Cover page

Official title: A mobile phone-based triage tool to identify discharged trauma patients in need of further care in Cameroon.

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STUDY PROTOCOL

A MOBILE PHONE BASED TRIAGE TOOL TO IDENTIFY DISCHARGED TRAUMA PATIENTS IN NEED OF FURTHER CARE IN CAMEROON

Protocol Summary

Title	A mobile phone-based triage tool to identify discharged trauma patients in need of further care in Cameroon
Study objectives	1. Establish the feasibility of using mobile phones to follow up on hospitalized trauma patients after discharge in Cameroon. 2. Cross-validate a telephone-based triage tool to identify trauma patients who would benefit from further medical care. 3. Characterize the impact of timely follow-up on long-term disability and socioeconomic consequences associated with trauma in Cameroon.
Study design	Objective 1: Cohort Study Objective 2: Stepped-wedge intervention, cross-validation of intervention (mHealth telephone triage tool questionnaire) and in-person, blinded physician exam Objective 3: Cohort study
Study sites	1. Laquintinie Hospital of Douala, (Littoral region) 2. Limbé Regional Hospital, (Southwest region) 3. Pouma Catholic Hospital, (Littoral region) 4. Edea Regional Hospital, (Littoral region)
Study population	A prospective cohort study of admitted trauma patients in the four-hospital trauma registry
Control arm	Pre-intervention population
Intervention arm	mHealth telephone triage tool implementation
Outcomes	Aim 1: 1) number and proportion of hospitalized trauma patients who are reached by mobile phone post-discharge. Aim 2: mHealth triage tool score; physician exam determination for “needs further care” or “does not need further care”. Aim 3: Proportion of injured patients who seek clinical follow-up evaluation; GOSE disability level at 2-weeks and at 1, 3, and 6 months
Sample Size	Estimating, that 10% of contacted patients will require further care, a sample size of 1300 patients in the triage cohort will be targeted.
Study duration	24 months

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1. BACKGROUND

Trauma kills more people annually than HIV, malaria, and tuberculosis combined; 90% of these deaths occur in the developing world. Despite the already-significant burden and the predicted future growth of trauma as a public health problem, trauma remains a non-prioritized public health issue, especially in LMICs. Improvements in trauma care in LMICs could potentially save two million lives each year. As access to adequate care for surgical diseases, like trauma, emerges as a global health priority, innovative methods to improve the quality and efficiency of surgical care are needed.

SSA is disproportionately impacted by injury. Cameroon may be more affected than other countries in the region. While 61% of injured patients are believed to seek formal medical care, there is no mechanism to ensure timely follow up for hospitalized patients. Once patients are discharged from the hospital, their fates are largely unknown. Complications related to injury may not receive further care until conditions are extremely advanced, or they may simply go untreated altogether. Lack of timely intervention for injury-related complications is a potentially preventable cause of morbidity and mortality related to injury.

While mobile phone use in Cameroon is increasing, the sparse literature on their use for health promotion is mainly focused on the use of text-messaging. The feasibility and utility of voice-contact by mobile phone to facilitate of health care services in this context is largely unknown. This growing network of mobile phones presents a potential opportunity to extend health services, even to historically hard-to-reach populations. We propose to use a mobile phone-based triage tool to identify discharged trauma patients who would benefit from further care. Our specific aims are designed to accomplish this objective.

visits.

2. STUDY AIMS

The primary study objectives are as follows:

Aim 1: Establish the feasibility of using mobile phones to follow up on hospitalized trauma patients after discharge in Cameroon.

Hypothesis: Mobile phones are a feasible way of contacting trauma patients after they are discharged from the hospital in Cameroon.

We will contact trauma patients discharged from four hospitals participating in the Cameroon National Trauma Registry at intervals of two weeks, one month, three months, and six months following discharge. The response rate and decay of response over time will be tracked.

Aim 2: Cross-validate a telephone-based triage tool to identify trauma patients who would benefit from further medical care.

Hypothesis: A triage tool administered over the telephone can effectively identify injured patients who would benefit from further care for their injuries.

An over-the-phone triage tool will be used to predict a binary outcome two-weeks after discharge: needs further care or does not need further care. An independent physician blinded to triage tool outcome who will also render a determination on the same binary outcome, will examine those patients contacted by telephone. Physician assessment will be used as the gold standard to calibrate the model, which will be validated in a separate patient cohort.

