Partners Human Research Committee Detailed Protocol

Protocol title: Using mHealth technology to identify and refer surgical site infections in Rwanda.

Version Date: 9/20/2017

BACKGROUND AND SIGNIFICANCE:

Surgical site infections (SSI) are a major source of morbidity and mortality worldwide and the leading health-care-associated infection in the developing world. [1] The burden is disproportionately felt in low- and middle-income countries (LMICs)[2] and especially in Africa, where the rate of post-operative SSI has been documented as high as 30.9%.[3] In these settings, SSIs often develop after patients are discharged from care,[2] and geographic and financial barriers can prevent patients from following up during the post-operative period. [4,5] One study from the Central African Republic reported that only 25% of surgical patients returned for their 30-day post-operative follow-up visit.[6] Failure to return or a delayed return to care among patients with SSI is linked with poor health outcomes, including sepsis, need for re-operation, and death,[7] and an increase in healthcare costs.

In many LMICs, community health workers (CHWs) play a major role in delivering household-based care to vulnerable populations who might otherwise be unable to access health facilities. These CHWs are typically lay individuals nominated by their communities with relatively low levels of education and training.[8] In Rwanda, villages typically have three CHWs: two "binomes" who are trained to provide care for malaria, pneumonia, and diarrhea for children[9] and a third CHW responsible for maternal health.[10] These CHWs are considered a critical component of the health system in a country that has seen a 59.5% decline in maternal mortality and 70.4% decline in under-five mortality since 2000.[11] In some limited geographic areas, CHWs are engaged in other health activities. For example, CHWs provide support for HIV patients, leading to improved treatment adherence and patient outcomes.[12,13]

The current Rwandan CHW network includes 45,000+ lay health workers who focus on basic health screening and education for pre- and post-partum women and children under-five years. The lack of professional training of the existing CHWs, combined with the large number of activities already included in their daily work, limits their ability to provide more complex care, such as monitoring post-operative patients.

The greatest challenge that prevents the national expansion of CHWs into specialized care areas such as surgical follow-up is their pre-existing heavy workload and limited training.[14] Globally, the range of responsibilities of CHWs vary by program,[15] whether polyvalent or topic-focused such as the maternal and child health CHWs in Rwanda. Regardless of the range, the number of responsibilities is typically great and additional activities will require extensive pre- or post-service training or provision of activity support aides.

Recent advances in telecommunications infrastructure and technologies and the increasing access to mobile phones in LMICs create opportunities to use mobile health (mHealth) strategies to

support CHWs in the efficient follow-up of specialized patients. In Rwanda, 63% of the population in 2014 reportedly own a cell phone, with 99% having access to mobile networks.[16] We have shown that real-time use of mHealth technologies increases adherence to health protocols in rural Africa even with minimal provider training,[17] and also improves the perceived quality of care.[18] Point-of-care mHealth technologies can also support the supervision and reporting of activities,[19] an existing challenge that we have identified for CHWs in Rwanda.[20]

Members of this study team previously conducted a small pilot study in Haiti[21] with sCHWs using mHealth tools to administer an SSI screening. Following the screening, the sCHWs used cell phones to photograph the surgical wound and record the GPS location of the visit. The mHealth tool was developed by Sana and administered on a Samsung Galaxy X-Cover 2 smart phone. Of the 33 surgical patients assessed, there was 85% agreement between the diagnoses of the CHW and a surgeon's assessment based on a physical exam.

Significance of this research:

In order to address the challenges of overburdened CHWs and the demand for improved identification and referral of SSIs, we plan to leverage mHealth technology. The proposed CHW-mHealth interventions could greatly improve the existing model for surgical patient follow-up in rural Rwanda. Under the current standard of care, post-operative patients are discharged from the hospital with verbal instructions to return to care if SSI symptoms develop. The interventions under investigation will allow routine contact with post-operative patients and support the delivery of a systematic protocol to identify and refer patients with SSI back to care. Since most operations at district hospitals in Rwanda are caesarian sections, this research will inform the way these mothers are followed after delivery, which is currently under the mandate of maternal CHWs. In addition, our findings will advance the research frontier by informing future studies employing CHWs equipped with mHealth tools to individually monitor other types of patients in their homes.

This research will generate new knowledge related to the diagnosis of SSI and surgical patient follow-up in low- and middle-income countries. The screening protocol to be validated will lower barriers to diagnosis and extend diagnostic services to surgical patients that would not otherwise present for follow-up care. Further, the mHealth tools developed to deploy the screening protocol will serve as models for similar initiatives related to other disease areas, allowing for improved patient follow-up in rural resource-poor settings. Finally, the process measures documented in Aim 3 will help other implementers better understand the feasibility of mHealth tools to support community health workers.

