RESEARCH STUDY PROTOCOL

Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool

Version 5.0
October 19, 2020

Confidentiality statement

This document is confidential and is to be distributed for review only to investigators, potential investigators, consultants, study staff, applicable regulatory authorities, and applicable independent ethics committees or institutional review boards. The contents of this document shall not be disclosed to others without written authorization, unless it is necessary to obtain informed consent from potential study participants.

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Administrative Information

1. Title

Title: Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool

Lay Title: Development and testing of a digital tool for recognizing sick children

2. Protocol Version

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3. Funding

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c. Role of study sponsor and funders

The study sponsor and funders do not have a role in in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication. They will not have ultimate authority over any of these activities.

d. Collaborating organizations

1. The University of British Columbia
2. Centre for International Child Health
3. Kenya Medical Research Institute (KEMRI)
4. Walimu
5. Jinja Regional Hospital
6. Mbagathi County Hospital
7. Kiambu County Referral Hospital

Introduction

5. Background and Rationale

The global burden of pediatric mortality in low- and middle-income countries (LMICs) remains high, with 4.9 million deaths in children under 5 in 2016 [1]. Most of these deaths are due to sepsis, which is defined as the body's response to an infection (such as pneumonia, diarrhea, or malaria) leading to organ damage and ultimately morbidity and mortality [2]. Sepsis is common worldwide, but countries in Africa report substantially higher case fatality rates (adjusted odds ratios: Africa, 7.89 [95% confidence interval (CI), 6.02-10.32]) as compared to the United States [3]. Recognizing the enormity of the global burden of sepsis (death, disability, social, and economic) led to a 2017 World Health Assembly resolution highlighting the need to prioritize prevention, recognition, and early treatment of sepsis [4].

Sepsis disproportionately affects socioeconomically disadvantaged populations in LMICs. Encouragingly, most deaths from sepsis are preventable by early detection and treatment. The majority of deaths occurring in health facilities happen occur as a result of delayed, inadequate, or inappropriate treatment. Every hour of delay in therapy is associated with an escalating risk of morbidity and mortality [5]. Simple, highly effective interventions to treat sepsis, including antimicrobials and intravenous (IV) fluids, are available at care facilities in LMICs. Yet availability and readiness to provide treatment is not always enough [6]—timely treatment may not occur because the sickest children are not prioritized.

The World Health Organization (WHO) advocates the use of Emergency Triage Assessment and Treatment (ETAT) guidelines to triage children in resource limited settings [7]. Although the ETAT system is widely adopted in LMICs, successful implementation of the guidelines into clinical practice is not always the case [8]. In LMICs, patients are frequently admitted and treated on a first-come, first-serve basis, leading to delayed care for children who are in need of

urgent treatment. These priority children can receive faster treatment if every child is rapidly triaged upon arrival to identify danger and priority signs of sepsis [9]. However, sepsis is a syndrome that mimics many conditions and few health workers can confidently triage and diagnose sepsis. Evidence-based trigger tools and protocols may be useful in skilled hands, but require complex decision-making based on physiological, clinical, social, and laboratory parameters.

The purpose of this study is to develop a digital triage tool that can be used rapidly and reliably, without the need for extensive memorization or training, by frontline health workers (including nurses and non-physician clinicians) to identify critically ill children (including those with sepsis). The digital platform consists of a mobile application integrating a pulse oximetry sensor attached to this device, with embedded smart algorithms that predict a critically ill state, or level of risk (below) in a child presenting at the hospital. The platform also includes an interactive dashboard located in strategic locations (e.g., laboratory, consultation rooms), which connects to the mobile application through a secure local network and displays the triage data to provide real-time monitoring for the physicians who manage the patients.

Over the past 10 years, we have developed, implemented, and evaluated the core technology of the Digital Triaging Platform including vital sign measurement devices (PhoneOx [10] and RRate [11]) and the mobile application and dashboard [12][13][14]. We have already identified candidate predictor variables using a modified Delphi process [15], and developed a risk prediction model based on the need for admission using predictors collected in over 1000 children at a Kenyan hospital [16].

6. Objectives

Objective A: To develop and clinically validate a digital trigger tool and clinical dashboard for improving the hospital wait time to treatment administration in children with severe infections/suspected sepsis.

Breakdown

1. To collect a pre-selected list of clinical variables from participants and use the data to develop a prediction model based on the need for hospital admission.
2. To develop a digital triage tool by implementing the derived prediction model and triage guidelines used in the study hospitals into the Digital Triaging Platform.
3. To evaluate the usability/feasibility of the digital trigger tool prior to implementation in the study hospitals.
4. To clinically evaluate effectiveness of the triage tool by comparing hospital wait times to treatment for children before and after implementation of the digital triage tool.

Additional objectives due to the impact of COVID-19 at the study sites:

1. Develop data driven prediction models for identifying vulnerable children with suspected sepsis that are robust during future COVID-19 surges and novel pandemics.

2. Identify the variables that contribute to vulnerability in children with suspected sepsis, during pandemic and non-pandemic times.
3. Collect additional COVID-19 related prediction variables to inform understanding of the severity, risk factors, and clinical features of this disease at our three study sites (rural, urban and peri-urban).

Objective B: To validate the use of an automated Radio-Frequency Identification (RFID) method to track timeliness of interventions.

RFID tags will be small paper or plastic objects that can be attached to clothing or worn as a bracelet, anklet, or necklace (as preferred by child's caregiver) that use Bluetooth frequency band. The tag sends signals which allows tracking exactly where a patient is at a given time for analysis. For example, if a patient wearing an RFID tag enters a room, a reader in the room will detect the signal and add a timestamp for when patient was in the room. The Bluetooth frequency is no different to that used by mobile phones and is not expected to interfere with other processes in the hospital.

Objective C: To conduct an economic evaluation to contextualize our results for informing budgetary decisions of scaling-up Smart Triage.

7. Trial Design

This is a pre-post intervention study involving pediatric patients presenting to the study hospitals in seek of medical care for an acute illness. The study involves three phases: (I) Baseline Period, (II) Interphase Period, (III) Intervention Period.

Changes due to the impact of COVID-19:
Due to the impact of COVID-19 at our study sites, there will be an addition of a pandemic phase during Phase I. This will allow us to explore any differences that exist in a pandemic period compared to a non-pandemic period and develop data driven prediction models for identifying vulnerable children with suspected sepsis that are robust during future COVID-19 surges and novel pandemics.

	Phase I (3 months) Baseline Period: Pandemic Cohort	**Phase I (3 months) Baseline Period: Post-Pandemic Cohort**	**Phase II (1-3 months) Interphase Period**	**Phase III (5-6 months) Intervention Period**	**Analysis Period**
Site 1: Mbagathi				Routine use of digital triage tool	

County Hospital, Nairobi	Data collection on predictors and outcomes by study nurses.	Data collection on predictors and outcomes by study nurses.	Technology development and usability testing	by **hospital nurses.** Data collection continues as done in Phase I by **study nurses.**	Determine effectiveness of intervention, results presentation and dissemination.
Site 2: Jinja Regional Referral Hospital, Jinja					
Control Site: Kiambu County Hospital, Nairobi	Ongoing baseline data collection (12 months)				

Figure 1. Study Schema.

Updated Timeline due to COVID-19:

Phase:	**Baseline**	**Training**	**Intervention**	**Analysis**
Duration:	**6 months**	**1 month**	**6 months**	**11 months**
Site 1: Kenya	Delayed	Delayed	Delayed	Baseline data collection
Site 2: Jinja	Baseline data collection	Model development, usability testing, and training	Routine use of PRST and continued data collection	Statistical analysis and reporting of Results
Control: Kenya	Delayed			Baseline data collection
Additional Site: Gulu **U**ganda		Baseline data collection		Routine use of PRST

<u>Phase I (6 months)</u> will be a prospective observational cohort at Mbagathi County Hospital in Nairobi, Kenya, and Jinja Regional Referral Hospital in Jinja, Uganda. During this period, there will be no changes to healthcare delivery procedures in the study hospitals. Triage will continue to be performed by hospital staff using ETAT+ guidelines, the system that is currently in effect at the study hospitals [7]. Data collection will be undertaken in the triage waiting area. While participants are waiting for their turn to be seen by the **hospital triage nurses**, our trained **study nurses** will collect data on a pre-selected list of predictor variables (see Appendix A). These data will be used to develop a clinical prediction model based on the need for hospital admission.

Changes due to the impact of COVID-19:

We anticipate that the weekly number of admissions will return to baseline over the next 2-3 months. Therefore, Phase I will be split into baseline data collation during a pandemic period (first 3 months), and non-pandemic period (latter 3 months)

Control Site (Phase I, 12 months): Kiambu County Referral Hospital in Nairobi, Kenya will serve as the control site and no intervention will be implemented. At this site, Phase I will commence for a period of 12 months. There will be no Phase II or Phase III.

Phase II (1-3 months) will involve technology development, usability testing, and training.

Phase IIa: Technology Development. A risk prediction model will be derived using the data collected in Phase I and implemented in a Digital Triaging Platform, along with a digitized version of the ETAT+ guidelines. The Digital Triaging Platform, including vital sign measurement devices (PhoneOx [10] and RRate [11]) and the mobile application and clinical dashboard [12][13][14] has already been developed and evaluated. Once the digital triage tool has been developed, it will be evaluated in potential users using simulated patient scenarios and a 'Think Aloud' method.

Phase IIb: Usability Testing and Training.

Usability Testing Initiative
The digital triage tool will be evaluated for ease of interface navigation, functionality and basic workflow. A sample of 15 potential users in the study hospitals to represent the primary user groups will be selected for participation in the 60-minute-long usability testing initiatives. Participants will be recruited through word of mouth as there is a very small cadre of potential participants. The objective of the training is to (1) ensure healthcare workers understand how to correctly collect and interpret patient information, and (2) to obtain feedback on the digitization of the tool. Training will use a framework that meets key international norms for testing digital tools, including, the think-aloud method and a questionnaire.

Each training session will be conducted by a moderator and observer. During the evaluation, the observer will be seated next to the participant and will record user interaction with each interface, comments, errors, and duration of each task. Participants will be given 3-5 patient scenarios which will list hypothetical information to be entered into the app (see Appendix B). This information will be designed to represent routine data collected during triage examination at the study hospitals. The moderator will provide the fictional charts to participants and instruct them throughout the tasks. During the simulated patient scenarios, participants will be asked to think aloud, in order to assess their thought process as they used the app. Participants will be specifically instructed to comment on the layout of the app screen, the dialogue on each interface, the order of tasks, and any additional observations or opinions. After learning the basics of the digital platform, the participants will be read the think aloud instructions and asked

to perform the list of tasks and answer questions (see Appendix C). The observer will complete a checklist to ensure that all tasks were completed, questions will be asked to evaluate task comprehension, and notes will be taken about whether help was needed in completing each task. At the end of the training session, participants will complete a triage tool training questionnaire (Appendix D) to provide an understanding of the practical benefits and drawbacks of incorporating the digital triage tool into a clinical context. The questionnaire will utilize open ended questions and comment responses. from this evaluation. Responses from the survey will be anonymous. The data generated from the training phase is fictitious and will not be linked to any individual subject. In light of ongoing physical restrictions due to COVID-19, the sessions will be recorded digitally with multiple audio and video feeds of each usability session. The session will record (1) the participant's screen from within the software using screen capture technology (video only); (2) the participant physically using the digital tool (video only); (3) the participant's reactions and comments towards the digital tool (audio and video).

Interviews

After the digital triage tool has undergone usability testing and updates, and has been implemented in the study hospitals, a one-week pilot period will take place. At the end of this period, healthcare workers and hospital staff will be invited to participate in an interview to allow evaluation of the acceptability, usability, and feasibility of the digital triage tool in the context of the hospital. A total of 30 staff, including clinicians, doctors, nurses, and administrators, will be selected to participate in focus group discussions and one-on-one interviews. Interviews will take place after the pilot phase, and periodically throughout the interventional phase (Phase III) to capture experiences and feedback from hospital staff throughout the course of the study. Interviews may be conducted either in person in a private room on site at the hospital, or, in consideration of personal safety and ongoing physical distancing restrictions due to COVID-19, through a secure digital conferencing software. Interviews will be facilitated by one interviewer and recorded digitally with an audio recorder. Interviews will last approximately 60 minutes, during which the interviewer will ask the interviewees series of questions from a semi-structured interview guide (Appendix E).

Transcriptions, Think Aloud observations, and interview recordings will be analyzed using the Framework Method [17] to assess attitudes of health workers. Responses will be transcribed and coded using NVivo [18], for the identification, examination and interpretation of emerging themes and patterns. Results from the analysis, feedback from the questionnaires, and comments on the observer checklists will be used to generate a report with suggested improvements to be shared with the quality improvement implementation team prior to Phase III.

Phase III (3-6 months) will be an interventional period involving routine use of the digital triage tool by the hospital triage nurses at Mbagathi County Hospital in Nairobi, Kenya, and Jinja Regional Referral Hospital in Jinja, Uganda. The digital triage tool will not replace triage policies already in place at the study hospitals, but rather it will supplement and strengthen existing triage systems. As done in Phase I, **study nurses** will collect data on the pre-selected list of predictor variables in the triage waiting area while participants are waiting to be seen by **the**

hospital triage nurses (who will be using the digital triage tool). Continued collection of predictor variables will allow comparison of participant characteristics in the pre-intervention cohort and the post-intervention cohort.

Methods: Participants, Interventions, and Outcomes

8. Study Setting

Involved in Phase I, Phase II, and Phase III:

1. **Experimental Site #1:** Jinja Regional Referral Hospital in Jinja, Uganda

Jinja, a city of approximately 90,000 people, is located in the Eastern region of Uganda. The Jinja Regional Referral Hospital pediatrics ward admits approximately 5000 patients per year and the outpatient department sees approximately 100 patients per day.

2. **Experimental Site #2:** Mbagathi County Hospital in Nairobi, Kenya

Involved in Phase I only:

3. **Control Site:** Kiambu County Referral Hospital in Nairobi, Kenya

A typical outpatient department (OPD) in the Kenyan study hospitals serves approximately 20,000 children per year and is staffed by one or two nurses who conduct triage and administer treatment, two or three clinicians who review patients and issue prescriptions, and one additional nurse who administers treatment and provides counselling to caregivers of children. The hospitals admit approximately 2,000 pediatric patients per year.

Changes due to COVID-19

The global COVID-19 has introduced many challenges to the successful completion of this project. We have been unable to initiate Phase I of the project in Nairobi, Kenya due to restrictions implemented to reduce the risk of spread of COVID-19. We have made good progress in recruitment in Jinja, Uganda. I consultation with our investigators, implementation partners and funders we have decided to add an additional site at Gulu Regional Hospital in Uganda. Gulu Regional Referral Hospital will serve as a control site while the intervention phase (Phase III) takes place at Jinja Regional Referral Hospital. Once the intervention period has been completed in Jinja, the intervention will be introduced at Gulu Regional Referral Hospital.

9. Eligibility Criteria

Inclusion Criteria:

1. All paediatric outpatients presenting to the study hospitals for medical treatment. The lower age limit will include children aged from 0 days, and the upper age limit will be in accordance to respective hospitals' practice for paediatric admissions (this may be 12, 15 or 19 years).
2. Informed parental/guardian consent provided.
3. Assent from children older than 13 years in addition to parental/guardian consent provided.

Exclusion Criteria:

1. Patients presenting to the outpatient department for elective cases (e.g. elective surgery or change of dressing) or for clinical review appointment.

10. Intervention

This is a pre-post intervention study to develop and evaluate the effectiveness of a digital triage tool. Prior to the intervention period, hospital nurses will be trained and prepared for routine use of the digital triage tool. Patients who enroll in the study during the intervention period will be triaged by the hospital nurses who will be using the digital triage tool. The digital platform will consist of a mobile application hosted on an Android tablet integrating a pulse oximetry sensor attached to the tablet, with embedded smart algorithms that predict a critically ill state, or level of risk in a child presenting to the hospital. The platform will also include an interactive dashboard which will display the triage data to provide real-time monitoring for the clinicians who manage the patients. The dashboard will be implemented as a password protected website accessible by registered medical staff on any computer or tablet on the local network, allowing for easy and non-disruptive integration into health systems with existing electronic health records. ETAT+ criteria for triage will be incorporated as part of the digital platform (in addition to model identified from Phase I).

11. Outcomes

Primary Outcomes

1. **Model Development:** Hospital admission (within 5 days of assessment) status determined from hospital records and information system, and a follow up call 7 days post discharge (to ascertain outcome). This will inform development of a clinical prediction model based on need for hospital admission.

2. **Effectiveness Evaluation of Digital Triage Tool:** Time to administration of an appropriate sepsis bundle of care, which includes at least one of antibiotics, intravenous

fluids, or oxygen as appropriate for age and clinical syndrome (treatment determined and administered by **hospital staff**). This will allow us to quantify the change from baseline in the proportion of children in each triage category (emergency, priority, queue) receiving treatment within 60 minutes of arrival at hospital.

Secondary Outcomes

1. Length of hospitalization determined from hospital records, and a follow up call 7 days post-discharge.
2. Final diagnosis determined from hospital records.
3. 7-day post-discharge mortality status determined from a follow up call 7 days post-discharge.
4. 7-day readmission status determined from a follow up call 7 days post-discharge.
    a. Facility of readmission.
    b. Treatment received during readmission.

12. Participant Involvement

Total study participation time is estimated to be a maximum of 60 minutes per participant in both the baseline (Phase I) and intervention (Phase III) periods.

Participant Involvement in Phase I and Phase III
Potential participants will be recruited by study nurses while they are waiting in line to be seen by the hospital triage nurses. Participants can anticipate study procedures (including consent, clinical examination, and interview) to take between 35 to 50 minutes. The **study nurses** will conduct study procedures in the triage waiting area, while the participant is waiting in line to be seen by the **hospital triage nurses.** If it is the participant's turn to be seen by the hospital triage nurses, study procedures will stop and there will be no interference or delays in accessing standard care. Participants will also engage in a short (10 minutes) follow up call 7-days post-discharge.

Additional Procedures in Phase III
In the intervention period, the **hospital triage nurses** will be conducting triage using the digital triage tool (which will include a digitized version of the triage guidelines in place at the study hospitals). Since our mobile health intervention will be integrated into standard care (**NOT replacing standard care**, but supplementing and strengthening existing triage systems), this will not require any additional time costs.