Aim 3: Characterize the impact of timely follow-up on long-term disability and socioeconomic consequences associated with trauma in Cameroon.

Hypothesis: Trauma patients in need of post-hospitalization medical care will have improved disability outcomes if follow-up care is delivered promptly.

Patients will be given a modified Glasgow Outcomes Scale-Extended (GOSE) survey to complete at two weeks, one month, three months, and six months after hospitalization to quantify the death and disability associated with traumatic injury for each patient. Pre- and post-intervention results will be compared.

3. METHODOLOGY

Overall: The study has two linked data collection systems: the trauma registry and the mHealth triage tool. Aims 1, 2, and 3 will run concurrently.

3A. Aim 1

Study design:

Aim 1: Prospective Cohort Study

Aim 2: Stepped-wedge intervention, cross-validation of intervention (mHealth triage tool questionnaire) and in-person, blinded physician exam

Aim 3: Cohort study

Study Population: The study will be conducted at 4 hospitals (see below) that are part of an existing centralized trauma registry in Cameroon.

1. Laquintinie Hospital of Douala, (Littoral region)
2. Limbé Regional Hospital, (Southwest region)
3. Pouma Catholic Hospital, (Littoral region)
4. Edea Regional Hospital, (Littoral region)

Intervention: Telephone triage tool

The study will consist of a cohort study (Aim 1), and cross-validation of the triage tool (Aim 2) that will be implemented in a step-wedge fashion to assess preliminary outcomes (Aim 3). Data will be collected using a cell phone follow-up protocol for patients initially presenting for traumatic injury to 4 hospitals in Cameroon: 1) Laquintinie Hospital, a 710-bed governmental public tertiary hospital serving as a national referral center and a local catchment population of over 3,000,000, located in Cameroon's largest urban center; 2) Limbé Regional Referral Hospital, a 170-bed government public hospital serving a mixed urban/rural catchment region of approximately 130,000 people in the Southwest Region of Cameroon; 3) Pouma Catholic Hospital, a 120-bed mission hospital serving a largely rural catchment of 200,000 in the Centre Region of Cameroon; and 4) Edea Regional Referral Hospital. We have an ongoing trauma registry in all 4 facilities. Demographic and clinical data, including cell phone number, are collected on all patients who present to the hospital for injury regardless of severity or disposition. All patients "captured" by the trauma registry who are admitted to the hospital or transferred to an outside hospital for treatment of injury will be included.

Trauma Registry: Our collaboration has developed a multi-institutional trauma registry that gathers data on trauma patients presenting to 4 hospitals in diverse contexts: a large, urban tertiary center; a regional referral hospital serving a mixed urban-rural population; and a smaller mission hospital serving a largely rural population. Currently in Cameroon, there is no formal follow-up mechanism for trauma patients discharged from the hospital. Patients return for care when they think there is a problem, often in an extremely delayed fashion that precludes effective intervention.

Trauma Registry Eligibility: Patients presenting to the Emergency Department (in four hospitals in Cameroon) with traumatic injury, as defined by the WHO, are approached for inclusion. WHO in its 2004 Injury Surveillance Guidelines defines an injury as "the physical damage that results when a human body is suddenly or briefly subjected to intolerable levels of energy. It can be a bodily lesion resulting from acute exposure to energy in amounts that exceed the threshold of physiological tolerance, or it can be an impairment of function resulting from a lack of one or more vital elements (i.e. air, water, warmth), as in drowning, strangulation or freezing. The time between exposure to the energy and the

appearance of an injury is short. The energy causing an injury may be: mechanical (e.g. an impact with a moving or stationary object, such as a surface, knife or vehicle); radiant (e.g. a blinding light or a shock wave from an explosion); thermal (e.g. air or water that is too hot or too cold); electrical; chemical (e.g. a poison or an intoxicating or mind-altering substance such as alcohol or a drug). Injuries are the acute, physical conditions listed in Chapter XIX (Injury, poisoning, and certain other consequences of external causes) and Chapter XX (External causes of morbidity and mortality) in the International Statistical Classification of Diseases and Related Health Problems, Tenth revision (ICD-10)."

Patients satisfying the following inclusion criteria will be included in the registry:

1. Trauma patients who are formally admitted to the hospital as in-patients.
2. Trauma patients who die upon arriving to the Emergency Departments or while admitted in the hospital.
3. Trauma patients who are transferred to other health facilities.
4. Trauma patients with indications for hospital admission (based on physicians' assessments) but leave against medical advice
5. Trauma patients who are kept under observation in the Emergency Department for over 24 hours.