SPECIFIC AIMS:

The present study aims to examine whether or not the use of mobile Health (mHealth) by community health workers (CHWs) can improve the identification of surgical site infection (SSI) and a timely return to care among patients who undergo surgery at a rural hospital in Rwanda.

With advances in mobile technology and telecommunications infrastructure in Rwanda, there is great potential to leverage mHealth strategies to support CHWs to identify SSI in the community and improve patient return to care. Here, we propose to optimize a simple screening protocol that can be implemented by CHWs with mHealth support to identify patients with SSI among surgical patients who return to the community following discharge from the hospital. We will then evaluate the impact of this intervention on appropriate return to care for patients with an SSI. We have previously piloted such strategies in rural Haiti where we found 85% agreement between the CHW diagnosis of SSI and the diagnosis of a surgeon.

Specific Aim 1: In order to determine whether or not the use of mHealth by CHWs improves the identification of SSI and timely return to care among surgical patients in rural Rwanda, we aim to optimize a simple screening protocol that can be implemented by lay CHWs in Rwanda that will help them to correctly identify SSI ten days post-surgery.

Specific Aim 2: We will assess the antibiotic prescribing practices during hospitalization and at discharge.

Specific Aim 3: We will describe water, sanitation and hygiene (WASH) resources at the hospital and at the mothers' homes.

Specific Aim 4: After optimizing the SSI screening protocol, we will compare the efficacy of the protocol across two groups: 1) patients who are visited by a surgical CHW who administers the protocol using a mobile phone 2) patients who receive a phone call from surgical CHWs who administer the protocol via phone. These groups will be compared to patients who receive the standard of care in Rwanda, which is no special follow-up after discharge.

Specific Aim 5: We aim to document process indicators measuring aspects of the CHW-mHealth intervention implementation. These measures will evaluate for successful and timely completion or compliance with each step of the specific aim 2.

Specific Aim 6: We will assess barriers to return to care, specifically in individuals in Arms 1 and 2 that receive follow-up and are recommended to return to care for suspected SSI, but fail to return to Kirehe District Hospital.

Specific Aim 7: We will determine standard post-operative follow-up care procedures for individuals who receive no additional follow-up (Arm 3).

Specific Aim 8: We will assess the direct and indirect costs incurred by the mother and her family, stratified by whether or not she has a surgical site infection, and describe the burden of these costs relative to the overall financial expenditures of the household.

SUBJECT SELECTION AND ENROLLMENT:

This study will follow patients who received cesarean-section surgery at KDH and reside in Kirehe District. KDH is a 145-bed facility operated by the Rwanda Ministry of Health (RMOH) and supported since 2005 by the medical non-profit organization Partners In Health (PIH). The hospital serves a catchment area of 364,000 people, primarily residing in rural, outlying villages. In preliminary work, we conducted a chart review that showed that 7.3% of obstetric surgical patients and 3.1% of non-obstetric surgical patients returned to the hospital with an SSI. Based on regional literature, we expect the true rate of SSI in patients receiving surgery KDH to be 10-20%.[22]

Phase 1

Participants will be adult (≥18 years) patients receiving cesarean-section surgery at KDH over a seven-month enrollment window. All patients receiving a cesarean section (c-section) surgery at KDH who reside in Kirehe district will be eligible and will be invited to participate on post-operative day 2. We anticipate enrolling 525 post-operative c-section patients who received surgery at KDH during the seven-month period. Patients will be enrolled consecutively. We will include patients from Mahama Refugee Camp when collecting information about the hospitalization and outcomes. However, these patients will not be asked to return for follow-up.

Phase 2

We will continue to consecutively enroll participants on post-operative day 2 from the adult female patient population receiving c-section surgery at KDH during a 14-month period. Randomization into the three study arms will take place at time of discharge. We will enroll 1092 participants in this phase of the study, 364 per study arm. Once enrolled, there will be no special retention strategies so as not to interfere with the outcomes under investigation in Aim 4 (return to care) or Aim 5 (process measures describing the CHW-mHealth intervention implementation). If the patient is still in the hospital 10 days following surgery, they will be excluded from the study given the inability to be randomized properly to the three arms of this phase. We will include patients from Mahama Refugee Camp when collecting information about the hospitalization and outcomes. However, these patients will not be asked to return for follow-up.

Sealed study packets, prepared in advance, will be available at KDH. Each study packet will have the arm assignment for the patient, which will be randomly assigned during the preparation of the materials using a random number generator. Both the research staff and the patient will be unaware of the arm assignment during the consent process and the assignment will be revealed only after the patient has agreed to participate. In this phase, no participants will receive travel vouchers, to ensure appropriate comparison between the intervention and standard of care groups. Per standard of care, all patients will receive information on the signs of SSI and will be instructed to return as soon as any of these present. (Appendix A).

