with the desired impacts of improved efficiency of neonatal care, increased postpartum contraception uptake, and reduced neonatal severe illness and deaths in Kenya.
Approach and Methodology
MWN will utilize the mHealth Assessment and Planning for Scale (MAPS) toolkit, a comprehensive self-assessment and planning guide designed to improve the capacity of projects to pursue strategies that increase their potential for scaling up and achieving long-term sustainability. Use of the toolkit will enable the project team to cover the key concerns, activities, and decisions related to six major areas that influence the scaling up of mHealth: groundwork, partnerships, financial health, technology & architecture, operations, and monitoring and evaluation (M&E).

MW Theory of Change Model
Behavioral Theories
The MWN project relies on theories and models at both individual and system levels. The core concept of MWN is to provide support in order to enable better decision-making and appropriate utilization of health care services. This conceptualization at the individual level and within the SMS design are based in Social Cognitive Theory and Theory of Reasoned Action. These behavioral theory models take into account the effect of the social environment on decisions and behavior and we utilize these theories to develop SMS messages and respond to messaging from participants. These theories help us to understand what influences the anticipated outcomes at the individual level and therefore how to thoughtfully design the MWN intervention and improve the effectiveness for the end-user.

Determinant Framework
The conceptual framework (Figure 2) depicts the determinants that are hypothesized to influence the activities and outcomes of the MWN project. The current inputs influencing the outputs include the experience of the MW team including three randomized controlled trials (RCTs) (two ongoing), promising results from the MW original RCT including large formative datasets, partnerships (both current and developing), mentorship from in-country organizations (example: Villgro Kenya) and finally the MW technology which has been tested and reworked to meet the needs of HWS. These inputs are all essential components of the proposed activities including the development of the business plan; drafting a pathway to scale and costing/feasibility evaluations within the demonstration project.

7) RATIONALE
SMS Messaging has potential not only to educate but also engage women and their families in MNCH care without placing an additional burden on health care workers. This project leverages the innovation of mobile communications to sustainably increase appropriate utilization of maternal and neonatal services. Personalized and dynamic messaging may be more effective in producing behavioral change. SMS interventions may be cost saving in avoiding unnecessary visits and preventing delays in seeking care.

8) AIMS & HYPOTHESES
The overarching hypothesis of our project is that a scalable design of mHealth technologies for MCH will yield sustainable, cost-effective, long-term benefits by connecting women, families and their babies to care. We propose to conduct this demonstration project, a longitudinal cohort study and post-cohort study IDIs, to determine the impact of this mHealth SMS strategy on process indicators that represent cost savings as well as MNCH outcomes such as facility delivery, postpartum contraception and neonatal mortality, with the following specific aims:
Aim 1: To evaluate the outcomes of mother-neonate pairs receiving systematic, tailored bidirectional SMS dialogue. Outcomes will be measured during 3-month postpartum follow-up, and will include:

- Facility delivery
- Postpartum contraception
- Appropriate presentation to care after SMS
- Efficiency (unnecessary visits avoided)
- Neonatal mortality
- Neonatal morbidity
- Maternal postpartum morbidity and mortality
- Messaging response rate/SMS interactivity
- Resolution of issues via SMS
- Perceived utility by women and providers

**Hypothesis 1:** Maternal/neonate outcomes will be enhanced by SMS. This approach will allow for resolution of issues via SMS therefore decreasing unnecessary visits and identifying infants in need of in person evaluation.

Aim 2: To assess the cost-effectiveness of bidirectional SMS interactions: a) Estimate net cost savings realized through the reduction of unnecessary visits and infant hospitalization averted, and b) Estimate incremental cost-effectiveness in improving infant and maternal health outcomes.

**Hypothesis 2:** This bidirectional SMS approach will be cost-saving.

Aim 3: To assess the perceived benefits and potential improvements of MWN by postpartum mothers.

**Hypothesis 3:** Mothers will find this system useful and have recommendations for how to tailor the approach to women in their community.

9) **STUDY DESIGN AND METHODOLOGY**

**Overview:** This is a mixed-methods study that has two phases:

- Phase 1: Longitudinal cohort study to evaluate an mHealth intervention to improve maternal and neonatal outcomes
- Phase 2: Post-intervention phase, participant and health provider in-depth interviews (IDIs)

**Study Area Description**

The proposed study will be conducted at two sites in Kenya: Mathare North Health Centre (Nairobi County) and Rachuonya Sub-County Hospital (Homa Bay County). These two sites provide a wide range of ANC, delivery, postnatal care, and human immunodeficiency virus (HIV) services in their catchment areas. Each of these sites sees more than 10 new mothers for ANC per day.