To reiterate, the **study nurses** will conduct the same study procedures (consent, clinical examination, and interview) in both the baseline (Phase I) and intervention (Phase III) periods. These procedures are conducted while the participants are waiting in line to be seen by the hospital triage nurses. The difference in Phase III is that the **hospital triage nurses** (that the participants are waiting in line to see) will be using the digital triage tool to triage participants.

13. Sample Size

Model Development Considerations
The sample size for model development is based on a sampling strategy that takes into account the number of predictor variables (either binary or continuous) to be used in a model which has been used in a similar study [13]. This accounts for a minimum standard of 10 events per effective variable and can be expressed mathematically as: N = [n x 10]/I, which demonstrates the relationship between the number of predictor variables (n), the event rate (I), and the required sample size (N). Our previous experience that allowed for a minimum of 10 events per selected variable (admission rate of 12% and 10 predictors) would estimate a sample of at least 833 children. The sample size needed to detect a 20% increase in the proportion of children who receive the bundle of care within one hour was calculated using the stats package in R.

Power to Detect Difference Considerations
We have estimated the proportion of children who currently receive a bundle of care within one hour in the pre-intervention group to be 27%, based on findings from previous studies [19] and confirmed in our feasibility trial of the application and dashboard in Uganda. We will need at least 750 children for each of the pre-intervention and post-intervention conditions, using an alpha of .05, at power of 80%, to detect a 20% decrease in the proportion of children who receive the bundle of care within one hour.

Selected Sample size
Based on the uncertainty commonly present in these smaller sample sizes [20], the desire to include the possibly of modelling non-linearities in our models (using machine learning methods) and the clinical feasibility (large case load) we plan to target a larger sample of 4000 at each site, with a minimum sample size of 1000 participants enrolled in Phase I. Based on the activity at our selected sites this would require no more than a 60% recruitment rate during a six-month period.

Changes due to the impact of COVID-19:
We hypothesize that the case mix of the "pandemic period" cohort is likely to be different to the case mix seen during "non-pandemic" times. This includes a potential increase in the average severity of disease in those children presenting at the facility. We are requesting support for the addition of a pandemic phase in Phase 1 – the baseline observational component of PRST. This will include a 25% increase in sample size at each experimental site (250 additional participants per experimental site). This increase in sample size is critical to developing a risk stratification model that is robust during pandemic and non-pandemic times.

14. Sampling and Recruitment Strategies

A systematic method for enrollment based on order of arrival at pre-selected time cut-offs will be adopted to avoid bias in participant selection by the study nurses. Patient arriving at the

outpatient are given a number upon registration (unless they are emergency cases that require resuscitation) and this number will be used to systematically sample patients during periods of busy workload.

A timekeeper will the record arrival time and sampling number for each patient in a notebook. When it is time to select a participant, the study nurse will report to the timekeeper, who will provide the sampling number of the first participant to arrive after the pre-selected time cut off. The study nurse will then approach and screen this patient. If the patient does not consent, the study nurse will move on to the second participant to arrive after the pre-selected time cut off, and so on.

The interval between time cut-offs will correspond to the estimated time taken for a study nurse to consent and collect data from a participant (35-50 minutes) to maximize productivity. When there is more than one study nurse on a given shift, the time intervals will be staggered.

Methods: Data Collection, Management, and Analysis

15. Data Collection

Predictors, Hospital Outcomes, 7-day Follow-up Calls
All study nurses will be trained and well versed on the standard operating procedures to facilitate standardization of all measurements. Study nurses will collect data using a custom-built Android application on a Samsung Galaxy Tablet A8. The list of predictors to be collected include clinical signs and symptoms, demographic/sociodemographic data, and pregnancy/birth information (see Appendix A). Similarly, designated study nurses will obtain hospital outcomes (see Appendix A) from patient records and enter them into the application on the Samsung Galaxy Tablet. Study nurses will conduct 7-day follow up calls in accordance with the standard operating procedures and enter the data into the application on the Samsung Galaxy Tablet.

Time Outcomes
Timing tracking will be automated using customised RFID. RFID uses radio-frequency electromagnetic fields to identify the location of patients carrying special tags, with the help of readers located in key locations around the hospital, including the registration area, triage examination rooms, and treatment rooms. We intend to use Low Energy Bluetooth (BLE) tags that have a diameter of approximately 3cm and weigh <20g (see Figure 1). These tags will be inserted into a custom, washable arm, wrist or leg band. The tag could also be retained by the caregiver if the child was not willing to have the tag attached to them. When in close vicinity to a reader (for example, in the same room), the tag (location beacon) sends a message to a strategically located receiver to track the time at which the patient was in that precise location. Initially, manual tracking will also be conducted by designated study staff who will be situated in the same key locations as the RFID readers in order to validate the RFID system and ensure optimal performance.

Figure 1: Picture of RFID patient tracking tag

Usability Testing Data
Think Aloud transcriptions and observer checklists will be entered into a computer and uploaded to REDCap. The Triage Tool Training Questionnaire (Appendix D) will be captured on paper and stored in a locked cabinet, in a locked room in our research spaces nearby the study sites.

Hospital Staff Interviews
Throughout Phase III of the study, healthcare workers and hospital staff will be invited to participate in an interview to allow for evaluation of the acceptability, usability, and feasibility of the digital triage tool in the context of the hospital. (Appendix E). This will be used to generate a report that provides insight on the overall perception of health worker's experiences with the digital triage tool and make updates as necessary.

16. Data Management

Data Collection Infrastructure
Study Nurses will collect data using a custom-built Android application, created using LambdaNative (lambdanative.org), the open-source cross-platform toolkit developed internally at BC Children's Hospital Research institute. All data entered into the mobile application is stored in an encrypted database using the encryption cipher Rabbit. Access to the tablet and application is secured by passwords; without using the application, the encrypted files are not readable. The Masimo iSpO2® Pulse Oximeter with Micro USB Connector will be used to collect pulse oximetry and heart rate (including 30 seconds of raw plethysmographic data) and the Masimo Caregiver™ non-contact thermometer will be used to measure core temperature. The data collection application also contains complex error checking specific to the survey questions such as date inconsistency checks and ensures only relevant data items are collected, by dynamically hiding redundant questions.

Due to the complex nature of a large multi-center study, data will be uploaded directly from the Android tablets to REDCap (Research Electronic Data Capture, https://projectredcap.org/). REDCap is a secure web-based application designed to support data capture for research studies and it has been used for over 300,000 projects, in over 100 countries, including prior studies in Uganda [17]. Encrypted data will be stored for less than 14 days after completion of data collection on the tablets. In Kenya, the data will be directly uploaded weekly (depending on internet availability) over a secured internet connection to KTWRP servers, where it will be stored. A deidentified copy will be sent to the central study server at the BC Children's Hospital Research institute where data will be checked for completeness and consistency with data definitions. In Uganda, the data will be sent to the central study server at the BC Children's

Hospital Research Institute. After this upload, the data on the tablets will be deleted. Each subject will be given a unique number and all data will be connected to this unique number. Using REDCap limits the amount of paper-based data, further ensuring data integrity and safety. The uploaded data will be accessible to only study team members with secure access to the server.

Data collected during follow-up interviews conducted by phone or in person will also be collected electronically and shared in the same secured manner. Personal identifiers are required for the collection of admission data and follow-up data. The data collection application contains several forms. All identifiers are collected on a single form, separate from the other forms containing non-identifying information, and stored in a separate and restricted REDCap form. Access to identifiers will be limited to those requiring this data for follow-up (i.e. only study personnel involved in follow-up or data verification). No analysts, co-investigators or principal investigators not directly involved in the follow-up or data verification will have access to this data. Access to REDCap will require 2-way authentication: in addition to the normal password process, a secure code (sent via SMS to the user) will be required for access to this data.

Paper based data collection items include consent forms and research assistant field notes (which do not contain identifiers). These will be stored in a locked cabinet, in a locked at our research spaces next to each study site.

Health Intervention Infrastructure

The bundle of care during the intervention will include triage in the OPD using an additional custom Android web-app, running locally on the device with no required Internet connection. As with the data collection app, this application will be password protected and data will be stored encrypted on the device. Following each triage, the triage data will be sent to a local low-cost Unix server Soekris box based in a secure room at each site. Data will be sent through encrypted HTTPS requests to server-side PHP scripts, which insert it within MySQL tables.

The clinician dashboard that will be used to clinically manage all children in the OPD who have been triaged will be implemented as a password protected website accessible by registered medical staff on any computer or tablet on the local network. As with the triage app, this website runs completely locally, independent of an outside Internet connection and is not accessible from off-site. The dashboard is implemented using the Laravel (https://laravel.com), a PHP web framework, which queries the MySQL server tables securely. Personal identifiers will be collected in the triage app and sent to the server for display on the dashboard as is necessary for correct identification of patients, but such information will never leave the hospital site. As the study hospitals already have computers in their OPDs, use of the clinical dashboard will not be extra work for the hospital staff or interfere with other tasks.

17. Statistical Analysis

Model Development

We will develop a logistic model that will predict severe infection and sepsis in children. Akaike's Information Criterion (AIC) will be used as a summary measure to select predictors for inclusion in the model. The final selection of a model will be judged on model parsimony, availability of the predictors (with respect to resources and cost), discrimination and calibration. Bootstrapping (with replacement) will be used for internal validation. Net Reclassification Index for external (Kenya) and geographical/high malaria prevalence (Jinja) will be used for validation of the prediction model. These cohorts will allow us to optimize and re-calibrate (if required) the prediction model. Appropriate triage risk threshold selected based on data, simulation and expert opinion. The final model will be integrated into an application for use on a mobile device and electronic dashboard.

Outcomes Analysis

We will compare the proportion of children at the two intervention sites receiving a completed bundle within 60 minutes to the historical and the contemporaneous control group (Marascuillo procedure). The median time to an appropriate bundle of care will be compared using a Mann–Whitney U test. The triage prioritization between the phases and the proportion of children who received and appropriate bundle of care within each triage categorization will be compared with Fisher's exact tests. Segmented regression analysis of the interrupted time series of the pre- and post- intervention periods will be used to assess immediate effects and effects over time, controlling for prior trends that may continue without our intervention. Quantile regression will be used to estimate the median differences. We will compare the estimated times at end of the intervention period with the expected counterfactual value, had the pre-intervention trend continued as if the intervention never occurred. We will compare the time to event (treatment bundle) using the Kaplan-Meier estimator with censure at 180 minutes. Secondary outcomes will be compared using generalized estimating equations.

Additional Analyses due to the impact of COVID-19:

Develop data driven prediction models for identifying vulnerable children with suspected sepsis that are robust during future COVID-19 surges and novel pandemics.

We will specifically look at the predictive performance of the model during this initial pandemic period (2-3 months) in comparison to following non-pandemic period. We will use traditional statistical modeling techniques (e.g. logistic regression) and data-driven algorithms (e.g. elastic net and random forest) to identify new predictors and calibrate existing predictors, exploring possible interactions between periods. We will validate the model using test sets that include both post-and during-pandemic data in order to ensure that any newly derived model performs consistently during both periods. Performance of prediction models will rely on area under receiver operating characteristics, and specificity corresponding to 80% sensitivity. Our goal is to develop a model for identifying those most at risk for sepsis that performs well despite changes in case mix of our cohort, even if this slightly degrades overall prediction performance. This will ensure that the final model will be more robust to future changes in case mix during future health crises.

Identify the variables that contribute to vulnerability in children with suspected sepsis, during pandemic and non-pandemic times.

We will use descriptive statistics and standard statistical tests to compare the clinical, demographic and social factors of the pre-pandemic and pandemic cohorts. These include important identity factors such as gender, age, economic indicators, and geography. Multivariate models such as clustering algorithms and Principal Component Analysis will be used to further understand if and how the pre-and during-pandemic cohorts separate and differ.

Economic Evaluation

We will conduct a cost-effectiveness analysis of Smart Triage by calculating the cost per averted year of life lost (YLL) using decision analysis. Previous models (21) and expert opinion has been consulted for potential pathways of healthcare utilization. We will model uncertainty using probabilistic sensitivity analysis and will take a societal perspective as our base case.

Probabilities of healthcare utilization will be calculated via primary data from the Smart Triage case report form. The primary outcome of "time to bundle of care" will be linked to mortality via existing evidence (22) as required in order to calculate YLL, as Smart Triage was not originally powered to detect mortality. We will use the World Health Organization's life expectancy data in Uganda (23) to calculate projected YLL before and after program implementation. Costs of healthcare utilization is available through existing literature (21, 24), and indirect costs due to lost wages will be gathered as primary data in Smart Triage. Costs of program setup and maintenance will be tracked from study expenses and incorporated into the analysis.

To contextualize our results for informing budgetary decisions of scaling-up Smart Triage, we will estimate a projected budget impact of scale up given the disease burden of pediatric sepsis in Uganda (25), as recommended for newly proposed healthcare programs (26). The results of this preliminary budget impact analysis can be refined in further multicenter trials and can be compared to that of other programs to facilitate healthcare resource allocation in Uganda.

Methods: Monitoring

18. Data Monitoring

Internal monitoring of study processes will be done regularly by the Study Coordinators at each hospital site. During monitoring, data and consent forms for 10% of enrolled participants will be reviewed for compliance. Retraining of study staff will be done to correct for any inconsistencies noted during monitoring and follow-up will be subsequently done by the Study Coordinator to ensure compliance.

Data completeness will be continuously monitored using daily, weekly and monthly reports. Accuracy of data will be verified using an audit of 5% of cases by a Data Manager who will not be involved in enrolling subjects. Preliminary data quality checks and analysis will be performed throughout the data collection stage to ensure that data collected is valid and secure. These data quality checks will include checking the quality of pulse oximetry waveform data via implementing a Signal Quality Index (SQI) algorithm and checking for completeness and validity of input data. Further data quality checks will inspect the number of patients enrolled, the number of patients admitted, and the timed outcome data. Upon completion of data collection, a summary of the data collected will be compiled and will be discussed by the investigators and the study nurses to ensure that data is clean, correct and useful.

19. Harms

We do not anticipate any adverse events directly attributable to the study. The most significant risk in this study is a small delay in treatment administration due to incorrect triage by the digital triage tool. However, this delay would not be significantly different from the hospital standard of care. The risk of an adverse event is unlikely because our digital health intervention will only be used to triage participants, and all subjects will be assessed by a healthcare provider regardless of triage status.

All children enrolled into this study will receive standard care according to local, regional and national guidelines. No study procedures will take place which in any way interfere with the prescribed care. Study procedures will be delayed, when necessary, to ensure that these procedures will not impact recommended care.

Ethics and Dissemination

20. Research Ethics Approval/Protocol Amendments

Ethical approval will be sought from Makerere University School of Public Health (MUSPH) Higher Degrees, Research and Ethics Committee. Ethical approval will also be obtained from from the Kenya Medical Research Institute (KEMRI) Scientific & Ethics Review Unit (SERU), and from The University of British Columbia/ Children's and Women's Health Centre of British Columbia Research Ethics Board (UBC C&W REB). A copy of the protocol proposed informed consent forms, other written participation information, and any proposed advertising material will be submitted for written approval. The investigators will submit and, where necessary,

obtain approval from the IRB/IEC for any major protocol amendments and changes to the informed consent document. The study team are responsible for assuring that this protocol and the associated informed consent documents and study-related documents are approved prior to implementation of the protocol. Any major amendments to the protocol, informed consents, or other study- related documents must be approved by the IRB/IEC prior to implementation.

21. Informed Consent and Assent

The study nurses will be responsible for screening and consenting participants. This would be the norm in Kenya and Uganda. The Study Nurses will be certified and trained to ensure that the caregiver has a complete understanding of the consent processes, the consent form, and that the caregiver is of legal age and competent to provide consent.

In obtaining and documenting informed consent, the site investigators and their designees will comply with applicable local and domestic regulatory requirements. This clinical study will have a paper-based informed consent form (ICF) for enrollment developed for local use that are in accordance with applicable guidelines. The consent form will include the purpose of the study, a description of the procedures to be followed and the risks and benefits of participation. The informed consent process will give individuals all of the relevant information they need to decide whether to participate, or to continue participation, in this study. Potential research participants' caregivers will be encouraged to ask questions and to exchange information freely with the study team. Participants will be informed on who to contact (Principal Investigator) should they have any questions during, or after the study period. If the caregiver providing consent is illiterate, an independent witness will be present to verify to the caregiver that all the information read aloud is contained in the ICF. In this instance, both the caregiver and witness will sign the ICF. The caregiver will voluntarily sign, thumbprint and date (thumbprint acceptable if illiterate who will also require a witness) the consent form if they wish to participate in the study and will be provided with a copy of the consent form. A signed and dated copy of the consent form will be kept in the documentation file at all times.

In emergency cases, consent will be deferred until the child is stable and study procedures will only begin after initiation of emergency treatment. Study procedures will not delay or interfere with access to standard care. If consent is not granted, the data will be deleted. This deferred consent procedure is to avoid introduction of bias by neglecting to obtain data from the most severely ill children while avoiding delays in providing care to the child. This procedure has been used in previous studies involving children with severe illness, including use by the Fluid Expansion As Supportive Therapy (FEAST) study [27].

There will be separate consent forms for Phase I (Appendix F) and Phase III (Appendix G). Assent will be sought for children aged 13 and older (Appendix H). Consent will also be sought for participation in usability testing initiatives (Appendix I), the Triage Tool Training Questionnaire (Appendix J), and the Hospital staff Interviews (Appendix K). In addition, there will be separate consent forms for Kenya and Uganda as site specific guidelines differ (see

Appendices F to K). All consent materials will be approved by the appropriate Institutional Review Boards prior to use.

22. Confidentiality

Data will be stored and distributed using password protected locations and secure data transfer. All data entered into the digital triage tool is stored in an encrypted database using the encryption cipher Rabbit. Access to the digital tool is secured by passwords and without using the application, the encrypted files are not readable. Encrypted data will be stored for a maximum of two weeks on the tablets before being directly uploaded and stored stored in a secure research server at MUSPH (Uganda), or KEMRI (Kenya), and UBC. After this upload, the data on the devices will be deleted. Data will be entered into the digital triage tool using a REDCap electronic data collection form. REDCap is a secure, web-based application designed to support data capture for research studies. Each subject will be given a unique number and data will be connected to this unique number. Using REDCap limits the amount of paper-based data; further ensuring data integrity and safety. The uploaded data will be accessible to any team member with secure access to the server, including investigators from MUSPH, KEMRI, and UBC. Standard operating procedures will be implemented for the security of data, physical devices and networks. All research staff will be well trained and understand that privacy and confidentiality are imperative. All paper forms used for consent will not contain the study number. These forms will be stored in our research spaces near the study sites under lock and key, for the duration of the study and for any additional time required by the local and/or national guidelines at the time.