Exclusion Criteria: No patients are excluded based on age, gender, or injury severity. If patients or their surrogate decision-maker do not give consent to participation, those patients will be excluded. According to the WHO definition above, the following will be excluded from the definition of "injury": "Whereas the above definition of an injury includes drowning (lack of oxygen), hypothermia (lack of heat), strangulation (lack of oxygen), decompression sickness or "the bends" (excess nitrogen compounds) and poisonings (by toxic substances), it does NOT include conditions that result from continual stress, such as carpal tunnel syndrome, chronic back pain and poisoning due to infections. Mental disorders and chronic disability, although these may be eventual consequences of physical injury, are also excluded by the above definition." Patients who are not formally admitted and discharged within 24hours will be excluded.

Implementation/Data Collection: The trauma registry data are collected by a single trained research assistant in the emergency department of each hospital under the supervision of a field supervisor. Clinical staff verbally collect information on demographics, injury context, and mechanism from all traumatically injured subjects and/or an adult surrogate. They record this information on a paper trauma registry data collection form. Clinical staff also collect clinical data during patient care.

Each hospital's trained research assistants will then follow up with patients' progress to record complications, outcomes, and final disposition of patients during their time as an inpatient. They will collect trauma registry data collection forms daily from patient's hospital records and managing team and follow the hospital course of each patient that is admitted for further care. By participating in daily rounds, the research assistants will collect information on further treatment and outcomes, including complications and mortality. Research assistants will enter data into the encrypted, password-protected, online database hosted on REDCap ("Research Electronic Data Capture," which is a HIPAA-compliant, secure web application for building and managing online surveys and databases).

mHealth telephone triage tool: Our community-based survey found that 95% of respondents had access to a cell phone in their household. Cell phone numbers are also routinely collected as part of the multi-institutional trauma registry's patient demographic data. Pilot data from the 3-site trauma registry suggests that about 57% of urban and 70% of rural households have cellphone access, and 54% of patients overall were willing to provide cell phone numbers for healthcare follow-up after injury. Preliminary testing was done to identify the best method of calling participants that yields the highest response rate. To test the hypothesis that patient-initiated follow-up would vary by time from discharge, we retrospectively identified patients at 3 contact points post-discharge from the hospital (3, 6, and 12 months) and called them during the same 2-week period. During these calls, participants answered the Glasgow Outcomes Score Extended (GOSE) survey. In data collected for 331 patients, 64% of cell phone numbers provided were reached and 39% of subjects or families participated in surveys. Contact rates were slightly higher for patients contacted at 3 months post-discharge (68%) than for those contacted at 6 months (61%) and 1 year (58%), but survey completion rates at all 3 time points were similar. Call outcomes when surveys were not done included failure of the respondent to

know the patient (37%), phone disconnection (29%), and no answer (26%). There were no significant differences in the distribution of non-response by contact time-point.

Several lessons were learned through this preliminary experience. The call testing was done using an account set up through Skype to minimize charges, but this generated an unrecognizable call number viewed by the recipient, potentially deterring them from responding. To mitigate this barrier, we created a dedicated mobile phone account with a recognizable Cameroonian phone number. Additional measures to optimize response rates were also identified based on our local stakeholder feedback: 1) reassurance at the time of data collection that the phone number was not to be used by hospital financial personnel for pursuit of fee collection; 2) initial testing of mobile phone numbers at the time of data collection to ensure that they were accurate; 3) provision of the study cell phone number to patients so the number would be recognizable to them when called; and 4) guarantee of transfer of mobile credits to their phone at the end of each call to reimburse participants for time spent speaking with study staff. These changes will be implemented with the proposed study protocol. Our preliminary study yielded critical information to optimize our proposed study protocol, but response rates when patients are contacted in prospective, longitudinal fashion are unknown; we expect them to increase with implementation of modifications to rectify the challenges identified.