**PHASE 1: Longitudinal cohort study**

a) **Study design**

This is a longitudinal cohort study. We will enroll 800 pregnant women to participate in the MWN demonstration project.

**SMS Message Development and Delivery**
SMS messages will be designed using an iterative process that integrates findings from a preliminary SMS intervention, MW, and utilize the community based assessment of neonates.\textsuperscript{13} SMS messages will provide tailored and actionable education, counseling, and reminders specific to pregnancy/postpartum status. Messages will be designed to target the appropriate outcomes. Counseling within the messaging will be consistent with the Focused Antenatal Care WHO guidelines, the Kenyan maternal child health handbook and the Young Infants Clinical Signs Study Group.\textsuperscript{13-16} SMS messages will be translated into local dialects.

**Interactive SMS Messaging**

SMS will be delivered at varying frequency depending on the pregnancy status of the women (Table 1). Initially, starting between 30 and 36 weeks, women will receive messaging weekly directed to preparation for delivering at a facility. These messages will include information about deciding on a facility, recruiting a partner or other companion to accompany them and finding childcare for other children as well as making a plan for transport. Immediately following delivery women will receive messages daily for one week and then every other day for 3 weeks. These messages will be designed to assess the neonate and postpartum mother’s status. Finally, for the next four weeks women will receive counseling via SMS regarding infant health and FP twice per week.

**Table 1: SMS Messaging Schematic**

<table>
<thead>
<tr>
<th>Period</th>
<th>Pregnancy (30 weeks gestational age - Delivery)</th>
<th>Early neonatal period (Delivery – 4 weeks infant age)</th>
<th>Postnatal period (4 weeks – 12 weeks infant age)</th>
</tr>
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<tbody>
<tr>
<td>Duration</td>
<td>Variable (~8 wks)</td>
<td>4 weeks</td>
<td>8 weeks</td>
</tr>
<tr>
<td>Frequency</td>
<td>Weekly</td>
<td>Daily → Every other day</td>
<td>Twice weekly</td>
</tr>
<tr>
<td>Topics</td>
<td>Birth preparation</td>
<td>Infant health evaluation</td>
<td>Infant health</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maternal evaluation</td>
<td>Family planning</td>
</tr>
</tbody>
</table>

Pre-programmed messages will be delivered at times and in languages based on patient preferences. If no response is received, the participant will receive a “check-in” SMS after failing to respond for 2 days. The check-in SMS will ask if participant is receiving SMS and if she is well. If no response is received from the participant, no further "check-in" SMS will be sent. However, she will continue to receive future SMS. Participants will also have the capability of texting spontaneously to the system. Interactive SMS communication will be responded to and managed by the study nurse.

We have partnered with a local premium rate service provider, Africa’s Talking, to provide SMS dialogue free of charge to participants.

Study nurses will manage the bidirectional SMS dialogue and standard operating procedures (SOPs) will be developed for standardizing responses. Thus, study nurses will follow national guidelines and local practice standards to respond. The process will be adaptive as new scenarios unfold with dialogue – a new question not addressed by the SOPs will be discussed by study team and SOP developed if it is a question likely to be encountered repeatedly. Weekly review of the log of SMS narrative will enable standardization, quality assurance, and understanding women’s use of the system and their level of interaction it. Issues to be examined within the bidirectional intervention arm include ability to standardize messaging, time demands, and time-cost.
b) Study population
The study population will consist of pregnant women seeking ANC services at public facilities in Nairobi and Nyanza regions. The source population is drawn from both rural and peri-urban areas, diverse in ethnicity, and of generally low socioeconomic status. Based on ANC attendance we anticipate being able to recruit 10 women per day, 3-4 at each site. This would allow us to complete recruitment in 16 weeks.

Sample size determination and formulas used
Expected outcome in the general population: neonatal mortality
Nairobi regional estimate: 39/1000 births; MW 1 estimate: 56/1000 births (project in Nairobi)
Nyanza regional estimate: 19/1000 births

Sample size estimates Assuming alpha=5%, power=80%, with a sample size of 800 we would have sufficient power to detect a decrease in neonatal mortality from approximately 39/1000 to 20/1000. Thus, the total cohort sample is 800 women.