STUDY PROCEDURES:

This research includes two distinct phases. During the first phase, we will optimize the SSI screening protocol by piloting it among a cross-section of patients receiving surgery at KDH, Rwanda. In the second phase, we will randomize patients receiving surgery at KDH to one of three arms – standard of care and the two intervention arms. At the conclusion of the study, we will compare rates of return and severity of SSI at return among the three arms and report process indicators describing the implementation of the CHW-mHealth interventions in the two intervention arms. In this study, patients will be assessed at 10 days after their operation, as symptoms for SSI usually develop during the first 6-9 post-operative days.[23]

Through PIH, we will hire four sCHWs with similar demographics to the existing CHWs specifically for this study. They will receive five days of training on the organization of the Rwandan health sector, post-operative follow-up, operation of the mHealth tools, best practices in wound photography, and basic SSI physiology and identification. The five-day training is similar in length to the specialized health trainings current CHWs receive and mirrors the training experience of sCHWs in the pilot project in Haiti. The mHealth tool was developed by Sana and is administered on a Samsung Galaxy X-Cover 2 smart phone. The tool prompts the CHW to evaluate the wound for 1) warmth, 2) increased pain, 3) swelling, 4) firmness of the wound, 5) wound opening, and 6) fluid drainage and quality. The phone also has the capability to take a photo of the wound and record GPS location.

PHASE 1:

During this phase, we will address Aim 1, optimization of the SSI screening protocol. The protocol will be piloted using the mHealth device among a cross-section of patients receiving surgery at Kirehe District Hospital (KDH), Rwanda. We will also embedded Specific Aims 2 and 3 (assessments of antibiotic prescribing practices and WASH resources) into this phase.

Consenting participants will be screened for surgical site infection (SSI) 10 days' post-operation. The screening window will be ± 3 days (7-13 days post-operation). During the screening visit, patients will be evaluated in two different steps. First, a GP will perform a clinical assessment. These data will be considered the gold standard against which to compare the SSI screening protocol. Secondly, the patient will be independently screened by a sCHW who will use the mHealth tool described above to administer the six basic screening questions.

For consenting participants that are discharged prior to their 10-day post-operative screening, a study data collector will administer a simple self-report survey to collect basic patient demographic and socioeconomic characteristics on the day of discharge. They will be asked to return to the clinic for screening. In line with national policies, these participants will receive a voucher worth approximately US $10, to compensate for travel and time, to return to the clinic. The voucher will be redeemed when the patient arrives to their assigned screening day. If a participant misses his assigned screening day, the participant will be contacted via his local community health worker.

Consenting patients that are not discharged prior to their 10-day post-operative screening will have demographic and socioeconomic data collected via self-report survey administered by the

study data collector as well as GPs and sCHW conducting the physical examination on the assigned screening day. These participants will not receive any voucher. Study staff will also extract clinical data from the patient files of all consenting participants.

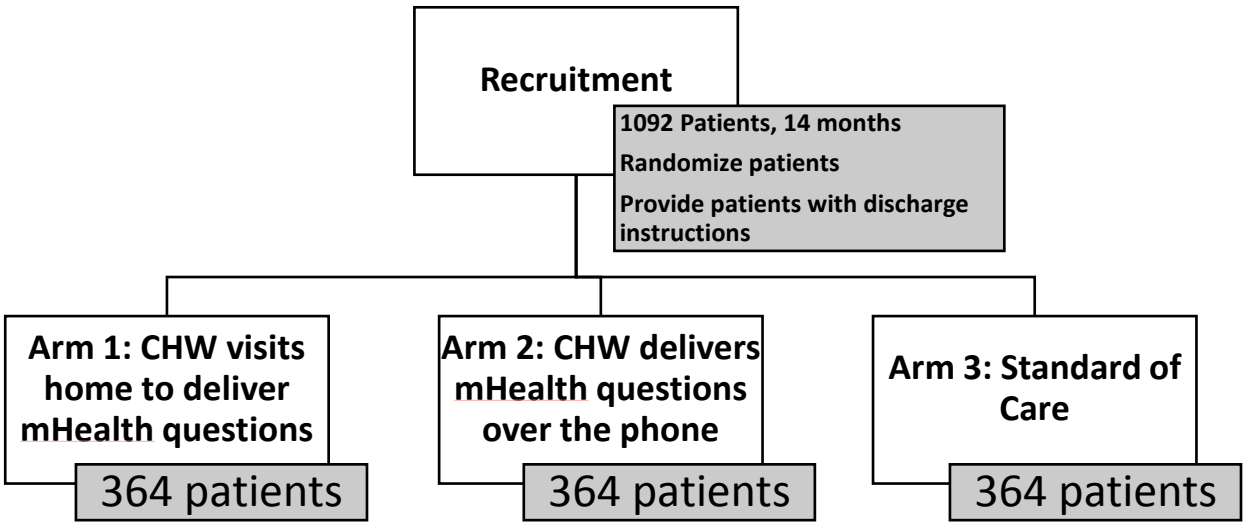
We anticipate enrolling a minimum of 525 post-operative patients during the five-month period. With an estimated overall SSI rate of 15% based on existing literature and 10% loss-to-follow-up (LTFU), we expect 71 patients will have a GP-diagnosed SSI and 402 patients will not have a GP-diagnosed SSI.