Triage Tool Development: Our extensive literature search for existing telephone-based follow-up triage tools for injured patients yielded no directly applicable studies conducted in LMIC settings. A few non-trauma related instruments were developed for HIC and LMIC settings. The one most relevant to our proposed project was a post-operative tool used to follow-up on elective surgery patients in an industrialized country setting. The lack of studies investigating mobile phone follow-up for trauma patients in LMICs led us to review mobile-based follow-up approaches in other fields of medicine and surgery in both HIC and LMIC. Based on this review, we generated a list of potential questions aimed at identifying post-injury individuals in need of further care and modified the questions to reflect relevance to the Cameroonian context. Potential questions were also solicited from local experts, including surgeons and physicians who take care of injured patients in Cameroon. All potential questions from both sources were compiled and reviewed by an expert panel of Cameroonian medical care providers. Redundant questions were combined and refined; ambiguous questions were revised. Any questions found to be non-essential or marginally contributory were removed. The resulting preliminary triage tool consisting of 7 questions (Figure 1) was then pre-tested for acceptability and understandability on a small group of hospitalized patients and family members. In preliminary testing, of 150 triaged patients, 20 (13%) tested as needing further care. The triage tool will be administered via mobile-phone by trained research assistants as described in Aim 2.

Table 1: Questions included in the mobile-phone based triage tool

#	Question	Answers
1	Is the patient currently alive?	☐ Yes ☐ No: Date of Death: _____* Stop interview
2	Since leaving the hospital how have they been feeling?	☐ Much better ☐ Somewhat better ☐ The same as when I left the hospital ☐ Sicker ☐ Much sicker
3	Have they been able return to usual daily activities?	☐ Yes ☐ They have returned to some activities, but they are harder and/or require extra help to do them ☐ No
4	Do they need daily help from another person to feed, clothe, bathe, and go to the toilet?	☐ Yes ☐ No
5	Since leaving the hospital have they had problems…	☐ Getting food or water? ☐ Taking medicines? ☐ Caring for your injury/wound as instructed?
6	Since leaving the hospital have any of the following things STARTED or GOTTEN WORSE?	☐ Fever ☐ Redness/Swelling of the injured part ☐ Pain ☐ Difficulty moving or feeling ☐ Drainage or opening of a wound/incision
7	Since leaving the hospital, have they seen another doctor or healer for the injury?	☐ No ☐ Considered seeking additional treatment ☐ Sought other care but no further treatment given ☐ Received additional treatment

APPROACH

Aim 1: Establish the feasibility of using mobile phones to follow up on hospitalized trauma patients after discharge in Cameroon. This aim will be addressed through a prospective cohort study following discharged trauma patients longitudinally over 6 months. The following data will be extracted from the existing trauma registry: patient demographics, clinical course, injury severity, disposition, and patient cell phone numbers. All admitted trauma patients who provided cell phone numbers in the emergency department will be contacted at intervals of 2 weeks and 1, 3, and 6 months post-discharge. Contact points at 2 weeks and 1 month correspond with traditional post-injury follow-up visits when intervention is theoretically likely to positively impact patient trajectory. These time points have also been used in prior mobile-health follow-up studies in traumatic brain injury and surgical patients in developed settings. Three and 6-month time points were selected because our preliminary data showed higher rates of disability and survey response at 3 and 6 months than at 12 months. Attempts will be made to contact patients at least 3 times by calling and once by text message over a 1-week interval at each time point.

Outcomes: number and proportion of successful attempts.

Sample Size: This overall study is powered for Aim 2 (see below), but the study population for Aim 2 will be used to calculate the number and proportion of successful attempts in Aim 1.

Data Analysis: Feasibility will be assessed through calculation of the number of successful contacts; number of attempts required to achieve success; cost associated with personnel and telephone time; reason for contact failure; and survey administration time. Frequencies and proportions of successful contacts will be calculated for each time interval and temporal trends will be described. Mean and standard deviation for personnel time and call cost will be used to calculate average cost per patient contact and determine the overall feasibility of cell phone interviewing as a follow-up method.

Aim 2: Cross-validate a telephone-based triage tool to identify trauma patients who would benefit from further medical care.

Study design: The 4 hospitals will start in a stepped wedge design the implementation of mHealth telephone triage tool (see Figure 1).

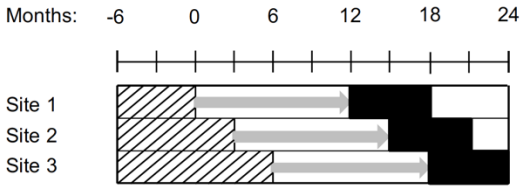

Figure 1: Step-wedge design of study. For each site: Diagonal lines depict aGOSE baseline data collection phase, gray arrows depict intervention phase (1 year/site), and black blocks depict follow-up phase (6 months/site).