Table 2: Sample size estimates

<table>
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<th>Interventions</th>
<th>Risk of outcome</th>
<th>Control</th>
<th>25/1000</th>
<th>30/1000</th>
<th>35/1000</th>
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<td>2417</td>
<td>1181</td>
<td>723</td>
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<tr>
<td>20/1000</td>
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<td>1016</td>
<td>630</td>
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<tr>
<td>15/1000</td>
<td>1668</td>
<td>848</td>
<td>553</td>
<td>379</td>
<td>288</td>
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</tbody>
</table>
Shading indicates detectable differences with n=800
Each clinic sees more than 10 new mothers per day. This will allow us to recruit at least 6 women per day at each clinic or 200 per month. Thus it will take 16 weeks or 4 months to recruit a total of 800 women. It is estimated that women will be in study for approximately 26 weeks or ~6.5 months total.

We will recruit from the time of approval (estimating December of 2017) until approximately. Follow-up will start after the first person delivers (~January 2017) and will continue until approximately 6.5 months after the last participant is recruited (~2018).

c) Recruitment procedures
CHWs will introduce the study to potential participants, answer any questions they have and invite women to participate. It will be emphasized that their participation would be completely voluntary and would not in any way affect their access to ANC, postnatal, or infant care services. In order to capture the proportion of women referred who meet our eligibility criteria and are interested in participating, a screening questionnaire will be used to collect data on eligibility. The screening questionnaire will record no personally identifiable information. Oral consent will be obtained for participation of interested women in the screening phase. Eligible women will be invited to participate in the intervention. Those eligible women who decide not to participate will be asked for their reasons for non-participation, and these will be recorded in the screening questionnaire.

Eligibility: Pregnant women will be recruited for the study. Women will be eligible if they have access to cell phone, ≥ 14 years and approximately >30 or <36 week gestation (Table 3).

To enhance generalizability, literacy will not be required if women have access to a partner or family member whom she would be comfortable to have read her the messages. This approach was developed in consultation with mothers in Kenya, who felt that involving their partner was acceptable and may engage more support. Eligible women will undergo screening, the informed consent process and be entered into the system. Participants will be asked their preferences for message delivery including language and time of the day.

Table 3: Layout of cohort study procedures, study populations, and eligibility

| Population & maximum sample size | Women  
N=800 (400 per site) |
<table>
<thead>
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<tbody>
<tr>
<td>Study procedures</td>
<td>Longitudinal cohort, intervention</td>
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<tr>
<td>Topic</td>
<td>Bidirectional SMS</td>
</tr>
<tr>
<td>Recruitment</td>
<td>ANC</td>
</tr>
</tbody>
</table>
| Eligibility                      | • Pregnant women ≥ 14 years  
• >28 and <36 weeks estimated gestational age  
• Daily access to mobile phone and willing to receive SMS  
• Literacy not required if women have access to a partner/family member whom she would be comfortable to have read her the messages.  
• Willing to provide informed consent |

d) Data collection procedures
Women will be followed during pregnancy and for three months postpartum; all clinical care will be managed through the existing MCH infrastructure. Because the study aims to determine mHealth benefits in a routine clinic setting, specific ANC/postnatal care services will be delivered by the MOH programs. **All data will be collected at one study visit approximately 14 weeks postpartum (coinciding with MCH scheduled immunization visit) and through the SMS communication.**

Check-in calls will be done by nurses to participants who do not attend their final follow up visit and will call the participants contacts if they fail to reach study participant.

At the recruitment and one follow-up visit a standardized questionnaire will be administered using a tablet-based system (Open Data Kit, ODK) developed by the UW Department of Computer Science and Engineering collaborators.