PHASE 2:

After the screening protocol has been optimized in phase 1, new patients receiving c-section surgery at KDH will be enrolled and randomized to one of three study arms. Rates of return and severity of SSI at return across the three arms will be compared (Aim 4). We will also report process indicators to describe the implementation of the CHW-mHealth interventions (Aim 5). For patients that have contact with a sCHW (Arms 1 and 2), and are suspected to have a SSI and referred back to care but fail to return, we will assess their barriers to care (Aim 6). For patients that have no special follow-up, we will assess their post-operative follow-up practices (Aim 7). Embedded in this study will be a small sub-study on the costs of care and impact of these costs on family expenses (Aim 8).

All consenting participants will have basic demographic and socioeconomic data collected by self-report via a survey administered by the study data collector at time of discharge. The study data collector will extract additional clinical data from the patient file. At time of discharge, participants will receive surgery follow-up instructions (Appendix A), including a set of warning signs for SSI and when to return to a health center, per standard of care. Additional human subjects contact will depend on study arm assignment. Individuals in Arm 1 will be visited at home by the sCHW who will administer the optimized SSI protocol via the mHealth device. Following the screening, the sCHWs will use the cell phone to photograph the surgical wound and record the GPS location of the visit. Individuals in Arm 2 will be phoned by the sCHW who will administer the SSI protocol over the phone. Individuals in Arm 3 will not have any additional contact beyond standard of care (Figure 1).

Figure 1:



BIOSTATISTICAL AND QUALITATIVE ANALYSIS:

Phase 1:

At the time of enrollment, study staff will administer a basic survey to record self-reported data on patient demographics (gender, age, weight, height, education level, location of residence, distance to hospital) and socioeconomic status (monthly household income, land ownership, cost of transport as a barrier to receiving health care). Study staff will also extract data from clinical charts on past medical history, type of surgery, time from surgery recommendation to operation, pre-operative antibiotic use/time, wound class, and any documented surgical complications. Clinical information will continue to be collected up to 90 days for any patients who are never discharged or for any patient who is readmitted for a surgical complication. For patients that are transferred to Kigali for tertiary care, we will use data collected routinely collected by the Right to Health Care program to complete their follow up information.

Specific Aim 1: During the follow-up screening visit, patients will be evaluated in two different steps. First, the patient will be screened by a CHW who will use the mHealth tool to administer the basic screening questions. The mHealth application will prompt the CHW to evaluate for warmth, increased pain, increased swelling, increased firmness of the wound, wound opening, and fluid drainage and quality. The CHW will take photo of the wound on the mHealth tool. Second, a GP will perform a clinical assessment and provide responses to two basic questions: 1) Do you diagnose the patient as having an SSI? And 2) Do you identify any other post-operative

complications that would warrant the patient's return to the clinic for physician review? These data will be considered the gold standard against which to compare the SSI screening protocol. The GP will also comment on the 6 characteristics from the mHealth tool for comparison.

Specific Aim 2: For one month of Phase 1, study nurses will observe the clinical interactions with patients during rounding and document in a case observation form (Appendix B) the prescription and taking of antibiotics during admission and at discharge.

Specific Aim 3: To assess the WASH infrastructure at the hospital, data collectors will administer a hospital assessment form (Appendix C). To assess variability, the data collectors will administer an abbreviated version of this form every 4 hours over the course of one week. At the follow-up visits, mothers will be asked about the access to sanitation facilities at home.

Analysis and Outcomes:

Aim 1:

Patients who are still admitted at the follow-up will be excluded from the developing of the screening algorithm. At 4 months into Phase 1, we will assess the validity of the SSI screening protocol. In this first assessment we will identify a cutoff *(c)* by optimizing the area under the receiver operating characteristic curve. We will consider the screen positive if the patient meets at least *c* of the 6 criteria. If the sensitivity of SSI screening protocol is less than 90% or the specificity is less than 80%, we will modify and optimize the screening protocol. Steps for modifying the algorithm include the following:

1. Adding, removing or modifying questions. We will use a classification and regression tree (CART) analysis to determine the best set of individual or combined items from the initial screening questions. We will develop maximal trees with all six screening questions, and then apply reduced error pruning, removing questions that do not reduce predictive error by 10%. We will choose optimal trees based on overall predictive properties of the pruned tree. If the optimal tree removes screening questions, we will propose new questions guided by a) Rwandan colleagues for contextual relevance and b) global surgery and infectious disease experts for subject matter input.