23. Risks

Altered medical management
The most significant risk in this study is a small delay in administration of treatment due to inappropriate triage. This delay should not be significantly different from the baseline standard of care. The study process will be optimised to minimise the delay in the delivery of care and will be deferred in participants who require emergency treatment.

RFID Tagging
The RFID tag is a new and unfamiliar piece of technology that needs to be worn or attached to participants who may not feel comfortable with it. We will ensure that participants/caregivers are fully aware of the purpose of wearing the RFID tag and how the system works. Further, the tag is a tiny piece of plastic that can be easily concealed and will not cause any discomfort to participants. This has been discussed with our local PI's and local ethics committees in Kenya and Uganda. This has been approved by both the local and national ethics committees.

Blood Sampling

Blood sampling will only be conducted when clinically indicated are already routine hospital procedures. We will be ensuring the supplies are available to do this testing if indicated. These will not be done for research purposes. These will be communicated by the consultant during the consultation that follows the triage process. These are all point of care tests so results will be immediately available.

Coercion
Caregivers may feel coerced to enroll in the study in order to receive care for their child within a research setting, which may be perceived as of a higher quality than the standard of care. This will be minimized by ensuring that study nurses emphasize that the child will receive medical care whether enrolled in the study or not.

24. Declaration of Interests

There are no competing interests for any investigators involved in this study.

25. Access to Data

After the study period, a de-identified copy of the data will be prepared for deposition in a repository with open access with proper governance mechanisms. We will make every effort to prevent re-identification of subjects by coding data that has the potential of being identifiable. For example, we will convert all dates into meaningful decimal numbers (date of birth into days since birth and date of recruitment will be reduced to month of recruitment) and all locations will coded into data that is useful but not specific (such as address converted to distance and direction from facility). We will ensure that data elements with small numbers of subjects (less than 10) will be coded or lumped to avoid identification. The de-identified study data will be made publicly available using the Harvard Dataverse (https://dataverse.harvard.edu/), which is the data repository for KWTRP, and a URL will be made accessible. To enhance visibility, sharing and collating datasets with other collaborating sites for increased usability/re-use, de-identified will also be shared availed to reputable data hosting service such as the INDEPTH Data Repository (http://www.indepth-ishare.org/index.php/home), or through the newly established Pediatric Sepsis CoLab (sponsored by the World Federation of Pediatric Critical and Intensive care Societies). Sharing and access will be managed and subject to institutional agreements (KEMRI and UBC) that will set terms for how requests and access will be managed. We will ensure that a rigorous data governance structure is used by the data hosting service. The distribution will only occur with agreement from Principal Investigators and the investigators at all of the study sites. Data will also be shared through peer reviewed publications and through the Wellcome Trust open data initiatives. Data will be made available within 12 months following completion of the study.

26. Presentation and Dissemination of Results

Presenting the Results

The results of this research will be primarily presented through at least one published manuscript with detailed description of the background, methods, results, and conclusion. The specific format and details of this manuscript will be in accordance with the requirements of the publishing journal. All usage of data for publications and other forms of data dissemination will occur jointly between collaborative institutions and include authors from both sites in all publications.

Disseminating the Results

Results will be disseminated to local hospital teams and key stakeholders such as at the annual conference held by the Kenya Pediatric Association (KPA). A robust knowledge translation approach is a key aspect of our transition and scale-up. An integrated equity-oriented cascade approach [28] will be used to guide knowledge translation across the duration of the project. We will engage the "6 Ps" stakeholder groups (public, patients/ caregivers, policymakers, practitioners, press, and private sector), all of which are critical to the successful outcome of our project. Our key knowledge translation activities will employ a rich range of communication channels and will be multifaceted: academic, governmental, policy-driven, and public-facing. Methods of dissemination will include social media, radio, websites, progress reports, workshops, community meetings, executive summaries, technical reports, verbal presentations to key stakeholders, peer-reviewed scientific publications and conference presentations. All relevant reports, publications and data will be freely available online.

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Appendix A

Data Dictionary

Field Name in REDCap	Variable Name	Standardized Prompt	Choices
Initial Contact			
Patient Information			
study_id	Study ID	Study ID	
eligible	Eligible	Is the child eligible to participate in this study?	0, No 1, Yes
IF eligible = no			
not_eligible	Reason for ineligibility	Why is the participant NOT eligible?	1, Non-infectious Cause 2, Special Clinic 3, Immunizations 4, Scheduled Appointment 5, Nutrition rehabilitation
IF eligible = yes			
enrolled	Enrolled	Is the child enrolled in the study?	0, No 1, Yes
IF enrolled = no			
not_enrolled	Reason for no Enrollment	Why was the child not enrolled in the study?	1, Declined consent 2, Insufficient time 3, Language barrier 4, No explanation 5, Already enrolled in the last 7 days 6, Referred for blood transfusion 7, Sent to do lab tests and never came back 8, Sent to a non-COIVD-19 facility 99, Other
IF not_enrolled = other			
not_enrolled_other	Other reason for no enrollment	If reason for no enrollment is 'other', please specify.	
sd	SmartDischarges Study	Did the child participate in the SmartDischarges study?	0, No 1, Yes
IF sd= yes			
sd_id	SmartDischarges Study ID	What is the child's SmartDischarges study ID number?	
arrival_time	Hospital Arrival Time	Enter the child's hospital arrival time. This can be found on a sticker, paper slip, or notebook which has been given to the caregiver.	
hosp_id	Hospital ID	Hospital ID	
first_name	First Name	First Name	
last_name	Last Name	Last Name	

date_enrolled	Date of Presentation	Current Date	
exam_time	Time of Initiation of Examination/interview (Current Time)	Current Time	
sex	sex	Enter biological sex.	1, Female 2, Male
dob_known	Precise date of birth known?	Ask: Do you know exactly what day the child was born?	0, No 1, Yes
IF dob_known = yes			
dob	Date of birth	Enter exact date of birth	
IF dob_known = no			
yob	Estimated year of birth	Enter estimated year of birth	
mob	Estimated month of birth	Enter estimated month of birth	
agecalc	Calculated age at admission.	Age (months)	
Vital Signs			
spo2	Oxygen saturation	Measure peripheral oxygen saturation using the mobile pulse oximeter (See SOP).	
sqi	Signal Quality Index	Enter the signal quality index achieved (See SOP).	
hr	Heart Rate	Record the patient's heart rate from previous pulse oximetry measurement (See SOP).	
rr	Respiratory Rate	Measure respiratory rate using the app provided (See SOP).	
temp	Temperature	Measure and record axillary temperature (See SOP).	
vitals_complete	Time at completion of vitals (calculated)	Time at completion of vital sign measurements.	
oxygen	Supplemental oxygen	Is the child receiving supplemental oxygen?	0, No 1, Yes
IF oxygen = yes			
o2_modality	Modality of oxygen delivery	What supplemental oxygen supply is the child receiving?	0, Room air 1, Nasal cannula 2, Face mask 3, Non rebreather 4, Ventilated 5, Other
IF o2_modality = other			
o2_other	Other modality of oxygen delivery	What supplemental oxygen is the child receiving?	
IF o2_modality = nasal cannula, face mask, non-rebreather mask			
o2_flow	Flow of oxygen delivered (L/min)	What the oxygen flow in L/min?	
Anthropometrics			

weight	Weight (measured in kg)	Measure and record the child's weight in kg (see SOP).	
height	Height (measured in cm)	Measure and record the child's height, or length if child is under 2 years old in cm (see SOP).	
muac	Middle upper arm circumference (measured in mm)	Measure and record the child's mid-upper arm circumference in mm (See SOP).	
Danger Signs			
complaint	Primary complaint (reported)	Ask: What is the main reason for bringing the child here today? Read out options.	1, Cough 2, Difficulty breathing 3, Nasal congestion 4, Skin Rash 5, Abscess 6, Fever 7, Eye pain/redness 8, Ear pain/discharge 9, Diarrhea 10, Constipation 11, Vomiting 12, Nausea 13, Abdominal Pain 14, Pain on urination 15, Jaundice 16, Lethargy (less energy than normal, unable to eat or drink) 17, Malaise (generalized aching) 18, Convulsions 19, Headache 20, Swelling (of any body part) 21, Anorexia 22, Trauma 23, Other
IF complaint = other			
complaint_other	Other primary complaint (reported)	Ask: What is the main reason for bringing the child here today? Enter **ONE** complaint only.	
Airway and Breathing			
cyanosis	Central cyanosis (observed)	Are the child's lips or tongue a blue or dark blue color?	0, No 1, Yes
difficulty_breath_rep	Difficulty breathing (reported)	Ask: Compared to when the child was well, is the child having difficulty breathing?	0, No 1, Yes
difficulty_breath_obs	Difficulty breathing (observed)	Is the child having difficulty breathing compared to a well child?	0, No 1, Yes
Circulation			
cap_refill	Capillary refill time > 3 seconds (upper limb)	Apply pressure to a thumb or finger for 3 seconds to blanch it. Does it take more than 3	0, No 1, Yes

		seconds to return to original pink color after you let go? (See SOP)	
IF cap_refill = yes			
cool_skin	Cool peripheries (observed)	Are the child's hands cold compared to the chest or trunk?	0, No 1, Yes
pulse_r	Weak or absent radial pulse (observed)	Does the child's radial pulse feel weak or absent?	0, No 1, Yes
IF pulse_r = yes			
pulse_c	Weak or absent central pulse (observed)	Does the child's central pulse feel weak or absent?	0, No 1, Yes
Coma/Convulsions			
alert	Alert (observed)	Is the child alert? (see SOP).	0, No 1, Yes
IF alert = no			
avpu	AVPU (observed)	Assess and select consciousness level using the AVPU scale (See SOP).	0, Alert 1, Responds to voice 2, Responds to pain 3, Unresponsive
convulsions	Convulsions (reported, history of)	Ask: Has the child had convulsions before? (See SOP).	0, No 1, Yes
convulsions_now	Convulsions during assessment, (observed)	Was the child actively convulsing during this assessment?	0, No 1, Yes
Dehydration/GI/GU			
vomiting	Vomiting (reported)	Ask: Does the child throw up everything they eat or drink?	0, No 1, Yes
diarrhoea	Diarrhoea (reported)	Ask: Has the child had diarrhoea 3 or times per day since getting sick?	0, No 1, Yes
IF diarrhoea = yes			
chronic_diarrhoea	Persistent Diarrhoea (reported)	Ask: Did the child have diarrhoea for more than two weeks?	0, No 1, Yes
dysentery	Dysentery (reported)	Ask: Has the child had blood in their stools?	0, No 1, Yes
IF HR > 120 for age < 5, or HR > 100 for age ≥ 5 or diarrhoea = yes			
skin_pinch	Skin pinch (observed)	Pinch the child's skin on the lower abdomen until it is tented, then release it. Does it take longer than 2 seconds to return to baseline?	0, No 1, Yes
sunken_eyes	Sunken eyes (observed)	Does the child's eyes appear to sink into their sockets?	0, No 1, Yes
IF sunken_eyes = yes			
sunken_eyes_rep	Sunken Eyes (reported)	Ask: Does the child's eyes appear to sink into their sockets	0, No 1, Yes

		compared to when the child is well?	
no_tears	No tears when crying (reported)	Ask: Has the child stopped making tears when crying?	0, No 1, Yes
dry_mouth	Dry oral mucosa (observed)	Does the child's oral mucosa (not lips) appear dry?	0, No 1, Yes
IF age < 18 months			
dep_fontanelles	Depressed fontanelle (observed)	Does the child's fontanelles appear depressed or sunken?	0, No 1, Yes
Priority Signs			
Trauma			
trauma	Major trauma (observed)	Has the child suffered trauma needing a designated trauma team or urgent surgery? OR Does he/she have a penetrating injury, pelvic or long bone fracture, or head or neck injury?	0, No 1, Yes
burn	Burns (observed)	Has the child suffered a burn resulting in skin breakdown?	0, No 1, Yes
poison	Poisoning (reported)	Ask: Has the child been poisoned from swallowing a chemical or drug?	
IF poison = yes			
poison_substance	Potentially Poisonous Substance (reported)	Ask: What did the child swallow?	1, Drug (medicine) 2, Chemcial (organophosphate) 3, Other
IF poison_substance = other			
poison_other	Potentially Poisonous Substance (other)	If poisonous substance is 'other', please specify.	
IF poison_substance = drug or chemical			
poison_name	Name of Potentially Poisonous Substance	If known, enter the name of the drug or chemical that was consumed.	
sev_pain	Severe Pain (observed)	Does the child seem to be in severe pain?	0, No 1, Yes
Circulation			
pallor	Palmar Pallor (observed)	Is the child pale at their palms compared to their caretaker?	0, No 1, Yes
Neurological			
irritable	Irritability/restlessness (observed)	Has the child been crying uncontrollably throughout the interview, even before you approached them?	0, No 1, Yes
IF age < 12 months			
cant_drink	Inability to drink/breastfeed/feed	Ask: Has the child been too sleepy or tired to breastfeed,	0, No 1, Yes 98, Don't know

	for longer than 6 hours (reported)	drink, or eat for more than 6 hours?	
IF age ≥ 12 months			
cant_sit	Inability to sit or stand for longer than 6 hours (reported)	Ask: Has the child been too sick to sit or stand for longer than 6 hours?	0, No 1, Yes 98, Don't know
Respiratory			
IF: difficulty_breathing_rep = yes OR difficulty_breathing_obs = yes OR RR > 40 OR spo2 < 90% OR cant_drink = yes OR cant_sit = yes OR cyanosis = yes			
stridor	Stridor (observed)	Does the child have stridor?	0, No 1, Yes
indrawing	Chest in-drawing (observed)	Does the child have chest indrawing?	0, No 1, Yes
flaring	Nasal flaring (observed)	Does the child have nasal flaring?	0, No 1, Yes
grunting	Grunting (observed)	Does the child have a grunt?	0, No 1, Yes
tracheal_tug	Tracheal tug (observed)	Does the child have a tracheal tug?	0, No 1, Yes
accessory_use	Accessory muscle use (observed)	Does the child use accessory muscles when breathing?	0, No 1, Yes
wheezing	Wheezing (observed)	Does the child have wheezing?	0, No 1, Yes
cough	Cough (observed)	Have you observed coughing from the child?	0, No 1, Yes
Malnutrition			
oedema	Visible oedema (feet, knees, face) (observed)	Does the child have pitting oedema on their feet, knees, or face?	0, No 1, Yes
IF: muac < 125 mm OR age < 12 months			
sev_wasting	Visible severe wasting (observed)	Does the child seem wasted?	0, No 1, Yes
Infection			
fever	History of fever (reported)	Ask: Does the child have a history of fever?	0, No 1, Yes
IF age < 1 month			
neo_jaundice	Neonatal jaundice (observed)	Does the child have yellowed sclera, palms, or soles?	0, No 1, Yes
umbilicus_red	Umbilicus - red (observed)	Is the child's umbilicus or surrounding skin red?	0, No 1, Yes
IF umbilicus_red = yes			
umbilicus_drain	Umbilicus-draining/pus (observed)	Does the child's umbilicus or surrounding skin have pus draining from it or trapped in it?	0, No 1, Yes

rash	Rash (observed)	Does the child have a rash?	0, No 1, Yes
IF rash = yes			
location_rash	Rash body part (observed)	Where is the rash located?	1, Generalized 2, Face 3, Neck 4, Torso 5, Arm 6, Hand 7, Leg 8, Foot 9, Genital 10, Perianal
lesion	Infective lesion (observed)	Does the child have an infective lesion on the skin, eye or ear?	0, No 1, Yes
IF age < 1 month			
oral_thrush	Oral thrush (observed)	Does the child have white patches on the roof of their mouth?	0, No 1, Yes
IF temp ≥ 37.5°C OR fever = yes			
neck_pain	Neck pain/stiffness (observed)	Does the child have pain on flexion of the neck?	0, No 1, Yes
bul_fontanelles	Bulging fontanelles (observed)	Does the child's fontanelles seem to bulge out above surrounding skin when lying supine and not crying?	0, No 1, Yes
muscle_tone	Abnormal muscle tone (observed)	Is the child's muscle tone abnormal? (see SOP)	0, No 1, Yes
IF muscle_tone = yes			
abnormal_tone	Type of abnormal muscle tone	Is the child's muscle tone increased or decreased? (see SOP)	1, Increased 2, Decreased
Laboratory Testing			
hiv	HIV testing	Enter HIV test result.	
malaria	Malaria test	Enter malaria test result.	
hb	Hemoglobin (g/dL)	Enter hemoglobin test result.	
hb_done	Hemoglobin test done?	Did the child receive a hemoglobin test today?	0, No 1, Yes
glucose	Blood sugar (mmol/L)	Enter blood glucose test result.	
glucose_done	Blood sugar test done?	Did the child receive a glucose test today?	0, No 1, Yes
lactate	Lactate (mmol/L)	Enter lactate test result.	
lactate_done	Lactate test done?	Did the child receive a lactate test today?	0, No 1, Yes
IF neo_jaundice = yes			
bilirubin	Bilirubin measurement (micromol/L)	Enter bilirubin test result.	
bilirubin_done	Bilirubin test done?	Did the child receive a bilirubin test today?	0, No 1, Yes