We will collect patient information at baseline and follow-up visits using participant surveys with questions about demographics, clinical history, experience with SMS and technology, intimate partner violence, and depression.

e) Variables: outcomes, indicators, and source documents

Table 4: Summary of proposed outcomes

<table>
<thead>
<tr>
<th>Primary Outcomes</th>
<th>Comparison data</th>
<th>Target</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Message response rate/ SMS interactivity</td>
<td>N/A</td>
<td>&gt;70% of mothers respond to &gt;80% or SMS received</td>
<td>Messaging data</td>
</tr>
<tr>
<td>Infants presenting to care due to messaging</td>
<td>N/A</td>
<td>&gt;80% of infants identified as &quot;at risk&quot; present to care</td>
<td>Messaging data/study visit</td>
</tr>
<tr>
<td>Resolution of infant issues via SMS</td>
<td>N/A</td>
<td>&gt;90% of infant medical issues* &quot;resolved&quot;** with SMS</td>
<td>Messaging data/study visit</td>
</tr>
<tr>
<td>Efficiency</td>
<td>N/A</td>
<td>50% unnecessary visits avoided</td>
<td>Messaging data/study visit</td>
</tr>
<tr>
<td>Perceived utility and efficiency</td>
<td></td>
<td>Support for system from health providers</td>
<td>Phase 2 provider IDIs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Secondary Outcomes</th>
<th>Comparison data</th>
<th>Target</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility delivery</td>
<td>National/regional estimates – 50%</td>
<td>Increase to 70% (Risk difference)</td>
<td>Messaging data, Self-report at study visit</td>
</tr>
<tr>
<td>Neonatal mortality</td>
<td>National/regional estimates – 39/1000</td>
<td>Decrease to 20/1000 (Risk difference)</td>
<td>Messaging data, Self-report at study visit</td>
</tr>
<tr>
<td>Postpartum contraception</td>
<td>National/regional estimates – 58%</td>
<td>Increase to 78% (Risk difference)</td>
<td>Messaging data, Self-report at study visit</td>
</tr>
</tbody>
</table>

**Notes: MCH: Maternal-Child Health; CRF: case report form**

**Outcomes**

A summary of proposed outcomes is provided above (Table 3).
Definitions
*Infant medical issues: We will consider any occasion of a participant asking for infant medical advice as a potential infant medical issue and an opportunity for either identifying the need for medical attention or the opportunity to resolve said issue by SMS. Examples of an infant medical issue would be—difficulty with feeding, fever or other signs of infection, signs of dehydration (lack or absence of wet diapers), weight loss, prolonged irritability, listlessness or limp posture.

**Resolution: The resolved medical issue is one that can and should be resolved by SMS communication. This is mainly applicable when an infant has a minor medical issue that does not require urgent medical attention and the parent can be provided reassurance through SMS.

f) Data collection instruments
Data collection instruments for the trial are being submitted with this application of this protocol. The trial will not commence until these instruments are reviewed and approved by the UW Human Subjects Division (HSD) and KNH-UoN ethical review committee (ERC).

g) Quality assurance procedures
Clinical care: The study will adhere to Government of Kenya guidelines for the care of pregnant/postpartum women and their infants; however, no clinical care will be provided by study staff. Data collected as part of the study will be abstracted from the mother’s “Mother & Child Health Booklet.”

Adherence to protocol: Weekly reporting of enrolment, follow-up, medical complications, laboratory results, and specimen collection will enable us to monitor that the study is running according to approved protocols. Frequent reporting will also enable us to quickly respond to any problems that arise during the study.

h) Training procedures
Dr. John Kinuthia, Dr. Jennifer Unger and Dyphna Mogaka will supervise training of clinical personnel in study procedures. This will include research ethics, neonatal health and FP counseling and completion of surveys.

PHASE 2: Post-cohort study

a) Study design
After participation in Phase 1 of MWN, all participants will be asked to participate in a post-intervention survey and a subset of women (n=40 (5%)) will be invited to participate in in-depth interviews (IDIs). Health care providers (n=20) at the study sites will also be invited to participate in IDIs regarding the MWN program. These IDIs will be conducted by a Kenyan team trained in qualitative research methods. Study investigators experienced in qualitative methods, Dr. John Kinuthia (site-PI) and Dr. Jennifer Unger (PI), have reviewed topic guides for content validity and cultural relevance.

b) Study populations
Participant IDIs
These IDIs will be instrumental in understanding whether the intervention worked, why it did or did not work, and possible recommendations for enhancement of the intervention.

Providers IDIs
After the study completion, we will also conduct IDIs with 40 providers (20 per site) to understand their experiences, perceptions of SMS intervention in terms of benefits to care, effect on workload,
barriers and facilitators of use, ability to integrate in long term care, and recommendations for enhancement of SMS intervention.

c) Recruitment procedures
Participant IDIs: After women complete the program, study staff will approach women with high, medium and low engagement with the program to describe the purpose of the IDIs and invite interested women to participate. It will be emphasized that participation is completely voluntary. If interested in participation, they will undergo the informed consent process and IDI.