2. Adding photo functionality with review by the GP. Email through the cellular network and uploading through the mHealth system could allow sCHWs to send a photo along with the screening question responses to a GP for their recommended diagnosis. If the SSI screening protocol is performing sub optimally, then we will explore the validity of the protocol with the photo and GP photo assessment added.

After 3 additional months (7 months into Phase 1), we will identify a new cutoff and reassess the sensitivity and specificity, with 95% confidence intervals, of the SSI screening protocol. This final algorithm will be considered optimal for Phase 2.

Aim 2:

We will describe the type of antibiotics prescribed, the median number of doses and amount of doses with interquartile ranges.

Aim 3:

We will describe the overall WASH infrastructure, variability in availability in WASH infrastructure and availability of WASH infrastructure in the mothers' homes using frequency and proportions with 95% confidence intervals.

Phase 2:

Basic demographic and clinical data will be recorded at baseline by study staff, as described in phase 1. For Arms 1 and 2, addresses/phone numbers and availability will be documented for patient follow-up. At ten post-operative days (±3 days), sCHWs will visit patients in Arm 1 at the address provided. The sCHW will be assisted by a local village CHW to identify the patients' homes. Once there, the sCHW will administer the SSI screening protocol with prompting from the phone, record responses into the phone, take a photo of the wound, and take GPS coordinates. Patients in Arm 2 will be phoned by the sCHW on the tenth post-operative day (±3 days). The sCHW will administer the SSI screening protocol over the phone, prompted by the smartphone application to ask the appropriate questions. For both arms, patients identified as having an SSI will be referred back to KDH for care. These patients will also be asked a set of questions to assess for possible barriers to return of follow up. In this phase, patients will not receive financial support to return to the clinic. Patients not identified with SSI will be reminded of the warning signs and follow-up instructions. Patients still hospitalized at the hospitalized on their assigned screening day will be excluded from the study as they will not be eligible for the expected study follow up.

A patient tracker log at the hospital will be used to document patient return for follow-up care. The log will also document patients that self-present with potential SSI. Study staff will extract from the clinical chart the presence of an SSI, severity, treatment obtained, need for operative intervention, hospitalization, and/ or complications as recorded by a KDH GP. During the study period, clinical charts will be audited for completeness and GPs will be trained in data quality to ensure the accuracy of this clinical data. In addition, study staff will track process measures related to Arms 1 and 2.

Patients in Arms 1 and 2, who are determined by the sCHW to have a suspected SSI and referred back to care, but fail to return back to care within one week will be identified. Data collectors will return to these patients' homes at 22-30 days post-operation to interview them on why they failed to return to care. The interviews will be semi-structured, including questions on established barriers to care and allowing for open-ended response. A random sample of patients in Arm 3 will be visited at home at 22-30 days post-operation by data collectors who will

interview them on their follow-up care procedures. The interviews will be semi-structured, including questions on standard care paths and allowing for open-ended response.

For a subset of 50 patients, we will administer at discharge a Financial Risk Protection Survey (Appendix D), an existing validated tool, to understand the total costs of care and the costs relative to normal household expenditures.

Analysis and Outcomes:

Aim 4:

For Aim 4, we will compare the proportion of patients who return for follow-up with an SSI in Arms 1 and 2 to Arm 3 (standard of care) using a two-sided, two-sample test of proportions at the α=0.05 significance level. We will use a logistic regression model to assess the impact of study arm on measures of severity at presentation (for example, readmission to hospital), controlling for potential confounders collected at enrollment. All analyses will be completed as intention to treat, regardless of whether the patient had contact with the sCHW or was screened by the mHealth tool in Arms 1 and 2. For Aim 4, for Arms 1 and 2, we will report percent for each of the process measures (for example, percent of home visits or calls completed on time) with 95% confidence intervals. We will assess the impact of study arm on measures of severity at presentation, controlling for potential confounders collected at enrollment. We will describe standard of care patient follow-up behavior using results from Arm 3. We will also report surgery-related reasons for return to care beyond SSI. We will perform a sensitivity analysis to determine under what range of SSI rates the results are still valid.

Aim 5:

For Aim 5, we will report percent for each of the process measures with 95% confidence intervals. Process measures include: ability to find the patient's home (Arm 1), willingness to allow sCHW into home (Arm 1), percent of home visits completed (Arm 1), successful use of GPS (Arm 1), availability of phone (Arm 2), availability of patient when called (Arm 2), visits or calls completed on-time (Arms 1 and 2), percent of reports successfully transmitted via the application (Arms 1 and 2) and presentation to care upon referral (Arms 1 and 2).