Implementation/Data Collection: Patients contacted two weeks after discharge will be asked to give additional consent for participating in the triage tool part of the study. Those who consent will be contacted by research assistants and will answer 7-question survey. Patients whose responses trigger concern about the need for further medical attention will be informed that they should return to care and given appropriate instructions. All patients, regardless of triaged status, will be asked to schedule a time for a physical exam and will undergo one either at the hospital or in their place of residence. If patients return to the hospital, compensation for travel expenses will be provided on a sliding scale. This exam will occur within 1 week of the phone interview. Trained study physicians will conduct a structured, standardized exam that will ultimately culminate in a dichotomous outcome for "needs further care" or "does not need further care". Based on the exam, the physician will determine if the patient would benefit from further services (including additional follow-up care, diagnostic or therapeutic interventions). Additional data will be collected regarding physician opinion as to whether the patient is demonstrating on-trajectory recovery for their age, health status, and injury, and whether the patient is at high, moderate, or low risk for a poor outcome. At the 2-week and 6-month time points, all contacted patients will be asked about their satisfaction with formal medical services, post-injury follow-up care, perceived convenience, and utility of mobile telephone follow-up.

Primary Outcomes

mHealth triage tool score; physician exam determination for "needs further care" or "does not need further care".

Sample Size: The preliminary triage instrument has 13 variables derived from 7 questions. A minimum sample size of 10 participants per variable per potential model outcome (either needing further care or not needing care) is required to adequately power regression analysis. Our preliminary data suggests that physician exams leading to a recommendation for further care occur for 13.7% of calls. Conservatively estimating that 10% of contacted patients will require further care, a sample size of 1300 patients in the triage cohort will be targeted.

Data Analysis: Data from the prospective cohort will be divided into training and validation groups (70% and 30% of the overall cohort respectively). Stepwise multiple regression with bidirectional elimination will be used on the training group dataset to build the best model for predicting physician recommendation for further care (considered as a binary outcome). Survey questions that are found not to contribute significantly to prediction will be dropped from the final triage tool. The resultant model will be applied to data from the validation cohort. To establish predictive accuracy, we will assess calibration of the model by comparing the mean error between the predicted risk and actual physician response in this cohort. Receiver operating characteristic (ROC) curves will be calculated to evaluate the discrimination of the model. As the consequences of a false-positive survey leading to unnecessary patient follow-up are minimal, whereas false-negatives may result in poor health outcomes, risk cutoffs will target a highly sensitive test with minimal false negatives. Ratings of telephone follow-up acceptability will be aggregated and summarized.

Aim 3: Characterize the impact of timely follow-up on long-term disability and socioeconomic consequences associated with trauma in Cameroon.

Implementation/Data Collection: Injured patients who are successfully contacted at any of the study time points following hospital discharge will answer an over-the-phone survey to assess disability using an augmented GOSE (aGOSE) instrument, which is a metric of multi-domain functional status initially targeted for patients following neurologic trauma. It has since been validated in diverse geographic locations and in broader clinical contexts. Additional questions to evaluate economic consequences of injury will be added to the existing GOSE instrument. As our preliminary experience indicates that respondents are extremely reticent to speak directly about money over the phone, indirect measures of economic consequences will be emphasized (**Table**). Respondents will also be asked whether they sought further care for their injuries and if so, whether care was rendered. Six months before we begin using the telephone triage tool we will collect baseline data at all 4 facilities, after which the triage tool will be implemented in a stepped-wedge fashion in the 4 facilities, staggered by three months for each facility's start date. The cohort of patients (or their surrogates) who answer the triage survey will also be asked to answer the aGOSE, which will be administered at 2-weeks and at 1, 3, and 6 months. This design will let us compare intervention patients with historical controls, while controlling for temporal trends.

Table: Examples of indirect measures of economic consequences

1. Borrowing or selling household assets as a result of injury
2. Loss of household income as a result of the injury
3. Lost work by any member of the household as a result of the injury
4. Missed school by any member of the household as a result of the injury
5. Household food insecurity as a result of the injury
6. Any member of the household serving as a caregiver for the injured person.