Patient History			
Demographic Information			
KENYA RESIDENTIAL INFORMATION			
district	District	Select district of residence from dropdown menu.	
county	County	Select county of residence from dropdown menu.	
division	Division	Select division of residence from dropdown menu.	
location	Location	Select location of residence from dropdown menu.	
sub_location	Sub location	Select sub location of residence from dropdown menu.	
village	Village or Estate	Select village/estate of residence from dropdown menu.	
UGANDA RESIDENTIAL INFORMATION			
district	District	Select district of residence from dropdown menu.	
county	County	Select county of residence from dropdown menu.	
sub_county	Sub-County	Select sub-county of residence from dropdown menu.	
parish	Parish	Select parish of residence from dropdown menu.	
village	Village	Select village of residence from dropdown menu.	
chairman	Chairman	Select chairman of residence from dropdown menu.	
BOTH SITES			
telephone_1	Telephone1	Enter a contact phone number.	
contact_1	Relationship to child	Ask: What is the relationship of this contact to the child?	
telephone_2	Telephone2	Enter a second contact phone number.	
contact_2	Relationship to child	Ask: What is the relationship of this contact to the child?	
telephone_3	Telephone2	Enter a third contact phone number.	
contact_3	Relationship to child	Ask: What is the relationship of this contact to the child?	
lo_illness	Length of Acute Illness (days, reported)	Ask: How many days has your child been sick in this illness?	
prev_admissions	Admission within 6 months (reported)	Ask: Has the child been admitted to a hospital or health center in the last 6 months?	0, No 1, Yes
IF prev_admissions = yes			

time_since_last_hosp	Time since last hospitalization (days, reported)	Ask: How long ago was the child last admitted to a hospital or health center?	1, <7 days 2, 7-14 days 3, 14-30 days 4, 1 month 5, 2 months 6, 3 months 7, 4 months 8, 5 months 9, 6 months
prev_hosps	Number of times hospitalized within 6 months (reported)	Ask: How many times was the child admitted to a hospital or health center in the last 6 months?	
urgent_referral	Referred within last 24 hours?	Ask: Was the child referred to this hospital from another health facility in the last 24 hours?	0, No 1, Yes
Sociodemographic Information			
primary_caregiver	Primary caregiver	Ask: Who is the primary caregiver of the child?	0, Mother 1, Father 2, Grandparent 3, Other relative 4, Non-relative 5, Day-care
IF primary_caregiver NOT = mother			
mother_alive	Mother alive	If mother not present, ask: Is the child's mother still alive?	0, No 1, Yes 98, Don't know
IF (primary_caregiver NOT = mother AND mother_alive = yes) OR primary_caregiver = mother			
maternal_age	Maternal age (years), if alive	Ask: How old is the child's mother?	
IF age < 12 months			
breastfeeding	Breastfeeding regimen (reported)	Ask: Was the child exclusively, partially or never breastfed for the first six months of life?	1, Exclusive 2, Partial 3, Never 98, Don't know
maternal_hiv	Maternal HIV status (reported)	Record HIV status if records available. Otherwise ask: Is the child's mother's HIV status?	0, Negative 1, Positive 98, Don't know
IF maternal_hiv = positive			
maternal_hiv_tx	Maternal HIV treatment (reported)	Ask: What HIV medication is the mother taking?	0, None 1, PMTCT 2, ART 98, Don't know
child_hiv	Child HIV status (reported)	Record HIV status if records available. Otherwise ask: Has your child tested positive for HIV?	0, No 1, Yes 98, Don't know
maternal_edu	Maternal education (reported)	Ask: What is the highest level of school completed by the child's mother? Read out options.	0, No school 1, Primary 2, Secondary 3, Post-secondary 98, Don't know
water_pure	All drinking water purified (reported)	Ask: Do you boil, filter (good sand/ceramic) or disinfect (using	0, No 1, Yes

		bleach/waterguard) all drinking water?	
water_source	Primary water source for drinking (reported)	Ask: Where does your child get most of his/her drinking water from? Read out options.	1, Bottled 2, Tap/Municipal water 3, Bore hole 4, Protected spring 5, Open source (unprotected, stagnant water dam) 6, Slow running water 7, Fast running water 98, Don't know 99, Other
IF water_source = other			
water_source_other	Other primary water source for drinking	Ask: Where does your child get most of his/her drinking water from?	
Pregnancy and Birth Information (children <12 months)			
IF age < 12 months			
bw_known	Exact birth weight known	Check yes if record of birth weight is available. Otherwise ask: Do you know the child's weight when they were born?	0, No 1, Yes
IF bw_known = yes			
birth_weight	Exact birth weight (records, use reported if unavailable)	Enter birth weight from records if available. Otherwise ask: What was the child's weight when they were born?	
IF bw_known = no			
low_bw_est	Estimated low birth weight (reported)	Ask: Was the child diagnosed to have low birth weight when they were born?	0, No 1, Yes 98, Don't know
IF age < 12 months			
gestage_known	Exact gestational age known	Check yes if record of gestational age is available. Otherwise ask: Do you know how many weeks the pregnancy was when the child was born?	0, No 1, Yes
IF gestage_known = yes			
gestage	Gestational age at delivery (records, use reported if unavailable)	Enter gestational age at delivery in weeks from records if available. Otherwise ask: How many weeks was the child when they were born?	
IF gestage_known = no			
gestage_est	Approximate gestational age in months (reported)	Ask: How many months (weeks) was the mom pregnant when the child was born?	0, < 7 (28) 1, 7-8 (28-32) 2, > 8 (32) 98, Don't know
IF age < 12 months			

facility_birth	Facility of birth (reported)	Ask: Where was the child born? Read out options.	1, Hospital 2, Health centre 3, Clinic 4, Home 5, Other 98, Don't know
Other			
parent_concern	Parental Concern	Ask: Do you think your child needs to be admitted to the hospital?	0, No 1, Yes 2, Healthcare workers should decide
COVID-19 QUESTIONS			
IF fever = YES or difficulty_breath_rep = YES or difficulty_breathing_obs = YES or temp >= 37.5			
covid_contact	Contact with a confirmed or suspected COVID-19 case	Ask: In the 14 days before getting sick, has the child been in contact with someone who tested positive for COVID-19 or someone suspected to have COVID-19?	0, No 1, Yes
IF covid_contact = YES			
covid_confirmed	Contact with a confirmed case	Ask: Was the contact with someone who tested positive for COVID-19?	0, No 1, Yes
contact_source	Source of contact	Ask: What is the relationship between the person of contact and the child?	1, Parent 2, Sibling 3, Grandparent 4, Extended family 5, Caregiver or nanny 6, Friend 99, Other
IF contact_source = OTHER			
source_other	Other source of contact	Please specify the relationship between the person of contact and the child.	
contact_setting	Setting in which the contact occurred	Ask: In what setting did the contact occur? (read options)	1, Child's home 2, Extended family's home 3, School/Daycare 4, Friend's house 5, Parent's workplace 99, Other
IF contact_setting = OTHER			
setting_other	Other setting in which the contact occurred	Please specify the setting in which the contact occurred.	
profession_risk	Family with a high-risk profession	Ask: Does the child have a parent or family member working in any of the following fields? (read out options)	1, Healthcare 2, Laboratory 3, Market 4, Driver/Public Transport 5, School teacher

facility_risk	Facility Risk	Ask: Has the child visited any healthcare facility in the 14 days prior to symptom onset?	0, No 1, Yes
covid_test	COVID-19 test done?	Has the child been tested for COVID-19?	0, No 1, Yes
IF covid_test = YES			
covid_result	COVID-19 test result	Select COVID-19 test result.	0, Negative 1, Positive 2, Inconclusive 3, Results not yet available
Outcomes			
Hospital Outcomes			
*admitted	Hospital Admission	Was the participant admitted to the hospital?	0, No 1, Yes
IF admitted = yes			
diagnosis	Final Diagnosis	Look at the child's record to find the clinician diagnosis. Select the best category.	1, Malaria 2, Pneumonia 3, Bronchiolitis 4, URTI (cold, flu, etc) 5, Reactive airway disease/asthma 6, Gastroenteritis/Diarrhoea 7, HIV/AIDS or AIDS related illness 8, Meningitis/encephalitis or other CNS infection 9, Malnutrition 10, Tuberculosis 11, Any skin or soft tissue infection 12, Measles 99, Other
IF diagnosis = other			
diagnosis_other	Final Diagnosis Other	If diagnosis is 'other', please specify.	
IF admitted = yes			
*admitted_date	Date of Admission	Enter date of admission from record.	
*discharge_date	Date of Discharge	Enter date of discharge from record.	
*los	Length of Stay at Hospital	Calculated length of hospitalization.	
IF admitted = no			
not_admitted_status	Status of Non-Admitted Children	What is the status of the child?	1, Prescribed oral medication and sent home

			2, Went to do lab tests and never came back 3, Sent to a non-COVID-19 facility 4, Sent to main Jinja hospital to see specialist 5, Sent for blood transfusion at another facility 99, Other
not_admitted_status = sent to a non-covid-19 facility OR sent for blood transfusion at another facility			
not_admitted_status_loc	Location for those non-admitted patients who were referred to another facility	What is the name of the facility the child was sent to?	
mort_enrol	Death on day of enrollment	Did the child die on the day of enrollment?	0, No 1, Yes
IF mort_enrol = YES			
deathcause_enrol	Cause of death on day of enrollment	What was the cause of death?	
Follow-up Call			
*mortality	7-day Mortality Status	Find out whether the child is alive (See SOP).	0, Alive 1, Dead
IF mortality = yes			
*mort_inhosp	Died in hospital?	Ask: Did the child die in hospital?	0, No 1, Yes
mort_location	Location of death	Where did the child die?	1, During the FIRST visit to Jinja hospital 2, During a READMISSION to any healthcare centre 3, At a healthcare centre without being readmitted 4, At home or in the community, not at a healthcare centre
mort_date	Date of death	What date did the child die?	
deathcause	Cause of death	What was the cause of death?	
confirm_admitted	Confirm Admission	Ask: Was your child admitted to Jinja hospital when we first met you?	0, No 1, Yes
IF admitted = yes			
confirm_admission	Confirm Date of Admission	Ask: What date was your child admitted to the hospital? (See SOP).	
confirm_discharge	Confirm Date of Discharge	Ask: What date was your child discharged from the hospital? (See SOP).	

*readmitted	7-day Readmission/admission to another hospital after discharge	Ask: Was the child admitted to any hospital after being discharged? (See SOP).	0, No 1, Yes
IF readmitted = yes			
readmitted_reason	Reason for readmission/admission to hospital after discharge	Ask: What was the reason the child was admitted?	1, Malaria 2, Pneumonia 3, Bronchiolitis 4, URTI (cold, flu, etc) 5, Reactive airway disease/asthma 6, Gastroenteritis/Diarrhoea 7, HIV/AIDS or AIDS related illness 8, Meningitis/encephalitis or other CNS infection 9, Malnutrition 10, Tuberculosis 11, Any skin or soft tissue infection 12, Measles 99, Other
*readmitted_location	Location of readmission/admission to hospital after discharge	Ask: Which hospital was the child admitted to?	
IF readmitted_reason = other			
reason_other	Readmission Reason Other	If reason for readmission is 'other', please specify.	
readmitted_tx	Treatment Received During Readmission	What treatment was the child given when readmitted?	0, None 1, Antibiotics 2, Intravenous Fluids 3, Oxygen 99, Other
IF readmitted_tx = other			
readmitted_tx_other	Treatment Received During Readmission Other	If treatment is 'other', please specify.	
*readmitted_date_known	Readmission dates known	Do you know exactly what dates the child was admitted again and discharged again from the hospital?	0, No 1, Yes
IF readmitted_date_known = yes			
*readmitted_start	Readmission date	What date was the child admitted again from the hospital after being sent home?	
*readmitted_end	Readmission discharge date	What date was the child sent home again after being readmitted?	

*readmitted_los_calc	Length of stay on readmission (calculated)	Calculated length of stay on readmission	
IF readmitted_date_known = no			
*readmitted_los_reported	Length of stay on readmission (reported)	When your child was admitted to the hospital again, how many days did your child stay in hospital?	
IF readmitted = yes			
*seek_help_before_readmit	Seeking help at medical facility before readmission	Ask: Other than the place where your child was readmitted, did you seek any other medical help?	0, No 1, Yes
IF readmitted = no			
*seek_help	Seeking help at medical facility (regardless of readmission)	Ask: Did you seek help from a medical facility after being discharged from hospital?	0, No 1, Yes
IF readmitted = yes OR seek_help = yes (invoke branching logic to find out what the care center of readmission/seeking help was)			
*center _district	District of care center	Ask: In what district was the care center where the child was readmitted/sought help?	Text field populated by app. 13 choices
*center_sub_district	Health Sub District of care center	Ask: In what sub-district was the care center where the child was readmitted/sought help?	Text field populated by app, choices depends on answer to readmitted_district.
*center_name	Health Facility of care center	Ask: What was the name of care center where the child was readmitted/sought help?	Text field populated by app. Choices depends on answer to readmitted_sub_district
*center_tier	Care center tier of health facility.		Auto-populated by app depending on answer to center_name
*center_own	Ownership of health facility		Auto-populated by app depending on answer to center_name Govt vs. PNFP vs. PFP (government, private not for profit, private for profit)
IF ask_missed_wages = 1 OR readmitted = yes or seek_help = yes (note: will ask about missed wages if patient was readmitted, sought help after discharge, or 20% of the time for everyone else). Included readmitted or seeking help to get a representative sample size in these grouops as N is smaller for these groups.			
*who_missed_wages	Person who missed wages, to calculate indirect costs of illness	Ask: During this illness, who missed daily wages as a result of the child being sick [read out	1, Mother 2, Father 3, Other relative

		options and check all that apply]?	98, Other 99, Don't know
IF who_missed_wages = Mother			
*days_missed_wages1	# days missed wage mother	Ask: During this illness, how many days of paid work did the mother miss?	Number, min:0, max: 10
IF who_missed_wages = Father			
*days_missed_wages2	# days missed wage father	Ask: During this illness, how many days of paid work did the father miss?	Number, min:0, max: 10
IF who_missed_wages = Relative			
*days_missed_wages3	# days missed wage relative	Ask: During this illness, how many days of paid work did the relative miss?	Number, min:0, max: 10
IF who_missed_wages = Other			
*days_missed_wages98	# days missed wage other	Ask: During this illness, how many days of paid work did this individual miss?	Number, min:0, max: 10
Clinical Timekeeper			
study_id	Study ID	Enter the study ID recorded in the participant's notebook.	
study_id_2	Study ID	Again, enter the study ID recorded in the participant's notebook.	
*abx_time	Time at start of antibiotics administration.	Time at start of antibiotics administration.	
*fluids_time	Time at start of intravenous fluids administration.	Time at start of intravenous fluids administration.	
*oxygen_time	Time at start of oxygen administration.	Time at start of oxygen administration.	
*antimalarial time	Time at the start of antimalarial administration.	Time at start of antimalarial administration.	
other_time	Time at start of treatments that are NOT antibiotics, fluids or oxygen.	Time at start of treatments that are NOT antibiotics, fluids or oxygen.	
IF tx = other			
tx_other	Treatment Received Other	If treatment is 'other', please specify.	
tx_delay	Patient received all treatments on time.	Patient received all treatments on time (choose No if a treatment was not received on time)	0, No 1, Yes
IF tx_delay = YES			

delay_reason	Reason for receiving delayed treatment	Why didn't the patient receive treatment on time?	1, Out of stock 2, All health workers were busy (no one available to treat)

Appendix B

Simulated Patient Cases

Simulated Patient Case V1

Field	Value
Username	Test
Password	Test
New ID	0001
First Name	Jane
Last Name	Doe
Phone Number	2565554321
Date of birth	April 15th 2017

Gender	Female
Weight	7.3 kg
Mid-upper arm circumference	Not Done
Pulse oximetry	Measure Pulse Ox on yourself, plug it in and put on the pulse oximeter.
Respiratory rate	Measure RRate on yourself, tap each time you breathe.
Temperature	37.8 degrees Celsius
Urgent referral?	No
HIV Status	Negative
Duration of illness/sign/symptom	2 days
Time since last hospitalization	Never
Symptoms	The mother reports Jane is coughing and vomiting. Yes, there are tears when crying and yes, Jane is able to eat and drink. No other symptoms.
Signs	Jane is alert and there are no other signs.

Simulated Patient Case V2

Field	**Value**
Username	Test
Password	Test
New ID	**4321**
First Name	**John**
Last Name	**Doe**
Phone Number	**2655554321**
Age	**Approximately 1 month**
Gender	**Male**
Weight	**4.2 kg**
Mid-upper arm circumference	**134 mm**
Pulse oximetry	Measure Pulse Ox on yourself, plug it in and put on the pulse oximeter.
Respiratory rate	Measure RRate on yourself, tap each time you breathe.
Temperature	Not done
Urgent referral?	Yes
HIV Status	Positive, but no signs or symptoms from HIV
Duration of illness/sign/symptom	1 day
Time since last hospitalization	3 weeks
Exclusive breastfeeding?	Yes
Symptoms	The mother reports John is wheezing and has no tears when crying. He is not able to eat or drink anything. No other symptoms.
Signs	John is not alert but responds to voice. You also notice chest-indrawing but no other signs.

Simulated Patient Case V3

Field	Value
Username	Test
Password	Test
New ID	0003
First Name	James
Last Name	Doe
Phone Number	2561234567
Date of Birth	Approximately 2.5 years
Gender	Male
Weight	13.3 kg
Mid-upper arm circumference	120 mm
Pulse oximetry	Measure Pulse Ox on yourself, plug it in and put on the pulse oximeter.
Respiratory rate	Measure RRate on yourself, tap each time you breathe.
Temperature	38.2 degrees Celsius
Urgent referral?	No
HIV Status	Negative
Duration of illness/sign/symptom	5 days
Time since last hospitalization	7 months
Symptoms	The father reports James is coughing and irritable. He vomited his dinner last night and has a runny stool since last night.
Signs	James is alert and there are no other signs.

Appendix C

Think Aloud Script and Triage Tool Instructions

"You are requested to assess several children who have arrived in the outpatient department. As you go through each patient's simulated patient file using the documentation provided, I ask that you think aloud. This means you say whatever you are thinking, doing, and feeling, as you use the triage tool. Please specifically comment on the layout of the triage tool, icons, and variables requested. Consider if the questions are worded in a way that is easy to understand and whether the order of tasks is appropriate. Feel free to comment on any areas of the tool that you feel could be improved. Let's do a short example. Please think aloud while determining the 4th letter after the letter 'L' in the alphabet.

We will now start the training session. Please verbalize all the thoughts you have about the use of the device and interface. Please provide specific comments on the suggestions and advice provided by the monitor."

[Participant may begin following instructions starting with step 1]

[Once participant has completed the 17 steps of the instructions]

"The training is now over. Do you have any remaining questions or comments about the function or design of the triage app? [Time for remaining questions]
The training for testing the mHealth tool is now concluded. Thank you."