Provider IDIs: Health providers working in MCH will be given information on the MW program and requested to participate in IDIs. Those who are willing and able will undergo the informed consent process and prior to IDIs.

Table 5: Phase 2 layout

<table>
<thead>
<tr>
<th>PHASE 2</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WOMEN</strong></td>
<td><strong>PROVIDERS</strong></td>
<td></td>
</tr>
<tr>
<td>Population &amp; maximum sample size</td>
<td>N=40 (~20 per site)</td>
<td>N=20 (~10 per site)</td>
</tr>
<tr>
<td>Study procedures</td>
<td>IDIs immediately following completion of follow-up in phase 1, N=40 (~20 per site)</td>
<td>IDIs immediately following completion of follow-up for all participants in phase 1, N=20 (~10 per site)</td>
</tr>
<tr>
<td>Topic</td>
<td>Experience with intervention, frequency/themes of SMS messages initiated by participants</td>
<td>Experience with intervention, frequency/themes of SMS messages initiated by participants</td>
</tr>
<tr>
<td>Recruitment</td>
<td>Participants in phase 1 will be recruited based on level of engagement with the program (~14 with high engagement, 12 with medium engagement, 14 with low engagement total).</td>
<td>Providers will be recruited from participating clinics.</td>
</tr>
<tr>
<td>Eligibility</td>
<td>• Phase 1 cohort study participants who complete the study • Willing to provide informed consent</td>
<td>• MNCH and/or FP provider • Willing to provide informed consent</td>
</tr>
</tbody>
</table>

d) Data collection procedures (clinical and non-clinical, field, data collection instruments)
IDIs will be performed in a private area. Participants will meet a trained interviewer or moderator who will ask questions and take notes. Consent will be obtained from participants to take notes and audio record the discussion. The interviewer/moderator will describe procedures and norms for discussion and participation. Participants will be given a chance to ask questions regarding procedures prior to the discussion. Their socio-demographic information will be documented in separate forms. Socio-demographic information that will be captured include: age, marital status, education level, employment, number of children, and HIV status as shown in the participant survey portion of each IDI guide. Interviews will be conducted in participant languages. Thereafter, notes will be compared to audio-recordings to fill in missing information and transcribed to English (if necessary). Transcribed data will be de-identified. Tape-recorded discussions will be destroyed no later than 3 years after conducting the IDI.
Participants will be provided Ksh. 400 to compensate for time and transportation expenses to participate in the study. We will provide this monetary compensation to each participant at the conclusion of each interview.

e) Data collection instruments
Data collection instruments for the IDIs will be submitted in a subsequent modification of this protocol. The IDIs will not commence until these instruments are reviewed and approved by the UW Human Subjects Division (HSD) and KNH-UoN ERC.

11) STUDY MATERIALS
Equipment: The grant award includes support for SMS platform messaging delivery and receipt, 2 tablets, field office supplies (stationary, paper, toner), 2 desktop computers.

Personnel: The grant award includes support for KNH, UW and MOH investigators, clinic personnel, the data team, and a study coordinator. Study personnel working in Kenya will be hired through KNH according to standard procedures.

Costs data
We will assess the cost of all services and equipment necessary to implement each of the three arms (direct medical costs). Using WHO guidelines and its ingredients approach\textsuperscript{17,18} direct medical costs will quantify the resources and associated unit costs to deliver the intervention, organized in standard expenditure categories: personnel (salaries), supplies including drugs and medications, equipment (e.g. computer programming), services (e.g. airtime, media, costs related to the mHealth such as cellular phones, wireless network), space and overhead, community awareness and mobilization. A particular emphasis will be put on the costs for the different types of personnel employed (e.g. nurses) and the time demanded from them in the intervention. In addition, direct non-medical costs quantifying transportation costs, food and housing expenses, and user fees; and indirect costs quantifying the time loss for patients to seek care and associated lost wages, due to long waiting times will be assessed in participant surveys.

Please see the attached budget for additional details on study costs.