Data Analysis:

As this study is powered for cross-validation of the triage tool, aim 3 is exploratory in nature and may not detect a difference in validated disability metrics between the intervention control cohorts. Therefore, process improvement indicators will serve as the primary outcome measures for this aim, and disability and economic outcomes will be secondary outcomes. These results will let us calculate effect size for future prospective validation of the triage tool. Summary measures of all outcomes will be calculated using medians and interquartile ranges for numeric and ordinal variables and proportions for binary and categorical variables. Outcome metrics will be stratified by hospital site, injury severity, age, and economic indicators at each time point. Trends in physical and economic disability will be assessed over time. Process outcomes, disability measures, and disability distributions will be compared between baseline and intervention cohorts using Kruskal-Wallis one-way analysis of variance for numerical and ordinal variables and chi-square tests for categorical variables. Univariate linear regression and multiple regression adjusting for age, gender, mechanism, injury severity, and hospital site will be used to assess triage-tool contact as a predictor of GOSE disability

level at 4 weeks, 3 months and 6 months after injury. Triage-tool contact will be evaluated for prediction of economic disability and presentation for follow-up care (both considered as binary variables) using univariate and adjusted multiple logistic regression.

Outcomes: Primary outcomes will include proportion of injured patients who seek clinical follow-up evaluation. Secondary outcomes will include GOSE disability level, work lost and other economic consequences of injury, such as spending savings and borrowing money.

INFORMED CONSENT

We have been collecting trauma registry data in Cameroon since 2008 in collaboration with the Ministry of Public Health. The protocol was reviewed and approved by the Cameroonian Ministry of Public Health, the National Ethics Review Committee in Cameroon, and the Institutional Review Board of the University of California, Los Angeles. Data collection is performed 24 hours per day and seven days per week. After obtaining patients' oral consent, trained staff at each of the four hospital sites collect all relevant information on trauma registry forms, which has a check box to ensure oral consent was given by the patients. At this time, trauma patients are also asked for household mobile phone numbers. If a trauma patient is a child under the age of 21, the mobile phone number of one of her/his parent(s) or guardian(s) is obtained. Where clinically possible, patients are reassured that mobile phone numbers, are being collected for research purposes only.

Two weeks after each trauma patient is discharged, the patient's household is contacted by trained research staff and invited to participate in the study. Consent for participation is obtained orally, over the phone. During this oral consent process, trained research assistants inform potential participants about the purpose of the research, the potential benefits and risks that are involved, and how potential risks are minimized. Potential participants are strongly encouraged to ask questions and have the research staff clarify any information that is not clear. If oral consent is received from the trauma patient or their caregiver the research assistant indicates this by checking a box on the triage tool. To consent to study participation, subjects or caregivers must be over the age of 21 and demonstrate understanding of the study. Households who decline consent are thanked for their time and no further contact is made. All households, regardless of consent status are offered the telephone number of the Cameroon-based Program Manager in the event that they have further questions or comments.

The request for consent as well as any study questionnaires is delivered in the subjects' primary language, either English or French. All research assistants are fluent in both English and French.

Data Management

Trauma Registry: Each hospital will require a securely locked, encrypted, password protected computer dedicated solely to trauma registry entry and management. Only the individual hospital trauma registry manager and trauma registry supervisor will have access to the computer. Each hospital will have a secure drop box in which trauma registry instruments may be placed by research personnel after completion. Only the trauma registrars and trauma registry supervisor will have access to the secure drop box. The supervisor will have an additional central locking file cabinet in which to store the retrieved trauma registry instruments after electronic conversion.

mHealth triage tool: Each follow up RA assigned to each hospital will have a securely locked, encrypted, password protected computer and mobile phone dedicated solely to data entry and management. Only the follow up RA and project manager will have access to this equipment. Each RA will have a secure cabinet to store completed paper instruments until transfer to the project manager. The project manager will have an additional central locking file cabinet in which to store the retrieved trauma registry instruments after electronic conversion.

All paper forms will be scanned and labeled appropriately on Box, and hard copy forms will be retained for 5 years before being shredded.

4. MONITORING AND QUALITY ASSURANCE

a) Real time Supervision of RAs/Study Staff

The Project Manager will supervise the activities of the mhealth follow up RAs. They will conduct biweekly checks on data collection and entry into REDCap to prevent data entry backlogs; routinely (at least monthly) retrieve completed paper forms from RAs and ensure secure storage at University of Buea Offices; Conduct biweekly checks on the scanning of paper forms for electronic storage on Box by RAs; perform biweekly data verification of 20% of project data by cross-referencing scanned paper forms with data entered on RedCap database.