Triage Tool Instructions

1. Open the triage tool on the tablet
2. Login (provided on data sheet)
3. Enter patient ID for new patient (provided on data sheet)
4. Enter clinical data (provided on data sheet)
5. Record patient results/risk score onto data sheet
6. Complete patient record
7. Send patient record to dashboard
8. Open dashboard
9. Identify the highest priority patient (If the participant does not identify the highest priority patient, prompt *"can you elaborate on why you chose the selected patient"*. If the participant identifies this correctly, prompt *"please list the reasons why you think this patient is highest priority.")*
10. Review the three priority identifiers. Prompt *"do you think this element is a good indicator of increased risk, and if not, how would you do it differently?"*
    i. Patient is at the top of the list
    ii. Patient's 'risk' icon is red
    iii. Patient timer is highlighted
11. Prompt *""We will now ask that you observe the dashboard as updates are made to it. Anytime you see a change on the dashboard, indicate to us that you've noticed a change. "*

    The moderator will trigger 3 updates. When the participant identifies and a change, the moderator will ask the following questions:

    a) *Describe what you have just seen and what it could mean.*
    b) *What do you think that triggered that change?*
    c) *Now that this change has occurred, what do you think the next steps are?*
    d) *Do you have any questions about this?*
12. Assign priority patient to consultation room (provided on priority patient data sheet)
13. Open digital patient file and compare to data sheet for errors
14. Edit patient's 'current status' (provided on priority patient data sheet)
15. Close patient file (if indicated on priority patient data sheet)
16. From menu, open patient log for last 24 hours
17. Log out and shutdown the triage tool

Appendix D

Triage Tool Training Questionnaire

Participant ID: _____ Date: _____ Time: _____

Impact

Question #1: Do you think the triage tool would be a positive addition to the patient risk assessment process at triage?

Response:

_____
_____
_____
_____

Question #2: Do you think the triage tool would improve the patient risk assessment processes at your hospital?

Response:

_____
_____
_____
_____

Question #3: Do you think the triage tool would be an important part of meeting your information needs related to patient risk levels?

Response:

_____
_____
_____
_____

Perceived Usefulness

Question #4: Do you think using the triage tool makes it easier for you to identify patients who may be at higher risk and need more attention?

Response:

_____
_____
_____
_____

Question #5: Do you think the triage tool enables you to identify higher risk patients more quickly?

Response:

_____
_____
_____
_____

Question #6: Do you think using the triage tool makes it more likely that you will identify patients who are higher risk at triage?

Response:

_____
_____
_____
_____

Question #7: Do you think that using the triage tool is useful for identifying high risk patients at triage?

Response:

_____
_____
_____
_____

Question #8: Do you think the triage tool presents a more equitable process for patient risk assessment at triage?

Response:

_____
_____
_____
_____

Question #9: Are you satisfied with the triage tool for risk management of patients at triage?

Response:

_____
_____
_____
_____

Question #10: Do you think you will be able to manage patients risk assessment at triage in a timely manner because of the triage tool?

Response:

_____
_____
_____
_____

Question #11: Do you think using the triage tool increases your ability to assess patients' risk levels at triage?

Response:

_____
_____
_____
_____

Question #12: Are you able to assess patient risk at triage whenever you use the triage tool?

Response:

_____
_____
_____
_____

Perceived Ease of Use

Question #13: Are you comfortable with your ability to use the new triage tool?

Response:

_____
_____
_____
_____

Question #14: Was learning to operate the triage tool easy for you?

Response:

_____
_____
_____
_____

Question #15: Was it easy for you to become skillful at using the triage tool?

Response:

_____
_____
_____
_____

Do you find the triage tool easy to use?

Question #16:

Response:

_____
_____
_____
_____

Question #17: Can you always remember how to log on to and use the triage tool?

Response:

_____
_____
_____
_____

User Control

Question #18: Do you find the triage tool gives error messages that clearly tell you how to fix problems?

Response:

_____
_____
_____
_____

Question #19: When you make a mistake using the triage tool, do you find you can recover easily and quickly?

Response:

_____
_____
_____
_____

Question #20: Do you think the information (such as on-screen messages and other documentation) provided with the triage tool is clear?

Response:

_____
_____
_____
_____

Healthcare Worker Satisfaction

Question #21: Do you feel like you are well trained and prepped to use the triage tool and standard protocols when they are implemented in the hospital?

Response:

_____
_____
_____
_____

Question #22: Overall, do you think the triage tool will be a positive addition to your hospital?

Response:

_____
_____
_____
_____

Additional Comments

Do you have any other feedback for us about the digital triage system?

_____
_____
_____
_____

Your input and comments are an important part of evaluating the tools and training of this program. Thank you!

Appendix E

Interview Guide

Administrative information – Filled out by participant	
ID number:	
Date of informed consent form signed: |D|D| - |M|M|M| - |Y|Y|Y|Y|	
First Name,	**Sex:** ☐ Female ☐ Male ☐ Prefer not to say
Last name,	**Age group: <20, 20-30, 30-40, 40-50, 50+**
Program and year graduated	
Total months/years worked in current field	|M|M| - |Y|Y|
Total months/years worked at current hospital	|M|M| - |Y|Y|
Current department	
Current position	
Administrative information – Filled out by researcher	
Interview Group number (if applicable)	
Does the participant agree to be audio recorded? ☐ Yes ☐ No (If no, participant will be excluded from the study)	
Name of interviewer:	
Date of interview: |D|D| - |M|M|M| - |Y|Y|Y|Y|	
Location of interview: ☐ **Jinja Regional Referral Hospital** ☐ **Other: _____**	
Interview start time: |H|H| : |M|M| *military time* **Interview end time:** |H|H| : |M|M| *military time*	

Instructions for qualitative research staff:

- Use this document as a guide to conduct the interviews with the **hospital staff (HS)**.
- Conduct the interview in the language with which the HS feels most comfortable.
- The interview should take place in a quiet place that allows privacy.
- Please introduce each question separately. The interview should flow as a conversation. If you notice that the HS is hesitant in answering, does not give an in-depth response, or the response is not satisfactory, please probe or ask follow-up questions, but do NOT prompt any specific answer. Several probes are suggested, and you may also ask follow-up questions that are not listed in this guide but are necessary for the complete expression of the HS's views.
- Please **record the interview** using the designated audio recorder and state the HS ID number at the beginning and end of the recording.
- All comments from the HS should be recorded.
- All responses must be kept confidential. Do not discuss or share responses with anyone outside of the PRST study team.

SCRIPT FOR PROSPECTIVE INTERVIEW

Ex. introduction:
"Welcome, my name is <interviewer>. I would like to thank you for participating in this interview today. I'm here today to ask you questions and hear your thoughts, opinions, and feelings about the digital triage tool that has been <piloted/operational> at your facility for the past <1 week/6 months>. <Interviewer will provide a brief description of the tool and events to clarify the subject of the interview>. I'll begin by asking you a few questions about yourself and your role at this hospital…"

A. Demographic Information
1. First, we will start with some questions about yourself;
2. What is your first and last name?
3. How many years of education and training have you completed?
4. What is your highest level of education completed?

B. Current role at this facility
1. How long have you been employed at this healthcare facility?
2. What is your current job title or current role at this facility?
3. How long have you been in this role at this facility and how long have you worked here in total?
4. What are your responsibilities in this role? *Probes: What does a typical day look like to you?*
5. Are you involved in patient care? If yes, explain your patient care responsibilities. (if no, skip question) *Probes: Are you involved with identifying/treating emergency patients? How?*
6. Do you have experience with technology? *Probes: At home? At work? At school? Elsewhere?*

C. Digital Triage Tool
Usability
1. Are you familiar with the PRST Digital Triage Tool?
2. In your own words, can you explain what the tool is and what it does? *Probes: Can you tell me more about risk prediction/triage/patient tracking/etc.*
3. Are you expected to use the digital triage tool as part of your regular clinical care in the hospital? *Probes: Have you ever used a system like this before? Tell me a bit about it.*
4. How do you feel about using a system like this at this facility? *Probes: benefits/challenges?*
Training
5. Tell me about the training you received to prepare you for using the digital triage tool. *Probes: who provided the training [**PHASE III**]-did you attend a training session/ were trained by*

other hospital staff, who?

6. Do you feel you were properly trained to use this tool? Were others?
   Probes: Was training long enough? What do think the appropriate length of time and method of delivery of training?

7. Which aspects of using this tool do you think were easy to learn? Which aspects were difficult?
   Probes: What barriers did you anticipate/experience during the test period (pilot)?

8. [Newborn] How do you think using this tool will/has affect providing care to newborns at this facility?
   Probes: How would it be different using the tool with newborns compared with older children?

9. What kinds of questions <do you think/have> caregivers or other hospital staff <would have/had> about this tool?
   Probes: basic functioning 'what does it do?'/changes in care/risk prediction/patient tracking?

10. Are there situations where you think this tool should not be used? If so, what are they?
    Probes: The baby is too sick? The hospital is too busy? Understaffed?

11. Are there any changes you would make to this tool before it becomes part of standard clinical care here? If so, what are they?

Acceptability

12. What do you like (if anything) about this tool overall? What do you dislike (if anything)?
    Probe: <key issues that we want responses about. Does it take too long? … >

13. How do you think other healthcare providers in your hospital <will feel/feel> about this tool?
    Probe: Do you think doctors will have a different opinion from nurses?

Parent/Caregiver perspectives

14. How do you think mothers and primary caregivers <will feel/feel> about this new tool?
    Probes: additional questions/technology/tracking/

15. Do you think fathers/mothers-in-law/other family members, <will feel/feel> the same way?
    Probes: Why/Why not?

16. Do you think we should ask caregivers and their families directly?

Facility

17. How do you think healthcare administrators and decision-makers in your facility <would/have> react to this tool?
    Probes: Discuss at each level (local, district, national) sequentially. What stakeholders might influence the uptake of this technology?

18. What do you think about using Bluetooth technology to track patient movement?
    Probe: Do you have specific concerns about Bluetooth technology? Have you heard others express concerns about Bluetooth technology? Do you use Bluetooth technology in your personal life? Description of the technology "Bluetooth is a wireless technology standard used for exchanging data between fixed and mobile devices over short distances using short-wavelength UHF radio waves"

Trustworthiness

19. Would you consider information collected and displayed by this tool trustworthy? Why or why not?

20. What information does the tool currently provide that is of interest and of use to you?
    Probes: Missing Information-Is there information isn't not giving you that you want? Usefulness-Is there information it currently gives that is not useful?

Feasibility

21. Do you think this tool is suitable for your facility?
    Probes: For example, staffing availability and skill to use the tool, training, complexity of the tool, availability of equipment and infrastructure needed for its use, durability and maintenance of tool and components, access to spare parts, protocols and guidelines for use, counselling caregivers and informational materials? What could be benefits/drawbacks?
22. What would need to happen in order to integrate this tool successfully at this facility? Please explain.
    Probes: For example, ease of use during a patient visit, integration into current flow of hospital operations, acceptance by administrators, etc.?

23. Do you think this tool is suitable for you and the work you do? Why/why not?

24. Do you have any other comments about this tool that we did not talk about?

Appendix F

Makerere University School of Public Health (MUSPH) Higher Degrees, Research and Ethics Committee

Informed Consent Form
(Phase I: Baseline Data Collection)
Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool

Principal Investigators

Dr. Mark Ansermino

Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia

Dr. Abner Tagoola

Senior consultant at Jinja Regional Referral Hospital, Jinja, Uganda

Co-Investigators

Samuel Akech	Kenya Medical Research Institute/Wellcome Trust Research Programme
Alishah Mawji	Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia
Matthew O. Wiens	Center for International Child Health, BC Children's Hospital Research Institute
Niranjan Kissoon	Department of Pediatrics, University of British Columbia

Edmond Li	School of Population and Public Health, University of British Columbia
Nathan Kenya Mugisha	Walimu

Introduction:
Your child is invited to be part of this research study because he/she is a paediatric patient and has come to the hospital to get medical help. You can decide if your child joins or not. Your child will get all normal medical care no matter what you decide about this study. You can talk to anyone you want to before deciding. If you want your child to join, we will ask you to sign this consent form. This form explains the study and how your child will help with the study. If you decide to have your child join, you are free to change your mind at any time. If you change your mind, you will not have to explain why. There will be no penalty if you change your mind. If you choose not to join, or to later quit the study, your child will still get all normal medical care. There will be more than 1000 children that join this study.

Who is carrying out this study?
This study is being done by Makerere University School of Public Health (in Jinja), and the University of British Columbia (in Canada). These organizations do medical research to find better ways of preventing and treating illness. This study is being funded by Wellcome Trust, which is a charity based in the United Kingdom but funds health research worldwide to improve lives.

What is this study about?
Many children become very sick from infections like malaria, pneumonia and diarrhea. It is very important for children with these infections who are very sick to be recognized as early as possible. In this study, we want to collect simple information about the health of children like your child to help us predict which children are very sick. If we can do that, we can give the sick children treatment quicker. If you do not want to answer any questions, you do not have to.

If you/your child fits the requirements of this research, we will:

1. Take 30 minutes today while you are waiting. **If it is your turn to see the nurse or doctor, you will still see them right away and we can finish the study interview afterwards.**
2. Put a radio-frequency identification (RFID) tag on your child. This tag lets us keep track of where your child is in the hospital. It will tell us how long your child had to wait to see the doctor and get treated.
3. Ask you questions about your child's sickness, general health and home life.
4. Measure numbers used in normal medical care like oxygen levels, breathing speed, heart speed, temperature, height, weight, and arm thickness. We will use devices that are used in normal medical care.
5. Examine your child for signs related to your child's sickness and general health.
6. Ask you a few questions about the child's mother and caregiver.
7. Record whether your child was admitted and for how long. Record how long your child had to wait before seeing the doctor and getting treated.
8. We may call you within 7 days with a few short questions to check your child's health.

We will use all this information to build a program that can tell us which children in the waiting room are the sickest.

Are there any risks or disadvantages to me/my child of taking part?

- Our priority for every participant is their well-being.
- It is safe to join the study. Your child will get the same medical care he/she would get if they do not join the study.
- Participation will take about 30 minutes of your time, and study procedures will not delay care for your child.

Are there any advantages to me/my child of taking part?

- This study offers no direct benefits to you or your child.
- By joining in the study, you will help us learn to recognize children with bad infections sooner. This information could save some future children from dying of infections by getting them treatment sooner.

Incentives/rewards for participating:

We would like to provide you with a bar of soap to thank you for your participation.

What happens if I refuse to participate?

All participation in research is voluntary. You are free to decide if you want your child to take part. Your child will still receive the recommended standard of care if they do not take part. If you do agree you can change your mind at any time and withdraw your child from the research. You do not need to give any reasons for your decision. This will not affect your child's care now or in the future.

Who will have access to information about me/my child in this research?

All our research records are stored securely in locked cabinets and password protected computers. Your confidentiality will be respected. Research records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the University of British Columbia for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent. No information or records that disclose your identity be removed or released without your consent unless required by law.

This study is being done by researchers from Kenya, Uganda and from Canada. The electronic data that is collected will be stored safely on servers at MUSPH, and a copy will be shared with University of British Columbia in Canada. You will be given a unique study number. This number will not include any personal information that could identify you like your name or initials. Only this number will be used on any research-related information collected about you, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate.

Any and all information that could potentially identify you will be removed before publication of this data. You can decide that you do not want your data made publicly available. If you decide

you do not want your data to be available to the public (without identifying information), this is the same as withdrawing from the study.

In future, information collected or generated during this study may be used to support new research by other researchers in Kenya, Uganda and Canada on preventable infections and sepsis. In all cases, we will only share information with other researchers in ways that do not reveal individual participants' identities. For example, we will remove information that could identify people, like names and address, and replace this information with number codes. Any future research using information from this study must first be approved by the MUSPH Higher Degrees, Research and Ethics Committee, to make sure that the interests of participants and their communities are protected.

Who has approved this research?
All research at MUSPH must be approved before it begins by several national and international committees who look carefully at planned work. They must agree that the research is important, relevant to Uganda and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What if I have any questions?
You are free to ask questions of any staff at any time. You can also contact the research team using these contacts:

Dr. Nathan Kenya-Mugisha
Walimu Office
Unit 4, Plot 5, Coral Crescent, Kololo, Kampala
Tel: 0772-731-751
Email: kenya@walimu.org

Dr. John Ssempebwa
Acting Chairperson
HD Research and Ethics Committee
Tel: +256-772-963-074

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the University of British Columbia Research Participant Complaint Line:
e-mail: RSIL@ors.ubc.ca
Toll Free Tel: 1-877- 822-8598

I, [being a parent/guardian of _____ (name of child),] have had the research explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I agree to allow my child to take part in the research.

I understand that I can change my mind at any stage, and it will not affect to my child in any way.

Subject/Parent/guardian's signature: _____**Date** _____

Subject/Parent/guardian's name: _____ **Time** _____
(Please print name)

Where parent/guardian cannot read, ensure a witness* observes consent process and signs below:

I attest that the information concerning this research was accurately explained to and apparently understood by the subject/parent/guardian and that informed consent was freely given by the subject/parent/guardian.

Witness' signature: _____ **Date** _____

Witness' name: _____ **Time** _____

**A witness is a person who is independent from the trial or a member of staff who was not involved in gaining the consent.*

Thumbprint of the parent as named above if they cannot write: _____

I have followed the study SOP to obtain consent from the [participant/guardian]. S/he apparently understood the nature and the purpose of the study and consents to the participation [of the child] in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ **Date** _____

Designee/investigator's name: _____**Time** _____
(Please print name)

THE SUBJECT/PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

KEMRI Wellcome Trust Research Programme: Patient Information and Consent Form

Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool [*Lay Title:* Development and testing of a digital tool for recognizing sick children]. Phase I.

Institution	Investigators
Kenya Medical Research Institute	Samuel Akech Mike English Grace Irimu Ambrose Agweyu Morris Ogero Cynthia Khazenzi Jalemba Aluvaala
Mbagathi Hospital	David Kimutai
Jinja Regional Hospital	Abner Tagoola
The University of British Columbia/BC Children's Hospital Research Institute	Mark J. Ansermino Niranjan Kissoon Matthew Wiens Guy Dumont Alishah Mawji

Introduction:
Your child is being invited to take part in this research study because he/she is under 19 years old and has come to the hospital to get medical treatment. Your participation is voluntary. You can decide whether or not your child joins. Before you decide, you can talk to anyone you feel comfortable with about your decision. If you want your child to participate, we will ask you to sign this consent form. This form explains the study and your child's role in the study. If you decide to have your child join, you are free to change your mind at any time. If you change your mind, you will not have to explain your decision. There will be no penalty if you change your mind. If you choose not to participate, or to later quit the study, your child will still get all normal medical care. There will be more than 1000 children that join this study.

Who is carrying out this study?
This study is being carried out by the Kenya Medical Research Institute (in Nairobi), and the University of British Columbia (in Canada). These organizations conduct medical research to find better ways of preventing and treating illness in the future. This study is being funded by Wellcome Trust, which is a charity based in the United Kingdom but funds health research worldwide to improve lives.