Aim 6:

For Aim 6, we will identify potential predictors for failure to return, comparing those who were recommended in Arms 1 and 2 to return and did return to those who failed to return using logistic regression. Demographic and clinical predictors collected at enrollment will be used as potential predictors. All factors significant at the α=0.2 significance level in the bivariate analysis will be considered for the multivariate analysis. We will build the final predictive model using backward stepwise regression, stopping when all factors remain significant at the α=0.05. For those that fail to return to care, we will report their barriers to care using proportions and 95% confidence intervals. Responses to open ended questions will be transcribed and translated, and we will identify any unaddressed themes using a general inductive approach.

Aim 7:

For Aim 7, we will evaluate patient post-operative care behaviors using proportions and 95% confidence intervals. Responses to open ended questions will be transcribed and translated, and we will identify any unaddressed themes using a general inductive approach.

Aim 8:

For Aim 8, we will describe the median and ranges of expenses incurred by patients, stratified by whether or not the patient had a surgical site infection. We will also describe the median and range for the normal household expenditures and compare the care expenses relative to normal household expenditures.

Power Analysis:

The sample size for Phase 2 of this study was driven by Aim 4. We assume that the rates of SSI in the three arms will be similar (due to randomization), and we anticipate more patients with SSI will return to care in Arms 1 and 2 than in Arm 3. In each arm, we will enroll 364 patients. Assuming a 15% SSI rate, this translates to 55 SSI cases per arm. In Arm 3, we expect approximately 6% of all surgical patients to return with an SSI corresponding to 40% of all SSI infections. In Arms 1 and 2, we hypothesize twice as many patients with SSI (80%, n=44) will return. We would have an 81% power to detect a difference between the rate of patients that returned with SSI in Arms 1 and 2 (12%) as compared to Arm 3 (6%) with a two-sided test at the α=0.05 significance level (Table 1).

Table 1: Sample size calculation in Phase 2

	Arm 1	Arm 2	Arm 3
Description	Home visit on 10th post-operative day (±3 days)	Phone call on 10th post-operative day (±3 days)	Standard of care
Number per arm	364	364	364
Anticipated number with SSI	55	55	55
Hypothesized number to return with SSI days 7-14	44 (80%)	44 (80%)	22 (40%)
Overall hypothesized proportion that	0.12	0.12	0.06

will return on POD 7-14 with SSI			

RISKS AND DISCOMFORTS:

The study does not alter the standard of care in any way that increases risk to the patient. Risks to privacy are minimized by accessing data on password protected mobile phones, storing data on HIPAA-compliant servers, and de-identifying the database as soon as is practicable after the conclusion of the study period.

The primary risk associated with participation in this study is a breach in confidentiality, resulting in the disclosure of patient information. This risk is considered minimal; as unique codes will be used in place of participant names. All study staff will be trained in confidentiality. To further reduce the likelihood of a breach in confidentiality, all digital information will be stored in a password-protected document on an encrypted study computer, and all paper records will be stored in a locked file cabinet in a secure room at KDH.

A second risk will be decreasing the likelihood of a patient return to care when needed under the CHW mHealth interventions. All patients will receive standard of care advice on surgical follow-up and when to return to care. Patients who have contact with a sCHW (Arms 1 and 2 of Aim 2) will be referred back to care if evidence of an SSI is present or will otherwise be reminded of advice on when to return to care. It is possible that the sCHW will give the wrong SSI diagnosis or that a patient may delay return to care because of an expected visit from a sCHW. This risk is moderate and will be monitored.

A third risk is exposure of patient's location due to the collection of GPS coordinates. To

minimize this, we will adopt the concept of geographic masking- the process of altering the coordinates of point location data to limit the risk of re-identification upon release of the data.[24]

POTENTIAL BENEFITS:

Participants likely will benefit from the research in that the intervention we hypothesize will lead to a timelier diagnosis of SSI. This in turn will lead to earlier presentation and faster treatment initiation. Diagnosis of SSI earlier will then prevent progression to sepsis, need for re-operation, and possibly death.

In addition, this study will help identify barriers to follow up care and improve access through the use of CHWs. The patients enrolled in Aim 1 will benefit directly by receiving vouchers to compensate for transportation costs (a known barrier) to return to follow up who otherwise would not routinely see a clinician post-operatively. Patients enrolled in both Arms 1 and 2 of Aim 2 will have additional contact with a health care provider (sCHW) beyond the current standard of care. While not all participants may need this earlier screening, as not all will have surgical complications, the risks and discomforts associated with the screening are minimal.

The long term goal of the present study is to scale up our mHealth technology by providing the intervention to all surgical patients, particularly mothers who received a caesarian section, leveraging our collaboration with the Rwanda Ministry of Health (RMOH) eHealth lead. Furthermore, the results of this disease-agnostic platform will inform other mHealth approaches to support patient follow-up by CHWs, allowing CHWs to expand to other specialized healthcare needs and better link these patients to care in rural African settings.