The project manager will report to the study PIs and co-investigators during a standing weekly meeting. Study investigators will also conduct at least annual supervisory visits to study sites.

5. STUDY TIMELINE

Months	-6	-3	0	3	6	9	12	15	18	21	24
Site 1	•	•	x	x	x	-	-	-			
Site 2	•	•	•	x	x	x	-	-	-		
Site 3	•	•	•	•	x	x	x	-	-	-	
Site 4	•	•	•	•	•	x	x	x	-	-	-

• baseline data collection
X mHealth triage tool intervention phase
- follow up phase

6. SAFETY AND ETHICAL ASPECTS OF THE PROJECT

a) Potential Risks: The proposed research project poses a minimal risk to subjects who choose to participate, using the NIH definition of "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."
The potential risks of this study include:
(1) Unintentional disclosure of private health or identifying information. This risk is unlikely to occur. If an information breech were to occur the risk to the subject(s) would likely be minimal, although it is theoretically possible that physical or emotional harm could result from information disclosure.
(2) Physical or psychological distress from participation. Asking patients to recall the context and discuss the consequences of their injury may cause them some psychological stress, but this risk should be minimal.
(3) Time and financial loss while participating in follow-up surveys. Study involvement will require some time lost for survey completion, however the risk to the subject will be minimal as the surveys should not take more than 15 -20 mins to complete.

Private Health or Identifying Information:
Mobile phone numbers, names, and addresses will be collected as part of the trauma registry at the ten collaborating hospital sites in Cameroon. Data on patient symptoms and well-being will be collected from all subjects at timepoints post-discharge. Data on subject's physical and economic disability will also be collected during all follow-up timepoints (2 weeks, 1 month, 3 months, and 6 months). No additional individually identifiable private information will be specifically collected for the proposed research project.

b) Protections Against Risk

To protect and minimize against the unintentional disclosure of private health or identifying information: Patient data will be recorded on paper forms which will be stored in secure lock boxes at each of the hospital site for up to five years prior to local destruction. Trauma registry research assistants will enter data into the encrypted, password-protected, online database hosted on REDCap. All personnel with the potential to handle patient data (i.e. program manager, study investigators, field supervisors, RAs) will undergo standard protection of human data training and certification.

While the risk for physical and psychological discomfort are low, subjects will be informed that they are free to skip any survey questions that make them feel uncomfortable. To offset any financial risks that research participation will cause,

post-discharge trauma patients will be transferred mobile phone credits after any phone interviews conducted for the study. Subjects will be informed that their responses will be entered into an electronic database, which will be encrypted and password-protected. Subjects will also be informed that the data will be accessible only to research personnel.

It is highly unlikely that adverse effects will result directly from the study interventions. However, it is possible that during follow-up calls, patients may disclose information that suggests immediate need for medical or professional intervention. If subjects are suspected to have urgent medical or safety needs, research assistants will promptly report this information to the Cameroon-based Project Manager and Dr. Alain Chichom for adjudication. Where necessary, subjects will be re-contacted to urge them to seek medical care.

7. TRIALS AND SPONSORS MANAGEMENT

The trial is sponsored by the National Institute of Health. The Study investigators will oversee the safety of the trial to ensure that the trial is conducted to quality and safety standards.

8. ROLES OF INVESTIGATORS AND COLLABORATORS

The study PIs and co-investigators are responsible for ensuring study fidelity and making changes in study protocol as needed. Project managers and field supervisors are responsible for day to day supervision of data collection by research assistants and informing study investigators of any adverse events. Study PIs core will provide logistic support and oversight to ensure smooth running of study activities.

9. DISSEMINATION PLAN

Results from the study will be presented at conferences, in peer-reviewed journals, and will be discussed with the Cameroon MOPH on an ongoing basis through our team's partnership with the MOPH. Our partnership has regularly presented interim analyses, lessons learned, and final results and recommendations of our research to the MOPH in Cameroon, so we will continue to do this throughout this project on an annual (or more, if needed) basis.

10. LIMITATIONS

The proposed phone-based approach to improve post discharge care will not reach individuals without access to a phone (either their own or in their household); however, given high levels of cell phone penetration in Cameroon which continues to increase, this will represent a small proportion of patients. In addition, patients may be concerned about hospital contact if they perceive it to be related to billing; however, in our prior trauma registry research we developed enhanced patient education protocols to mitigate this possibility. Self-reported outcomes in Aim 3 will be verified with medical record review whenever possible; nevertheless, it may not be feasible for everyone.