What is this study about?
Many children become very sick from infections like malaria, pneumonia and diarrhea. It is very important for children with these infections who are very sick to be recognized as early as possible. In this study, we want to collect simple information about the health of children like your child to help us predict which

children are very sick. If we can do that, we can give the sick children treatment quicker. If you do not want to answer any questions, you do not have to.

If you/your child fits the requirements of this research, we will:

1. Take 30 minutes today while you are waiting. **If it is your turn to see the nurse or doctor, you will still see them right away and we can finish the study interview afterwards.**
2. Put a radio-frequency identification (RFID) tag on your child. This tag lets us keep track of where your child is in the hospital. It will tell us how long your child had to wait to see the doctor and get treated.
3. Ask you questions about your child's sickness, general health and home life.
4. Measure numbers used in normal medical care like oxygen levels, breathing speed, heart speed, temperature, height, weight, and arm thickness. We will use devices that are used in normal medical care.
5. Examine your child for signs related to your child's sickness and general health.
6. Ask you a few questions about the child's mother and caregiver.
7. Record whether your child was admitted and for how long. Record how long your child had to wait before seeing the doctor and getting treated.
8. We may call you within 7 days with a few short questions to check your child's health.

We will use all this information to build a program that can tell us which children in the waiting room are the sickest.

Are there any risks or disadvantages to me/my child of taking part?

- Our priority for every participant is their well-being.
- It is safe to join the study. Your child will get the same medical care he/she would get if they do not join the study.
- Participation will take approximately 30 minutes of your time, and study procedures will not delay care for your child.

Are there any advantages to me/my child of taking part?

This study offers no direct benefits to you or your child. By participating in the study, you will help us learn how to better recognize children with bad infections. This information could protect some children in future with infections from dying by helping them get treated earlier.

What happens if I refuse to participate?

All participation in research is voluntary. You are free to decide if you want your child to take part. Your child will still receive the recommended standard of care if they do not take part. If you do agree you can change your mind at any time and withdraw your child from the research. You do not need to give any reasons for your decision. This will not affect your child's care now or in the future.

Who will have access to information about me/my child in this research?

All our research records are stored securely in locked cabinets and password protected computers. Your confidentiality will be respected. However, research records identifying you may be inspected in the presence

of the Investigator or his or her designate by representatives of the University of British Columbia for the purpose of monitoring the research. No information or records that disclose your identity will be published

without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

This study is being done by researchers from Kenya, Uganda and from Canada. The electronic data that is collected will be stored safely on servers at KEMRI Wellcome Trust Research Programme, and a copy will be shared with University of British Columbia in Canada. You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your identify number or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate.

Any and all information that could potentially identify you will be removed before publication of this data. You can decide that you do not want your data made publicly available. If you decide you do not want your data to be available to the public, this is equivalent to withdrawing from the study.
In future, information collected or generated during this study may be used to support new research by other researchers in Kenya, Uganda and Canada on preventable infections. In all cases, we will only share information with other researchers in ways that do not reveal individual participants' identities. For example, we will remove information that could identify people, such as their names and where they live, and replace this information with number codes. Any future research using information from this study must first be approved by the Scientific Ethics and Review Unit in Kenya, to make sure that the interests of participants and their communities are protected.

Who has approved this research?
All research at KEMRI has to be approved before it begins by several national [and international] committees who look carefully at planned work. They must agree that the research is important, relevant to Kenya and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What if I have any questions?
You are free to ask questions of any staff at any time. You can also contact the research team using these contacts:
Dr. Samuel Akech, KEMRI Wellcome Trust Research Programme, P.O, Box 43640-00100 Nairobi, Kenya.
Telephone: +254 721490166 or +254 20 270163

If you want to ask someone independent about this research please contact:
Community Liaison Manager, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi.
Telephone: 041 7522 063, Mobile 0723 342 780 or 0705 154 386
And
The Head, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 0717 719477; 0776 399979 Email address: seru@kemri.org

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the University of British Columbia Research Participant Complaint Line:
e-mail: RSIL@ors.ubc.ca
Toll Free Tel: 1-877- 822-8598

KEMRI Wellcome Trust Research Programme consent form for Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool [*Lay Title:* Development and testing of a digital tool for recognizing sick children]. Phase I.

I, [being a parent/guardian of _____ (name of child),] have had the research explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I agree to allow my child to take part in the research.

I understand that I can change my mind at any stage, and it will not affect to my child in any way.

Subject/Parent/guardian's signature: _____**Date** _____

Subject/Parent/guardian's name: _____ **Time** _____
(Please print name)

Where parent/guardian cannot read, ensure a witness* observes consent process and signs below:

I attest that the information concerning this research was accurately explained to and apparently understood by the subject/parent/guardian and that informed consent was freely given by the subject/parent/guardian.

Witness' signature: _____ **Date** _____

Witness' name: _____ **Time** _____

**A witness is a person who is independent from the trial or a member of staff who was not involved in gaining the consent.*

Thumbprint of the parent as named above if they cannot write: _____

I have followed the study SOP to obtain consent from the [participant/guardian]. S/he apparently understood the nature and the purpose of the study and consents to the participation [of the child] in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ **Date** _____

Designee/investigator's name: _____**Time** _____
(Please print name)

THE SUBJECT/PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

Appendix G

Makerere University School of Public Health (MUSPH) Higher Degrees, Research and Ethics Committee

Informed Consent Form
(Phase III: Intervention)
Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool

Principal Investigators

Dr. Mark Ansermino

Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia

Dr. Abner Tagoola

Senior Consultant at Jinja Regional Referral Hospital, Jinja, Uganda

Co-Investigators

Samuel Akech	Kenya Medical Research Institute/Wellcome Trust Research Programme
Alishah Mawji	Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia
Matthew O. Wiens	Center for International Child Health, BC Children's Hospital Research Institute
Niranjan Kissoon	Department of Pediatrics, University of British Columbia
Edmond Li	School of Population and Public Health, University of British Columbia
Nathan Kenya Mugisha	Walimu

Introduction:
Your child is invited to be part of this research study because he/she is a paediatric patient and has come to the hospital to get medical help. You can choose to participate or not. You can decide if your child joins or not. Your child will get all normal medical care no matter what you decide about this study. You can talk to anyone you want to before deciding. If you want your child to join, we will ask you to sign this consent form. This form explains the study and how your child will help with the study. If you decide to have your child join, you are free to change your mind at any time. If you change your mind, you will not have to explain why. There will be no penalty if you change your mind. If you choose not to join, or to later quit the study, your child will still get all normal medical care. There will be around 4000 children that join this study.

Who is carrying out this study?
This study is being done by Makerere University School of Public Health (in Jinja), and the University of British Columbia (in Canada). These organizations do medical research to find better ways of preventing and treating illness. This study is being funded by Wellcome Trust, which is a charity based in the United Kingdom but funds health research worldwide to improve lives.

What is this study about?
Many children become very sick from infections like malaria, pneumonia and diarrhea. It is very important for children with these infections who are very sick to be recognized as early as possible. In this study, we are testing a computer program that can help health workers find very sick children so they can get treatment earlier. We want to collect simple information about the health of children coming to the hospital. This information will let us test if we can predict which children are very sick and give them treatment earlier. This information will also help us make that computer program better.

If you/your child fits the requirements of this research, we will:
1. Take 30 minutes today while you are waiting. **If it is your turn to see the nurse or doctor, you will still see them right away and we can finish the study interview afterwards.**
2. Put a radio-frequency identification (RFID) tag on your child. This tag lets us keep track of where your child is in the hospital. It will tell us how long your child had to wait to see the doctor and get treated.
3. Ask you questions about your child's sickness, general health and home life.
4. Measure numbers used in normal medical care like oxygen levels, breathing speed, heart speed, temperature, height, weight, and arm thickness. We will use devices that are used in normal medical care.
5. Examine your child for signs related to your child's sickness and general health.
6. Ask you a few questions about the child's mother and caregiver.
7. Record whether your child was admitted and for how long. Record how long your child had to wait before seeing the doctor and getting treated.
8. We may call you within 7 days with a few short questions to check your child's health.

Are there any risks or disadvantages to me/my child of taking part?

- Our priority for every participant is their well-being.
- It is safe to join the study. Your child will get the same medical care he/she would get if they do not join the study.
- Participation will take about 30 minutes of your time, and study procedures will not delay care for your child.

Are there any advantages to me/my child of taking part?

- This study offers no direct benefits to you or your child.
- By joining in the study, you will help us learn to recognize children with bad infections sooner. This information could save some future children from dying of infections by getting them treatment sooner.

What happens if I refuse to participate?

All participation in research is voluntary. You are free to decide if you want your child to take part. Your child will still receive the recommended standard of care if they do not take part. If you do agree you can change your mind at any time and withdraw your child from the research. You do not need to give any reasons for your decision. This will not affect your child's care now or in the future.

Who will have access to information about me/my child in this research?

All our research records are stored securely in locked cabinets and password protected computers. Your confidentiality will be respected. Research records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the University of British Columbia for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent. No information or records that disclose your identity be removed or released without your consent unless required by law.

This study is being done by researchers from Kenya, Uganda and from Canada. The electronic data that is collected will be stored safely on servers at MUSPH, and a copy will be shared with University of British Columbia in Canada. You will be given a unique study number. This number will not include any personal information that could identify you like your name or initials. Only this number will be used on any research-related information collected about you, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate.

Any and all information that could potentially identify you will be removed before publication of this data. You can decide that you do not want your data made publicly available. If you decide you do not want your data to be available to the public (without identifying information), this is the same as withdrawing from the study.

In future, information collected or generated during this study may be used to support new research by other researchers in Kenya, Uganda and Canada on preventable infections. In all cases, we will only share information with other researchers in ways that do not reveal individual participants' identities. For example, we will remove information that could identify people, like names and address, and replace this information with number codes. Any future research using information from this study must first be approved by the MUSPH Higher Degrees, Research and Ethics Committee, to make sure that the interests of participants and their communities are protected.

Who has approved this research?

All research at MUSPH has to be approved before it begins by several national [and international] committees who look carefully at planned work. They must agree that the research is important, relevant to Uganda and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What if I have any questions?
You are free to ask questions of any staff at any time. You can also contact the research team using these contacts:

Dr. Nathan Kenya-Mugisha
Walimu Office
Unit 4, Plot 5, Coral Crescent, Kololo, Kampala
Tel: 0772-731-751
Email: kenya@walimu.org

Dr. John Ssempebwa
Acting Chairperson
HD Research and Ethics Committee
Tel: +256-772-963-074

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the University of British Columbia Research Participant Complaint Line:
e-mail: RSIL@ors.ubc.ca
Toll Free Tel: 1-877- 822-8598

I, [being a parent/guardian of _____ (name of child),] have had the research explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I agree to allow my child to take part in the research.

I understand that I can change my mind at any stage, and it will not affect to my child in any way.

Subject/Parent/guardian's signature: _____**Date** _____

Subject/Parent/guardian's name: _____ **Time** _____
(Please print name)

Where parent/guardian cannot read, ensure a witness* observes consent process and signs below:

I attest that the information concerning this research was accurately explained to and apparently understood by the subject/parent/guardian and that informed consent was freely given by the subject/parent/guardian.

Witness' signature: _____ **Date** _____

Witness' name: _____ **Time** _____

**A witness is a person who is independent from the trial or a member of staff who was not involved in gaining the consent.*

Thumbprint of the parent as named above if they cannot write: _____

I have followed the study SOP to obtain consent from the [participant/guardian]. S/he apparently understood the nature and the purpose of the study and consents to the participation [of the child] in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ **Date** _____

Designee/investigator's name: _____**Time** _____
(Please print name)

THE SUBJECT/PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool [*Lay Title:* Development and testing of a digital tool for recognizing sick children]. Phase III.

Institution	Investigators
Kenya Medical Research Institute	Samuel Akech Mike English Grace Irimu Ambrose Agweyu Morris Ogero Cynthia Khazenzi Jalemba Aluvaala
Mbagathi Hospital	David Kimutai
Jinja Regional Hospital	Abner Tagoola
The University of British Columbia/BC Children's Hospital Research Institute	Mark J. Ansermino Niranjan Kissoon Matthew Wiens Guy Dumont Alishah Mawji

Introduction:

Your child is being invited to take part in this research study because he/she is under 19 years old and has come to the hospital to get medical treatment. Your participation is voluntary. You can decide whether or not your child joins. Before you decide, you can talk to anyone you feel comfortable with about your decision. If you want your child to participate, we will ask you to sign this consent form. This form explains the study and your child's role in the study. If you decide to have your child join, you are free to change your mind at any time. If you change your mind, you will not have to explain your decision. There will be no penalty if you change your mind. If you choose not to participate, or to later quit the study, your child will still get all normal medical care.

Who is carrying out this study?

This study is being carried out by the Kenya Medical Research Institute (in Nairobi), and the University of British Columbia (in Canada). These organizations conduct medical research to find better ways of preventing and treating illness in the future. This study is being funded by Wellcome Trust, which is a charity based in the United Kingdom but funds health research worldwide to improve lives.

What is this study about?

Many children become very sick from infections like malaria, pneumonia and diarrhea. It is very important for children with these infections who are very sick to be recognized as early as possible. In this study, we are testing a computer program that can help health workers find very sick children so they can get treatment earlier. We want to collect simple information about the health of children coming to the hospital. This information will let us test if we can predict which children are very sick and give them treatment earlier. This information will also help us make that computer program better.

If you/your child fits the requirements of this research, we will:

1. Take 30 minutes today while you are waiting. **If it is your turn to see the nurse or doctor, you will still see them right away and we can finish the study interview afterwards.**
2. Put a radio-frequency identification (RFID) tag on your child. This tag lets us keep track of where your child is in the hospital. It will tell us how long your child had to wait to see the doctor and get treated.
3. Ask you questions about your child's sickness, general health and home life.
4. Measure numbers used in normal medical care like oxygen levels, breathing speed, heart speed, temperature, height, weight, and arm thickness. We will use devices that are used in normal medical care.
5. Examine your child for signs related to your child's sickness and general health.
6. Ask you a few questions about the child's mother and caregiver.
7. Record whether your child was admitted and for how long. Record how long your child had to wait before seeing the doctor and getting treated.
8. We may call you within 7 days with a few short questions to check your child's health.

Are there any risks or disadvantages to me/my child of taking part?

- Our priority for every participant is their well-being.
- It is safe to join the study. Your child will get the same medical care he/she would get if they do not join the study.
- Participation will take approximately 30 minutes of your time, and study procedures will not delay care for your child.

Are there any advantages to me/my child of taking part?

This study offers no direct benefits to you or your child. By participating in the study, you will help us learn how to better recognize children with bad infections. This information could protect some children with infections from dying by helping them get treated earlier.

What happens if I refuse to participate?

All participation in research is voluntary. You are free to decide if you want your child to take part. Your child will still receive the recommended standard of care if they do not take part. If you do agree you can change your mind at any time and withdraw your child from the research. You do not need to give any reasons for your decision. This will not affect your child's care now or in the future.

Who will have access to information about me/my child in this research?

All our research records are stored securely in locked cabinets and password protected computers. Your confidentiality will be respected. However, research records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the University of British Columbia for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

This study is being done by researchers from Kenya, Uganda and from Canada. The electronic data that is collected will be stored safely on servers at KEMRI Wellcome Trust Research Programme, and a copy will be shared with University of British Columbia in Canada. You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your identify number or your initials, etc.). Only this number will be used on any research-related information collected about you during the course

of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate.

Any and all information that could potentially identify you will be removed before publication of this data. You can decide that you do not want your data made publicly available. If you decide you do not want your data to be available to the public, this is equivalent to withdrawing from the study.

In future, information collected or generated during this study may be used to support new research by other researchers in Kenya, Uganda and Canada on preventable infections. In all cases, we will only share information with other researchers in ways that do not reveal individual participants' identities. For example, we will remove information that could identify people, such as their names and where they live, and replace this information with number codes. Any future research using information from this study must first be approved by a local or national expert committee to make sure that the interests of participants and their communities are protected.

Who has approved this research?

All research at KEMRI has to be approved before it begins by several national [and international] committees who look carefully at planned work. They must agree that the research is important, relevant to Kenya and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What if I have any questions?

You are free to ask questions of any staff at any time. You can also contact the research team using these contacts:

Dr. Samuel Akech, KEMRI Wellcome Trust Research Programme, P.O, Box 43640-00100 Nairobi, Kenya. Telephone: +254 721490166 or +254 20 270163

If you want to ask someone independent about this research please contact:

Community Liaison Manager, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 041 7522 063, Mobile 0723 342 780 or 0705 154 386

And

The Head, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 0717 719477; 0776 399979 Email address: seru@kemri.org

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the University of British Columbia Research Participant Complaint Line:

e-mail: RSIL@ors.ubc.ca
Toll Free Tel: 1-877- 822-8598

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THE UNIVERSITY OF BRITISH COLUMBIA

KEMRI Wellcome Trust Research Programme consent form for Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool [*Lay Title:* Development and testing of a digital tool for recognizing sick children]. Phase III.

I, [being a parent/guardian of _____ (name of child),] have had the research explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I agree to allow my child to take part in the research.

I understand that I can change my mind at any stage, and it will not affect to my child in any way.

Subject/Parent/guardian's signature: _____**Date** _____

Subject/Parent/guardian's name: _____ **Time** _____
(Please print name)

Where parent/guardian cannot read, ensure a witness* observes consent process and signs below:

I attest that the information concerning this research was accurately explained to and apparently understood by the subject/parent/guardian and that informed consent was freely given by the subject/parent/guardian.

Witness' signature: _____ **Date** _____

Witness' name: _____ **Time** _____

**A witness is a person who is independent from the trial or a member of staff who was not involved in gaining the consent.*

Thumbprint of the parent as named above if they cannot write: _____

I have followed the study SOP to obtain consent from the [participant/guardian]. S/he apparently understood the nature and the purpose of the study and consents to the participation [of the child] in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ **Date** _____

Designee/investigator's name: _____**Time** _____
(Please print name)

THE SUBJECT/PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

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Appendix H

Makerere University School of Public Health (MUSPH) Higher Degrees, Research and Ethics Committee

Participant Information and Assent Form
(*For participants aged over 13 years to under 18 years*)

Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool

Principal Investigators

Dr. Mark Ansermino

Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia

Dr. Abner Tagoola

Senior Consultant at Jinja Regional Referral Hospital, Jinja, Uganda

Co-Investigators

Samuel Akech	Kenya Medical Research Institute/Wellcome Trust Research Programme
Alishah Mawji	Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia
Matthew O. Wiens	Center for International Child Health, BC Children's Hospital Research Institute
Niranjan Kissoon	Department of Pediatrics, University of British Columbia
Edmond Li	School of Population and Public Health, University of British Columbia
Nathan Kenya Mugisha	Walimu

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What is this study about?
Many children become very sick from infections like malaria, pneumonia and diarrhea. It is very important for children with these infections who are very sick to be recognized as early as possible. In this study, we want to collect simple information about the health of children coming to the hospital. This information will let us test if we can predict which children are very sick and give them treatment earlier, using a computer program that we made. This information will also help us make that computer program better. Sometimes research involves only talking and asking questions of different people about what they know, feel or do about something; this can be done with one person or a few people at a time. For this research we will ask you questions about your health, for example, "Do you have a cough?"