MONITORING AND QUALITY ASSURANCE:

Data monitoring

Data will be monitored for accuracy, completeness and appropriateness of evaluations by the surgical research fellow and study staff every 2 weeks. Consent procedures will be conducted by the research team. Adherence to the protocol will be reviewed with feedback given to study personnel on a weekly basis

Data Safety

Only study staff, sCHWs and investigators Evrard Nahimana, Caste Habiyakare and the surgical research fellow will have access to identifiable data. These individuals will receive training in data confidentiality and research ethics. The remaining co-investigators will only have access to de-identified data including data collection forms that only have a study ID captured or final databases with all identifiers removed.

The following includes the specific data that will be collected for the purposes of this study and the study design to ensure patient confidentiality, randomization, and patient safety.

1) Demographic and socio-economic data (Phase 1 and 2). This data will be collected by study staff at the time of study enrollment via a self-report questionnaire administered to the

participants. Responses will be recorded onto a paper data collection form that will be stored in a locked file cabinet in a secure room at KDH. A unique study ID will be recorded on the paper data collection form in place of participant names. The file linking study IDs to patient identifiers will be kept separately. Once this data is double entered into a password-protected electronic database by study staff, the paper data collection form will be destroyed.

2) Clinical data from patient files (Phase 1 and 2). This data will be extracted by study staff at time of enrollment or after the patient's return visit (Aim 2 only). Co-investigators Evrard Nahimana, Caste Habiyakare and the surgical research fellow may assist with data extraction from files. Data will be recorded onto a paper data collection form that will be stored in a locked file cabinet in a secure room at KDH. A unique study ID will be recorded on the paper data collection form in place of participants' names. The file linking the study ID to patient identifiers will be kept separately. Once this data is double-entered into a password-protected electronic database by study staff, the paper data collection form will be destroyed.

3) Screening assessments by GP and sCHW (Phase 1). This data will be captured on a paper data collection form by the GP for the GP screening and directly into the mHealth tool by the sCHW for the sCHW screening. GP responses will be recorded onto a paper data collection form that will be stored in a locked file cabinet in a secure room at KDH. Only a study ID will be captured on the paper data collection form and a file linking the study ID to patient identifiers will be kept separately. Once this data is double entered into a password-protected electronic database by study staff, the paper data collection form will be destroyed. Data/photos collected on mHealth devices will be stored locally on a password protected phone before uploaded into the research database. Only the study id will be captured in the phone at the time of screening.

4) Patient tracking information (Phase 2). This data is needed to identify patients in Arm 1 and Arm 2 of the study for appropriate follow-up. For Arm 1, which requires follow-up in the patient's home, study staff will record the location of the participant's home and the name of the existing CHW. For Arm 2, which requires a call to the patient, the study staff will record a phone number that can be used to reach the patient (if available). Patient tracking information will only be used by the study staff and the sCHW responsible for the patient's follow-up. This information will be stored on a paper form, separate from any patient data and will be destroyed at the end of the study.

5) CHW-mHealth process measures data (Phase 2). Study staff and community health workers will document the ability to find the patient's home (Arm 1), participants' willingness to allow sCHWs into their homes (Arm 1), percent of home visits completed (Arm 1), successful use of GPS (Arm 1), availability of phone (Arm 2), availability of patient when called (Arm 2), visits or calls completed on time (Arms 1 and 2), percent of reports successfully transmitted via the mHealth application (Arms 1 and 2) and whether a patient referred back to care returned to care (Arms 1 and 2). This data will be collected on a paper form with only the study ID captured. Once this data is double-entered into a password-protected electronic database by study staff, the paper data collection form will be destroyed.

Outcome Monitoring

To minimize the risk of a breach in confidentiality, unique codes will be used in place of participant names and all study staff will be trained in confidentiality. Personal health information will be coded and collected on password-protected mobile phones. All digital information will then be stored on an encrypted study computer. All paper records, including consent forms, will be stored in a locked filing cabinet at KDH. At the conclusion of the study period, all datasets for analysis will be de-identified and all identifiable information will be destroyed.

Adverse Event Reporting

A Data and Safety Monitoring Board (DSMB) will be designated to oversee the safety and effectiveness of the Aim 4 in this study. This committee will include one surgery expert, one global health delivery expert, one Rwandan health practitioner and one statistician. After seven months of accrual, we will compare rates of return between the three study arms. We anticipate 600 patients (200 per arm) will be included in this interim analysis. If the proportion who have returned in Arms 1 and 2 (intervention arms) is significantly lower compared to standard of care, then the study will be stopped or one study arm will be dropped. Further, if there are significantly more complex cases at return (higher rates of readmission or reoperation) in Arms 1 or 2, then the study will be stopped or one study arm will be dropped. The DSMB will meet once, immediately after the interim analysis, and the outcome of the DSMB review will be summarized in a letter to the IRBs of all participating institutions.