The recruitment and retention of study subjects will be monitored by the study PIs on a quarterly basis. Every quarter, the project manager will prepare a written report presenting data —in aggregate and by hospital site—on: patient enrollment, comparison of target to actual enrollment, study subjects' demographics and overall status, and the retention of subjects in the study overtime. Additionally, the Cameroon-based project manager will provide information on any adverse events among study subjects or alert study investigators to subjects whose responses to the mhealth screening tool trigger concern. Following the review of these interim analysis reports, the PIs will (1) recommend any modifications that are required to enhance recruitment and retention of study participants and (2) determine whether it would be necessary to reconsider the study's design.

ADDENDUM:

A pilot phase was started in July 2019 with actual recruitment for the study commencing in August 2019. Baseline data was collected from August 2019 using the aGOSE survey till February 2020 when the intervention phase commenced at the first site. New patients' recruitment for aGOSE data was stopped in June 2021 with 6-month follow-up completed by December 2022-January 2023.

The study's original research strategy included 3 hospitals. During the time from notice of award to receipt of funding and initiation of study procedures, approximately 14 months elapsed. This delay was in part due to the US PI moving institutions from UCSF to UCLA. During that time, the Cameroon Trauma Registry (CTR) Expanded from 3 hospitals to 4. Correspondingly, the mHealth study was implemented in all four hospitals included in the CTR (as indicated in the final study protocol).

Under the parent award, the intervention (a telephone-based triage tool) and associated follow-up physician exams were designed to be implemented in a stepped-wedge fashion at partner hospital sites, staggered by three months for each facility's start date. This step-wedge study design would have enabled us to compare intervention patients with historical controls, while controlling for temporal trends. However, research delays and interruptions due to the suspension of data collection activities at the peak of the COVID-19 pandemic in 2020 (April – September 2020) led us to discontinue this approach to maximize patient recruitment for the cross-validation of our triage instrument. We abandoned our original step-wedge study design in the revised research plan as it was no longer feasible to implement under the remaining study timeline and would incur unacceptable delays at the potential expense of instrument validation.

Adhering to local and national guidelines in Cameroon, we temporarily suspended all follow-up physician exams of discharged trauma patients to prevent direct contact between patients and research staff, as well as to reduce patient exposure during travel. Consequently, we were forced to delay the implementation of our intervention (telephone-based triage tool) at all sites due to a lack of capacity to cross-validate triage results with physician assessments. Physician exams (Aim 2) had been initiated only one month prior to this suspension at our first partner hospital site in accordance with our step-wedge study design. We resumed all research activities in September 2020, after the Cameroonian Ministry of Public Health had established protocols for COVID-19 control and prevention in the workplace, and our team could reliably supply personal protective equipment for all research staff. Patient recruitment in our intervention cohort was thus delayed for a total period of six months. COVID-19 impacted patient recruitment and we applied for a 12-month funded supplement to enable us to accrue a sample size enough to validate our tool.

Supplement Sample Size Calculations Adjustment: Data collected from our prospective cohort will be divided into training and validation groups (70% and 30% of the overall cohort respectively). Our original sample size was calculated to account for a conservative prevalence of 10% of contacted patients needing further follow-up care. Based upon detecting a significant departure from 50% specificity, we estimate that we would require approximately 400 patients who are not recommended for follow-up care to be included in our validation sample. We will therefore target a sample size of 1330 trauma patients in our triage cohort. New multicenter preliminary data, however, suggest that physician exams leading to a recommendation for further care occur for 50% of contacted patients. This is a significant deviation from prior single-institution Cameroon pilot data that estimated 13.7% of contacted trauma patients would need further care. The inclusion of additional hospital sites that receive patients with more severe injuries as well as selection bias are likely contributing to this difference. If our preliminary findings remain consistent, we anticipate only requiring 220 patients not recommended for follow-up care to be included in our validation sample and 730 patients to be targeted in our triage cohort. Using a conservative estimate for our sample size calculation approach enables us to create a buffer and ensure our study is adequality powered to achieve statistical significance.

Triage tool was administered at 2 weeks with physician examination assessments from February 2020 till August 2022 (with the pauses noted above). Final 2 weeks follow-up was completed on September 14, 2022.