Who is carrying out this study?
This study is being carried out by the Makerere University School of Public Health (in Jinja), and the University of British Columbia (in Canada). These organizations do medical research to find better ways of preventing and treating sickness.

You can choose if you want to be in this study:
We have talked to your parent about this research and they know that we are talking to you. You are free to decide whether you want to answer our questions or not, even if your (parent/guardian) has said yes. If you say yes, you can change your mind and stop participating in the future and no one will be upset with you.

What will happen to the information I give?
The information you give in this study will only be shared with people who are concerned with the research.

The information will be summarised, and all the names of the participants will be removed from the documents. This study information may be used for future research; the information will only be provided after a national independent committee checks and agrees that you will not be affected in any way.

What if I have any questions?

You are free to talk to your parent/guardian or other people about being in this study. You can ask to have time to go talk to them about this. You are free to ask me any questions to any of the staff at any time. You can also contact:

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Dr. Nathan Kenya-Mugisha
Walimu Office
Unit 4, Plot 5, Coral Crescent, Kololo, Kampala
Tel: 0772-731-751
Email: kenya@walimu.org

Dr. John Ssempebwa
Acting Chairperson
HD Research and Ethics Committee
Tel: +256-772-963-074

Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool

I, _____ (write your name), have had the study explained to me. I have understood everything that was explained to me. And I agree to take part in this study.

I understand that I can change my mind at any time, that if I do, nothing bad will happen to me and I will still get medical help.

Child's signature: _____**Date** _____

Child's name: _____ **Time** _____

Thumbprint of the child as named above if they cannot write: _____

For the Investigator:
I certify that I have followed all the study specific procedures for obtaining informed assent from this child.
Investigator's signature: _____ **Date** _____
Investigator's name: _____**Time** _____
(Please print name)

THE PARTICIPANT SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

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THE UNIVERSITY OF BRITISH COLUMBIA

KEMRI Wellcome Trust Research Programme: Participant Information and Assent Form (*For participants aged over 13 years to under 18 years*)

Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool [*Lay Title:* Development and testing of a digital tool for recognizing sick children].

Institution	Investigators
Kenya Medical Research Institute	Samuel Akech Mike English Grace Irimu Ambrose Agweyu Morris Ogero Cynthia Khazenzi Jalemba Aluvaala
Mbagathi Hospital	David Kimutai
Jinja Regional Hospital	Abner Tagoola
The University of British Columbia/BC Children's Hospital Research Institute	Mark J. Ansermino Niranjan Kissoon Matthew Wiens Guy Dumont Alishah Mawji

What is this study about?

Many children become very sick from infections like malaria, pneumonia and diarrhea. It is very important for children with these infections who are very sick to be recognized as early as possible. In this study, we want to collect simple information about the health of children coming to the hospital. This information will let us test if we can predict which children are very sick and give them treatment earlier, using a

computer program that we made. This information will also help us make that computer program better. Sometimes research involves only talking and asking questions of different people about what they know, feel or do about something; this can be done with one person or a few people at a time. For this research we will ask you questions about your health, for example, "Do you have a cough?"

Who is carrying out this study??

This research is being carried out by KEMRI in collaboration with The University of British Columbia (in Canada). KEMRI is a government organization that carries out medical research to find better ways of preventing and treating illness in the future for everybody's benefit.

You can choose if you want to be in this study:

We have spoken to your parent about this research and they are aware that we are talking to you. You are free to decide whether you want to answer our questions or not, even if your (parent/guardian) has agreed. If you agree now, you can change your mind and stop participating in the future and no one will be upset with you.

What will happen to the information I give?

The information you give in this study will only be shared with people who are concerned with the research.

The information will be summarised, and all the names of the participants will be removed from the documents. This study information may be used for future research; the information will only be provided after a national independent committee checks and agrees that you will not be affected in any way.

What if I have any questions?

You are free to discuss your decision about taking part in this study with your parent/guardian or other people and you can ask to be given time to go and discuss this with them.

You are free to ask me any questions to any of the staff at any time. You can also contact:

Dr. Samuel Akech, KEMRI Wellcome Trust Research Programme, P.O, Box 43640-00100 Nairobi, Kenya. Telephone: +254 721490166 or +254 20 270163

If you want to ask someone independent anything about this research please contact:

Community Liaison Manager, KEMRI – Wellcome Trust, P.O. Box 230, Kilifi. Telephone: 0723 342 780 or 041 7522 063

And

The Head, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 0717 719477; 0776 399979 Email address: seru@kemri.org

MAKERERE UNIVERSITY
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Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool [*Lay Title:* Development and testing of a digital tool for recognizing sick children].

I, _____ (write your name), have had the study explained to me. I have understood everything that was explained to me. And I agree to take part in this study.

I understand that I can change my mind at any time, that if I do, nothing bad will happen to me and I will still get medical help.

Child's signature: _____**Date** _____

Child's name: _____ **Time** _____

Thumbprint of the child as named above if they cannot write: _____

For the Investigator:
I certify that I have followed all the study specific procedures for obtaining informed assent from this child.
Investigator's signature: _____ **Date** _____
Investigator's name: _____**Time** _____
(Please print name)

THE PARTICIPANT SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

MAKERERE UNIVERSITY
THE UNIVERSITY OF BRITISH COLUMBIA

Appendix I

Makerere University School of Public Health (MUSPH) Higher Degrees, Research and Ethics Committee

Informed Consent Form
(Usability Testing)
Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool

Principal Investigators

Dr. Mark Ansermino

Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia

Dr. Abner Tagoola

Senior consultant at Jinja Regional Referral Hospital, Jinja, Uganda

Co-Investigators

Samuel Akech	Kenya Medical Research Institute/Wellcome Trust Research Programme
Alishah Mawji	Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia
Matthew O. Wiens	Center for International Child Health, BC Children's Hospital Research Institute
Niranjan Kissoon	Department of Pediatrics, University of British Columbia
Edmond Li	School of Population and Public Health, University of British Columbia
Nathan Kenya Mugisha	Walimu

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THE UNIVERSITY OF BRITISH COLUMBIA

Invitation:
You are invited to participate in this research study because you are a nurse or student nurse at Jinja Regional Referral Hospital.

Your participation is voluntary:
Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts.

If you wish to participate in this study, you will be asked to sign this form. Please take time to read this information and ask any questions that may help you understand the study before you decide whether to participate.

Who is carrying out this study?
This study is being done by Makerere University School of Public Health (in Jinja), and the University of British Columbia (in Canada). These organizations do medical research to find better ways of preventing and treating illness. This study is being funded by Wellcome Trust, which is a charity based in the United Kingdom but funds health research worldwide to improve lives.

Background
There is an urgent need for low-cost, easy-to-use tools that can accurately predict critical illness in children. We have developed a digital triage tool comprised of an application on a mobile device and attachable pulse oximeter sensors that predicts a critically ill state, or level of risk in a child presenting at the hospital. The risk prediction is based on clinical signs and symptoms including vital sign measurements. This digital tool is to be used by frontline health workers to identify critically ill children (including those with sepsis) and trigger timely treatment administration.

What is the purpose of this study?
We would like to evaluate the digital triage tool for ease of interface navigation, functionality, and basic workflow. The objective of the training is to ensure health workers understand how to correctly collect and interpret patient information and obtain feedback on the digitization of the tool. We will recruit 15 health workers for this study.

What does the study involve?

You will be asked to perform a simulated clinical scenario to interact with the digital triage tool to examine its usability. You will be given a list of tasks to complete. You will be given instruction on how to "think aloud" (we will audio record your speech). When the test period is completed, you will be asked to fill out a short questionnaire, for your feedback and comments on the interface. The test will be completed in less than one hour and will be audio and video recorded.

What are the possible harms and discomforts?
There are no foreseeable risks in participating in this research study.

What are the potential benefits of participating?
There is no direct benefit to you for participating in this study. The results of this study will determine the usability of the digital triage tool, including possible areas for improvement. This will allow us to optimize and update the tool to meet hospital specific needs.

What happens if you decide to withdraw consent to participate?
Your participation in this research is entirely voluntary. You may withdraw from this study at any time without providing any reasons. If you decide to enter in the study and withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled.

Will my taking part in this study be kept confidential?
Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or her/his designate by representative, and the University of British Columbia Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a subject in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity (i.e. your name or any other information that could identify you) as a subject in this study will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request.

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What will the study cost?
There will be no cost to you for your participation in the study. You will not receive any payment for participation.

Who has approved this research?
All research at MUSPH must be approved before it begins by several national and international committees who look carefully at planned work. They must agree that the research is important, relevant to Uganda and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

Who do I contact if I have questions about the study during my participation?
You are free to ask questions of any staff at any time. You can also contact the research team using these contacts:

Dr. Nathan Kenya-Mugisha
Walimu Office
Unit 4, Plot 5, Coral Crescent, Kololo, Kampala
Tel: 0772-731-751
Email: kenya@walimu.org

Dr. John Ssempebwa
Acting Chairperson
HD Research and Ethics Committee
Tel: +256-772-963-074

Who do I contact if I have any questions or concerns about my rights as a subject?
If you have any concerns or complaints about your rights as a research subject and/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

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Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool

I, _____ (print name), have had the research explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I consent to participate in this study.

I understand that I can change my mind at any stage, and it will in any way affect the quality of care that I receive.

Participant's signature: _____ **Date** _____

Participant's name: _____ **Time** _____
(Please print name)

I have followed the study SOP to obtain consent from the participant. S/he apparently understood the nature and the purpose of the study and consents to the participation in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ **Date** _____

Designee/investigator's name: _____**Time** _____
(Please print name)

THE SUBJECT/PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

THE UNIVERSITY OF BRITISH COLUMBIA

KEMRI Wellcome Trust

KEMRI Wellcome Trust Research Programme: Patient Information and Consent Form

Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool [*Lay Title:* Development and testing of a digital tool for recognizing sick children]. Usability Testing.

Institution	Investigators
Kenya Medical Research Institute	Samuel Akech Mike English Grace Irimu Ambrose Agweyu Morris Ogero Cynthia Khazenzi Jalemba Aluvaala
Mbagathi Hospital	David Kimutai
Jinja Regional Hospital	Abner Tagoola
The University of British Columbia/BC Children's Hospital Research Institute	Mark J. Ansermino Niranjan Kissoon Matthew Wiens Guy Dumont Alishah Mawji

Invitation:
You are invited to participate in this research study because you are a nurse or student nurse at Mbagathi District Hospital.

Your participation is voluntary:
Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts.

If you wish to participate in this study, you will be asked to sign this form. Please take time to read this information and ask any questions that may help you understand the study before you decide whether to participate.

Who is carrying out this study?
This study is being carried out by the Kenya Medical Research Institute (in Nairobi), and the University of British Columbia (in Canada). These organizations conduct medical research to find better ways of preventing and treating illness in the

future. This study is being funded by Wellcome Trust, which is a charity based in the United Kingdom but funds health research worldwide to improve lives.

Background
There is an urgent need for low-cost, easy-to-use tools that can accurately predict critical illness in children. We have developed a digital triage tool comprised of an application on a mobile device and attachable pulse oximeter sensors that predicts a critically ill state, or level of risk in a child presenting at the hospital. The risk prediction is based on clinical signs and symptoms including vital sign measurements. This digital tool is to be used by frontline health workers to identify critically ill children (including those with sepsis) and trigger timely treatment administration.

What is the purpose of this study?
We would like to evaluate the digital triage tool for ease of interface navigation, functionality, and basic workflow. The objective of the training is to ensure health workers understand how to correctly collect and interpret patient information and obtain feedback on the digitization of the tool. We will recruit 15 health workers for this study.

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What are the potential benefits of participating?
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What happens if you decide to withdraw consent to participate?
Your participation in this research is entirely voluntary. You may withdraw from this study at any time without providing any reasons. If you decide to enter in the study and withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled.

Will my taking part in this study be kept confidential?
Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or her/his designate by representative, and the University of British Columbia Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a subject in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity (i.e. your name or any other information that could identify you) as a subject in this study will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request.

What will the study cost?
There will be no cost to you for your participation in the study. You will not receive any payment for participation.

Who has approved this research?
All research at KEMRI has to be approved before it begins by several national and international committees who look carefully at planned work. They must agree that the research is important, relevant to Kenya and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What if I have any questions?
You are free to ask questions of any staff at any time. You can also contact the research team using these contacts:

Dr. Samuel Akech, KEMRI Wellcome Trust Research Programme, P.O, Box 43640-00100 Nairobi, Kenya. Telephone: +254 721490166 or +254 20 270163

If you want to ask someone independent about this research please contact:
Community Liaison Manager, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 041 7522 063, Mobile 0723 342 780 or 0705 154 386
And
The Head, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 0717 719477; 0776 399979 Email address: seru@kemri.org

Who do I contact if I have any questions or concerns about my rights as a subject?
If you have any concerns or complaints about your rights as a research subject and/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

KEMRI Wellcome Trust Research Programme consent form for Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool [*Lay Title:* Development and testing of a digital tool for recognizing sick children]. Usability Testing.

I, _____ (print name),] have had the research explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I consent to participate in this study.

I understand that I can change my mind at any stage, and it will in any way affect the quality of care that I receive.

Participant's signature: _____**Date** _____

Participant's name: _____ **Time** _____

(Please print name)

I have followed the study SOP to obtain consent from the participant. S/he apparently understood the nature and the purpose of the study and consents to the participation in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ **Date** _____

Designee/investigator's name: _____**Time** _____

(Please print name)

THE SUBJECT/PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

Appendix J

Makerere University School of Public Health (MUSPH) Higher Degrees, Research and Ethics Committee

Informed Consent Form
(Triage Tool Training Questionnaire)
Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool

Principle Investigators

Dr. Mark Ansermino

Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia

Dr. Abner Tagoola

Senior Consultant at Jinja Regional Referral Hospital, Jinja, Uganda

Co-Investigators

Samuel Akech	Kenya Medical Research Institute/Wellcome Trust Research Programme
Alishah Mawji	Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia
Matthew O. Wiens	Center for International Child Health, BC Children's Hospital Research Institute
Niranjan Kissoon	Department of Pediatrics, University of British Columbia
Edmond Li	School of Population and Public Health, University of British Columbia
Nathan Kenya Mugisha	Walimu

What you should know about this questionnaire:

- You are being invited to complete a questionnaire.
- This consent form explains the nature of the questionnaire and your role when answering the questions.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to quit the study.

What is this questionnaire about?

We would like to invite you to complete a questionnaire that aims to learn from healthcare workers who have finished training on the *PRST tool* to help us evaluate the acceptability, usability and feasibility of the tool prior to implementation.

Who is carrying out this study?

This study is being carried out by the Makerere University School of Public Health (in Jinja), and the University of British Columbia (in Canada). These organizations conduct medical research to find better ways of preventing and treating illness in the future for everybody's benefit. This study is being funded by the Wellcome Trust Innovator Award.

What is the purpose of this questionnaire?

We will use this information gathered from the questionnaire to (1) ensure healthcare workers understand how to correctly collect and interpret patient information, and (2) ensure that healthcare workers are receiving the right kind of support from the training of the PRST tool.

Why are you being asked to participate?

You are being asked to partake in this questionnaire because you are currently a healthcare worker who has participated in a training session of the digital PRST tool. It is important that the staff who have received training in using the tool are consulted in order to properly evaluate the efficacy of the training for using the tool, and the tool itself.

Procedures:

If you agree to participate, we will ask you to complete a questionnaire form by paper and pen. The questionnaire will take less than half an hour. Your personal information will not be collected, so you feedback will not be linked back to you as an individual.

You may at any point during the questionnaire decide to withdraw. Feedback is welcome. If you consent to participate, and decide to withdraw at a later stage, an opt-out option will be provided.

Risks/Discomforts:

There are no potential risks associated with completing this questionnaire.

Benefits:

There are no direct benefits from completing this questionnaire.

Incentives/rewards for participating:

You will not be paid for completing this questionnaire.

Protecting data confidentiality:
The paper copies of the questionnaires will be kept in locked filing cabinets at the research office in the hospital. The electronic data obtained from these questionnaires will be stored on secure servers at BC Children's Hospital in Canada for analysis by the Kenyan, Ugandan and Canadian researchers.

Protecting subject privacy during data collection:
This questionnaire will be held in private. Your information will be kept completely confidential. No information that can identify you will be collected. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this program. This evaluation is being done by researchers from Kenya, Uganda and Canada.

What happens if you refuse to participate?
All participation in research is voluntary. It is up to you to decide whether or not you are to take part in the questionnaire. If you agree to participate, you will be asked to sign this form. If you do agree you can change your mind at any time and withdraw from the research. If you decide to complete this questionnaire, you are still free to withdraw at any time without giving any reasons for your decision.

What happens if you leave the study?
If you choose not to participate or to withdraw your consent, there will be no penalty or loss of benefits.

Who has approved this research?
All research at MUSPH has to be approved before it begins by several national [and international] committees who look carefully at planned work. They must agree that the research is important, relevant to Uganda and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What if I have any questions?
You are free to ask questions of any staff at any time. You can also contact the research team using these contacts:

Dr. Nathan Kenya-Mugisha
Walimu Office
Unit 4, Plot 5, Coral Crescent, Kololo, Kampala
Tel: 0772-731-751
Email: kenya@walimu.org

Dr. John Ssempebwa
Acting Chairperson
HD Research and Ethics Committee
Tel: +256-772-963-074

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the University of British Columbia Research Participant Complaint Line:
e-mail: RSIL@ors.ubc.ca
Toll Free Tel: 1-877- 822-8598

What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about the purpose, procedures, possible benefits and risks of this questionnaire.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to complete this survey.

Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool

I, _____ (name of participant), have had the research explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I agree to take part in this questionnaire.

I understand that I can change my mind at any stage, without penalty or loss of benefits.