12) ETHICAL CONSIDERATIONS
a. Consent explanation
Please see the attached consent forms:
Consent 1: Cohort study participation
Consent 2: Participant IDI
Consent 3: Provider IDI

13) DATA MANAGEMENT PLAN
Overall Data management systems: The SMS software tracks message delivery and receipt. This software is password protected. Clinical and baseline data are collected at recruitment and entered into study data collection tools. Delivery and postpartum data will be collected and entered into study data collection tools. Data will be uploaded daily via ODK Survey from Android phones to the ODK Aggregate web server. Data will transported via secure socket layer (SSL) and only accessible by authenticated users. SMS system data is password protected and stored on a web server. Weekly reports will be generated to monitor study progress and troubleshoot problems. All data collection instruments will be kept in a locked study office accessible to study staff only. All computers, tablets (used for primary data collection), and individual study databases
will be password protected. Participants will be assigned a non-identifiable study code upon enrollment. Study analysts will receive only coded data. The links to patient identifiers will be retained in a locked cabinet.

Data Ownership
The proposed project is a collaborative effort between investigators at the UW and KNH. The aforementioned institutions will jointly share ownership of the data. Study investigators at the UW and KNH will have full access to the data. Authorship on publications, conference presentations, abstracts and other materials generated from this study will reflect contribution to design, execution and analysis of the study.

14) STUDY LIMITATIONS AND HOW TO MINIMIZE THEM
The study evaluates several concepts, first whether this SMS communication approach decreases neonatal and infant mortality, improves family planning and facility delivery uptake, and increases efficiency of visits. The study is powered to detect a difference in neonatal mortality but this is a rapidly changing environment and we will attempt to measure these changes to see if there may be an influence. Fidelity and generalizability of dialogue interventions are challenging. We have proposed SOP-driven dialogue and implementation and evaluation in two sites to address these issues, but it will not be possible to completely standardize bidirectional interventions. Finally, defining programmatic cost-savings or effectiveness is based on specific time/costs of the sites. We believe that these sites reflect other national and regional settings.
15) TIMELINE

<table>
<thead>
<tr>
<th>Activities</th>
<th>Timeframe/Estimated Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2016</td>
</tr>
<tr>
<td>Site evaluation</td>
<td>N</td>
</tr>
<tr>
<td>Meet with the MO and country officials</td>
<td></td>
</tr>
<tr>
<td>Obtain human subjects approval</td>
<td></td>
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<tr>
<td>Develop and complete demonstration project work plan</td>
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<tr>
<td>Develop and complete data collection tools</td>
<td></td>
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<tr>
<td>Develop and complete costing evaluation work plan</td>
<td></td>
</tr>
<tr>
<td>Develop and complete costing evaluation tools</td>
<td></td>
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<tr>
<td>Develop and complete MWN communication system training handbook</td>
<td></td>
</tr>
<tr>
<td>Train staff</td>
<td></td>
</tr>
<tr>
<td>Recruitment of subjects</td>
<td></td>
</tr>
<tr>
<td>Follow-up of subjects</td>
<td></td>
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<tr>
<td>Track all costs</td>
<td></td>
</tr>
<tr>
<td>Identify and pursue sources of revenue</td>
<td></td>
</tr>
<tr>
<td>Develop an M&amp;E plan</td>
<td></td>
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<tr>
<td>Evaluate project</td>
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</tr>
</tbody>
</table>

16) HUMAN SUBJECTS

**Ethical Approval**

We will obtain ethical approval from the UW Human Subjects Division and the KN-UoN Ethics and Research committee.

**Collaborating sites**

The study will be conducted in collaboration with the UW, KNH, and UoN. The study will be reviewed by the KNH ERC and UW IRB and will not be started before approvals are obtained from all two organizational review boards. For this specific study, UW investigators will not be directly involved in fieldwork, data collection, or study recruitment or consenting processes. Data analysis performed by investigators, co-investigators and personnel will be performed using only de-identified data.

17) BUDGET (total budget period)

See attached
APPENDICES/ATTACHMENTS
I) CONSENT FORMS
II) CURRICULUM VITAE
III) GRANT APPLICATION
IV) BUDGET
18) REFERENCES

6. Lawn JE, Blencowe H, Oza S, et al. Every Newborn: progress, priorities, and potential beyond survival. Lancet 2014;384:189-205.
15. Focused Antenatal Care.
http://www.who.int/pmnch/media/publications/aonsectionIII_2.pdf.)