REFERENCES

1. Allegranzi B, Nejad SB, Combescure C, et al. Burden of endemic health-care-associated infection in developing countries: systematic review and meta-analysis. *The Lancet*. 2011;377(9761):228–241. doi:10.1016/S0140-6736(10)61458-4.

2. World Health Organization. *Report on the Burden of Endemic Health Care-Associated Infection Worldwide*. 2011.

3. Nejad SB, Allegranzi B, Syed SB. Health-care-associated infection in Africa: a systematic review. *Bulletin of the WHO.* 2011.

4. Grimes CE, Bowman KG, Dodgion CM. Systematic review of barriers to surgical care in low-income and middle-income countries. *World journal of surgery*. 2011.

5. Hsia RY, Mbembati NA, Macfarlane S. Access to emergency and surgical care in sub-Saharan Africa: the infrastructure gap. *Health policy Plan* 2012.

6. Bercion R, Gaudeuille A, Mapouka PA. [Surgical site infection survey in the orthopaedic surgery department of the“ Hopital communautaire de Bangui,” Central African Republic]. *Bulletin de la Societe Path Exot.* 2007.

7. Gottrup F, Melling A, Hollander DA. An overview of surgical site infections: aetiology, incidence and risk factors. *EWMA Journal*. 2005.

8. Lehmann U, Sanders D. *Lehmann: Community Health Workers: What Do We Know about them? -The state of the evidence on Programmes, activities, costs and impact of health. Google Scholar*. Geneva: 2007.

9. Mugeni C, Levine AC, Munyaneza RM. Nationwide implementation of integrated community case management of childhood illness in Rwanda. *Global Health: Science and Practice* 2014.

10. Health RMO. *Third Health Sector Strategic Plan*.

11. Farmer PE, Nutt CT, Wagner CM, Sekabaraga C. Reduced premature mortality in Rwanda: lessons from success. 2013.

12. Rich ML, Miller AC, Niyigena P, Franke MF. Excellent clinical outcomes and high retention in care among adults in a community-based HIV treatment program in rural Rwanda. *JAIDS Journal of Acquir. Immune Def.* 2012.

13. Franke MF, Kaigamba F, Socci AR. Improved retention associated with community-based accompaniment for antiretroviral therapy delivery in rural Rwanda. *Clinical Infectious Disease* 2012.

14. Condo J, Mugeni C. Rwanda's evolving community health worker system: a qualitative assessment of client and provider perspectives. *Human Resource Health* 2014.

15. Palazuelos D, Ellis K, Im DD, Peckarsky M. 5-SPICE: the application of an original framework for community health worker program design, quality improvement and research agenda setting. 2013.

16. National Institute of Statistics of Rwanda. *Statistical Yearbook 2014*. Kigali

17. Mitchell M, Hedt-Gauthier BL. Using electronic technology to improve clinical care–results from a before-after cluster trial to evaluate assessment and classification of sick children according to integrated Management of childhood illness protocol in tanzania. *BMC medical Inform. Decis. Mak.* 2013.

18. Mitchell M, Getchell M, Nkaka M. Perceived improvement in integrated management of childhood illness implementation through use of mobile technology: qualitative evidence from a pilot study in Tanzania. *Journal of health Commun.* 2012.

19. DeRenzi B, Borriello G, Jackson J. Mobile Phone Tools for Field-Based Health care Workers in Low-Income Countries. *Mount Sinai Journal of Medicine* 2011.

20. Mitsunaga T, Hedt-Gauthier B, Ngizwenayo E. Utilizing community health worker data for program management and evaluation: systems for data quality assessments and baseline results from Rwanda. *Social Science & Medicine.* 2013.

21. Matousek A, Addington S, Paik KE. *Community Health Workers for Surgery: a Pilot Study of an mHealth Application for the Early Detection of Surgical Site Infection in*

Rural Haiti. Journal of the Am. Col. Surg; 2014.

22. Taye M. Wound infection in Tikur Anbessa hospital, surgical department. *Ethiopian medical journal*. 2005.

23. Barie PS, Eachempati SR. *Surgical Site Infections*. Surgical Clinics of North America; 2005.

24. Zandbergen PA. Ensuring confidentiality of geocoded health data: assessing geographic masking strategies for individual-level data. *Advances in medicine*. 2014.

25. Rich ML, Miller AC, Niyigena P, et al. Excellent Clinical Outcomes and High Retention in Care Among Adults in a Community Based HIV Treatment Program in Rural Rwanda. J Acquir. Immune Defic. Syndr. 2012; 59(3):35-42.