Participant's signature: _____**Date** _____

Participant's name: _____ **Time** _____
(Please print name)

I have followed the study SOP to obtain consent from the participant. S/he apparently understood the nature and the purpose of this questionnaire and consents to participation in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ **Date** _____

Designee/investigator's name: _____**Time** _____
(Please print name)

THE SUBJECT/PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

KEMRI Wellcome Trust Research Programme: Informed Consent Form (Triage Tool Training Questionnaire)

Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool [*Lay Title:* Development and testing of a digital tool for recognizing sick children].

Institution	Investigators
Kenya Medical Research Institute	Samuel Akech Mike English Grace Irimu Ambrose Agweyu Morris Ogero Cynthia Khazenzi Jalemba Aluvaala
Mbagathi Hospital	David Kimutai
Jinja Regional Hospital	Abner Tagoola
The University of British Columbia/BC Children's Hospital Research Institute	Mark J. Ansermino Niranjan Kissoon Matthew Wiens Guy Dumont Alishah Mawji

Introduction:

What you should know about this questionnaire:

- You are being invited to complete a questionnaire.
- This consent form explains the nature of the questionnaire and your role when answering the questions.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to quit the study.

What is this questionnaire about?

We would like to invite you to complete a questionnaire that aims to learn from healthcare workers who have finished training on the *PRST tool* to help us evaluate the acceptability, usability and feasibility of the tool prior to implementation.

Who is carrying out this study?

This study is being carried out by the Kenya Medical Research Institute (in Nairobi), the Centre for International Child Health at the British Columbia Children's Hospital (in Canada), and the University of British Columbia (in Canada). These

organizations conduct medical research to find better ways of preventing and treating illness in the future for everybody's benefit. This study is being funded by the Wellcome Trust Innovator Award.

What is the purpose of this questionnaire?

We will use this information gathered from the questionnaire to (1) ensure healthcare workers understand how to correctly collect and interpret patient information, and (2) ensure that healthcare workers are receiving the right kind of support from the training of the PRST tool.

Why are you being asked to participate?

You are being asked to partake in this questionnaire because you are currently a healthcare worker employed at Mbagathi Hospital who has participated in a training session of the digital PRST tool. It is important that the staff who have received training in using the tool are consulted in order to properly evaluate the efficacy of the training for using the tool, and the tool itself.

Procedures:

If you agree to participate, we will ask you to complete a questionnaire form by paper and pen. The questionnaire will take less than half an hour. Your personal information will not be collected, so you feedback will not be linked back to you as an individual.

You may at any point during the questionnaire decide to withdraw. Feedback is welcome. If you consent to participate, and decide to withdraw at a later stage, an opt-out option will be provided.

Risks/Discomforts:

There are no potential risks associated with completing this questionnaire.

Benefits:

There are no direct benefits from completing this questionnaire.

Incentives/rewards for participating:

You will not be paid for completing this questionnaire.

Protecting data confidentiality:

The paper copies of the questionnaires will be kept in locked filing cabinets at the research office in the hospital. The electronic data obtained from these questionnaires will be stored on secure servers at BC Children's Hospital in Canada for analysis by the Kenyan, Ugandan and Canadian researchers.

Protecting subject privacy during data collection:

This questionnaire will be held in private. Your information will be kept completely confidential. No information that can identify you will be collected. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this program. This evaluation is being done by researchers from Kenya, Uganda and Canada.

What happens if you refuse to participate?

All participation in research is voluntary. It is up to you to decide whether or not you are to take part in the questionnaire. If you agree to participate, you will be asked to sign this form. If you do agree you can change your mind at any time and withdraw from the research. If you decide to complete this questionnaire, you are still free to withdraw at any time without giving any reasons for your decision.

What happens if you leave the study?

If you choose not to participate or to withdraw your consent, there will be no penalty or loss of benefits.

Who has approved this research?

All research at KEMRI has to be approved before it begins by several national [and international] committees who look carefully at planned work. They must agree that the research is important, relevant to Kenya and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What if I have any questions?

You are free to ask questions of any staff at any time. You can also contact the research team using these contacts:

Dr. Samuel Akech, KEMRI Wellcome Trust Research Programme, P.O, Box 43640-00100 Nairobi, Kenya. Telephone: +254 721490166 or +254 20 270163

If you want to ask someone independent about this research please contact:

Community Liaison Manager, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 041 7522 063, Mobile 0723 342 780 or 0705 154 386

And

The Head, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 0717 719477; 0776 399979 Email address: seru@kemri.org

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the University of British Columbia Research Participant Complaint Line:

e-mail: RSIL@ors.ubc.ca

Toll Free Tel: 1-877- 822-8598

What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about the purpose, procedures, possible benefits and risks of this questionnaire.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to complete this survey.

MAKERERE UNIVERSITY
THE UNIVERSITY OF BRITISH COLUMBIA

KEMRI Wellcome Trust Research Programme consent form for Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool [*Lay Title:* Development and testing of a digital tool for recognizing sick children].

I, _____ (name of participant), have had the research explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I agree to take part in this questionnaire.

I understand that I can change my mind at any stage, without penalty or loss of benefits.

Participant's signature: _____**Date** _____

Participant's name: _____ **Time** _____
(Please print name)

I have followed the study SOP to obtain consent from the participant. S/he apparently understood the nature and the purpose of this questionnaire and consents to participation in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ **Date** _____

Designee/investigator's name: _____**Time** _____
(Please print name)

THE SUBJECT/PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

MAKERERE UNIVERSITY
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Appendix K

Makerere University School of Public Health (MUSPH) Higher Degrees, Research and Ethics Committee

Informed Consent Form
(Interviews)
Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool

Principal Investigators

Dr. Mark Ansermino

Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia

Dr. Abner Tagoola

Senior Consultant at Jinja Regional Referral Hospital, Jinja, Uganda

Co-Investigators

Samuel Akech	Kenya Medical Research Institute/Wellcome Trust Research Programme
Alishah Mawji	Department of Anesthesiology, Pharmacology & Therapeutics, University of British Columbia
Matthew O. Wiens	Center for International Child Health, BC Children's Hospital Research Institute
Niranjan Kissoon	Department of Pediatrics, University of British Columbia
Edmond Li	School of Population and Public Health, University of British Columbia
Nathan Kenya Mugisha	Walimu

MAKERERE UNIVERSITY
THE UNIVERSITY OF BRITISH COLUMBIA

Invitation:
You are being invited to take part in a research study that uses interviews to understand more about the *PRST Digital Triage Tool*. We are interested in your experience with the *PRST Digital Triage Tool*. We would still like to hear from you even if you don't feel you have the necessary exposure or are not comfortable with using the tool.

Your participation is voluntary:
The following pages explain the study so that you can decide if you want to take part. It is up to you whether you would like to participate in an interview, so feel free to ask us any questions. If you want to take part you will be asked to sign this form. If you later change your mind you can quit at any time without giving a reason.

Who is carrying out this study?
This study is being done by Makerere University School of Public Health (in Jinja), and the University of British Columbia (in Canada). These organizations do medical research to find better ways of preventing and treating illness. This study is being funded by Wellcome Trust, which is a charity based in the United Kingdom but funds health research worldwide to improve lives.

You can take part in this study if you are:
- A hospital staff, including, doctors, clinicians, nurses, and administrators who have used or are familiar with the *PRST Digital Triage Tool*.
- Able to spend 60 minutes for an in-person interview on a pre-arranged date.
- Able to speak, read, and understand English.

We expect that about 30 hospital staff will be interviewed for this study.

What is the purpose of this study?
This study is part of the 'Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool' project. We would like to conduct an interview with you to hear your feedback and experiences with the PRST digital triage tool platform so that we can identify areas needing improvement and additional supports that may be required.

What happens if I decide to participate?

- You will be interviewed by the research team member at a private office here at the hospital facility either by yourself or in a small group. The total time this will take is approximately 60 minutes (approximately 45-minute interview, plus paperwork).

- This interview itself will take about 1 hour and will be audio recorded.

- We will type up the words from the audio recording and keep that version, called a transcript, for use in the study. You will have a chance to check this transcript to make sure it is correct and does not contain any information that could identify you.

- Before you begin the interview, we will ask you to complete a voluntary questionnaire about yourself (e.g., age, job position). This will help us understand who is participating in this study.

What are the possible harms and discomforts?
We do not expect this study to expose you to any risks. You can refuse to answer any question you do not wish to answer, and you can stop the interview at any time. You can withdraw from (or leave) the study at any time without any negative consequence. Information about you that is collected before you quit may still be used in a study report if you withdraw *after* the report has been written.

What are the potential benefits of participating?
By participating in the study, you will help our team better understand the experiences and feelings of hospital staff like yourself about the *PRST digital triage tool* platform and what additional support they may require.

How will you keep my personal information confidential?

- Any information you share with researchers will be kept confidential; all audio files and study notes will be kept secure at UBC in Vancouver. No documents or audio files which identify you by name or specific personal information will be allowed to leave the study team's offices.
- Only the UBC and Walimu team will have access to your personal information.
- You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you. Only this number or a pseudonym (made up name) will be used on any research related information that goes outside the study team. Your real name will not be used in any publications or reports.
- Your personal information will not be given to anyone outside the research team; however, research records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the UBC Children & Women Research Ethics Board and Makerere University School of Public Health (MUSPH) Higher Degrees, Research and Ethics Committee for the purpose of monitoring the research.
- All original study documents will be kept at UBC or in off-site storage locations in British Columbia for 5 years after the study is complete, and then destroyed (documents will be shredded, and digital files will be deleted).
- Transcripts with no names or identifying personal information in them will be kept secure at UBC for use in this study and possible future research by members of Mark Ansermino and Abner Tagoola's research team.

Risks/Discomforts:
There are no potential risks associated with participating in this interview.

Benefits:
There are no direct benefits from participating in this interview.

Incentives/rewards for participating:
You will not be paid for participating in this interview.

Who has approved this research?
All research at MUSPH must be approved before it begins by several national and international committees who look carefully at planned work. They must agree that the research is important, relevant to Uganda and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What if I have any questions?
You are free to ask questions of any staff at any time. You can also contact the research team using these contacts:

Dr. Nathan Kenya-Mugisha
Walimu Office
Unit 4, Plot 5, Coral Crescent, Kololo, Kampala
Tel: 0772-731-751
Email: kenya@walimu.org

Dr. John Ssempebwa
Acting Chairperson
HD Research and Ethics Committee
Tel: +256-772-963-074

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the University of British Columbia Research Participant Complaint Line:
e-mail: RSIL@ors.ubc.ca
Toll Free Tel: 1-877- 822-8598

What does your signature on this consent form mean?
Your signature on this form means:

- You have been informed about the purpose, procedures, possible benefits and risks of this questionnaire.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to complete this survey.

MAKERERE UNIVERSITY
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Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool

I, _____ (name of participant), have had the research explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I agree to take part in this study.

I understand that I can change my mind at any stage, without penalty or loss of benefits.

Participant's signature: _____**Date** _____

Participant's name: _____ **Time** _____
(Please print name)

I have followed the study SOP to obtain consent from the participant. S/he apparently understood the nature and the purpose of this questionnaire and consents to participation in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ **Date** _____

Designee/investigator's name: _____**Time** _____
(Please print name)

THE SUBJECT/PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

THE UNIVERSITY OF BRITISH COLUMBIA

KEMRI Wellcome Trust

KEMRI Wellcome Trust Research Programme: Informed Consent Form (Interviews)

Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool [*Lay Title:* Development and testing of a digital tool for recognizing sick children].

Institution	Investigators
Kenya Medical Research Institute	Samuel Akech Mike English Grace Irimu Ambrose Agweyu Morris Ogero Cynthia Khazenzi Jalemba Aluvaala
Mbagathi Hospital	David Kimutai
Jinja Regional Hospital	Abner Tagoola
The University of British Columbia/BC Children's Hospital Research Institute	Mark J. Ansermino Niranjan Kissoon Matthew Wiens Guy Dumont Alishah Mawji

Invitation:

You are being invited to take part in a research study that uses interviews to understand more about the *PRST Digital Triage Tool*. We are interested in your experience with the *PRST Digital Triage Tool*. We would still like to hear from you even if you don't feel you have the necessary exposure or are not comfortable with using the tool.

Your participation is voluntary:

The following pages explain the study so that you can decide if you want to take part. It is up to you whether you would like to participate in an interview, so feel free to ask us any questions. If you want to take part you will be asked to sign this form. If you later change your mind you can quit at any time without giving a reason.

Who is carrying out this study?

This study is being done by the Kenya Medical Research Institute and the University of British Columbia (in Canada). These organizations do medical research to find better ways of preventing and treating illness. This study is being funded by Wellcome Trust, which is a charity based in the United Kingdom but funds health research worldwide to improve lives.

You can take part in this study if you are:

- A hospital staff, including, doctors, clinicians, nurses, and administrators who have used or are familiar with the *PRST Digital Triage Tool*.

- Able to spend 60 minutes for an in-person interview on a pre-arranged date.
- Able to speak, read, and understand English.

We expect that about 30 hospital staff will be interviewed for this study.

What is the purpose of this study?

This study is part of the 'Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool' project. We would like to conduct an interview with you to hear your feedback and experiences with the PRST digital triage tool platform so that we can identify areas needing improvement and additional supports that may be required.

What happens if I decide to participate?

- You will be interviewed by the research team member at a private office here at the hospital facility either by yourself or in a small group. The total time this will take is approximately 60 minutes (approximately 45 minute interview, plus paperwork).
- This interview itself will take about 1 hour and will be audio recorded.
- We will type up the words from the audio recording and keep that version, called a transcript, for use in the study. You will have a chance to check this transcript to make sure it is correct and does not contain any information that could identify you.
- Before you begin the interview, we will ask you to complete a voluntary questionnaire about yourself (e.g., age, job position). This will help us understand who is participating in this study.

How will you keep my personal information confidential?

- Any information you share with researchers will be kept confidential; all audio files and study notes will be kept secure at UBC in Vancouver. No documents or audio files which identify you by name or specific personal information will be allowed to leave the study team's offices.
- Only the UBC and KEMRI team will have access to your personal information.
- You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you. Only this number or a pseudonym (made up name) will be used on any research related information that goes outside the study team. Your real name will not be used in any publications or reports.
- Your personal information will not be given to anyone outside the research team; however, research records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of the UBC Children & Women Research Ethics Board and the KEMRI Scientific Ethics and Review Unit for the purpose of monitoring the research.
- All original study documents will be kept at UBC or in off-site storage locations in British Columbia for 5 years after the study is complete, and then destroyed (documents will be shredded and digital files will be deleted).

- Transcripts with no names or identifying personal information in them will be kept secure at UBC for use in this study and possible future research by members of Mark Ansermino and Samuel Akech's research team.

Risks/Discomforts:

There are no potential risks associated with participating in this interview.

Benefits:

There are no direct benefits from participating in this interview.

Incentives/rewards for participating:

You will not be paid for participating in this interview.

Protecting data confidentiality:
The paper copies of the questionnaires will be kept in locked filing cabinets at the research office in the hospital. The electronic data obtained from these questionnaires will be stored on secure servers at BC Children's Hospital in Canada for analysis by the Kenyan, Ugandan and Canadian researchers.

Protecting subject privacy during data collection:
This questionnaire will be held in private. Your information will be kept completely confidential. No information that can identify you will be collected. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this program. This evaluation is being done by researchers from Kenya, Uganda and Canada.

What happens if you refuse to participate?
All participation in research is voluntary. It is up to you to decide whether or not you are to take part in the questionnaire. If you agree to participate, you will be asked to sign this form. If you do agree you can change your mind at any time and withdraw from the research. If you decide to complete this questionnaire, you are still free to withdraw at any time without giving any reasons for your decision.

What happens if you leave the study?
If you choose not to participate or to withdraw your consent, there will be no penalty or loss of benefits.

Who has approved this research?
All research at KEMRI has to be approved before it begins by several national [and international] committees who look carefully at planned work. They must agree that the research is important, relevant to Kenya and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What if I have any questions?

You are free to ask questions of any staff at any time. You can also contact the research team using these contacts:

Dr. Samuel Akech, KEMRI Wellcome Trust Research Programme, P.O, Box 43640-00100 Nairobi, Kenya. Telephone: +254 721490166 or +254 20 270163

If you want to ask someone independent about this research please contact:

Community Liaison Manager, KEMRI Wellcome Trust Research Programme, P.O. Box 230, Kilifi. Telephone: 041 7522 063, Mobile 0723 342 780 or 0705 154 386

And

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If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the University of British Columbia Research Participant Complaint Line:

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What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about the purpose, procedures, possible benefits and risks of this questionnaire.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to complete this survey.

KEMRI Wellcome Trust Research Programme consent form for Saving young lives: Triage and management of sepsis in children using the point-of care Paediatric Rapid Sepsis Trigger (PRST) tool [*Lay Title:* Development and testing of a digital tool for recognizing sick children].

I, _____ (name of participant), have had the research explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I agree to take part in this study.

I understand that I can change my mind at any stage, without penalty or loss of benefits.

Participant's signature: _____**Date** _____

Participant's name: _____ **Time** _____
(Please print name)

I have followed the study SOP to obtain consent from the participant. S/he apparently understood the nature and the purpose of this questionnaire and consents to participation in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature: _____ **Date** _____

Designee/investigator's name: _____**Time** _____
(Please print name)

THE SUBJECT/PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

BMC Health Services Research

STUDY PROTOCOL Open Access

Smart triage: triage and management of sepsis in children using the point-of-care Pediatric Rapid Sepsis Trigger (PRST) tool

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Abstract

Background: Sepsis is the leading cause of death and disability in children. Every hour of delay in treatment is associated with an escalating risk of morbidity and mortality. The burden of sepsis is greatest in low- and middle-income countries where timely treatment may not occur due to delays in diagnosis and prioritization of critically ill children. To circumvent these challenges, we propose the development and clinical evaluation of a digital triage tool that will identify high risk children and reduce time to treatment. We will also implement and clinically validate a Radio-Frequency Identification system to automate tracking of patients. The mobile platform (mobile device and dashboard) and automated patient tracking system will create a low cost, highly scalable solution for critically ill children, including those with sepsis.

Methods: This is pre-post intervention study consisting of three phases. Phase I will be a baseline period where data is collected on key predictors and outcomes before implementation of the digital triage tool. In Phase I, there will be no changes to healthcare delivery processes in place at the study hospitals. Phase II will involve model derivation, technology development, and usability testing. Phase III will be the intervention period where data is collected on key predictors and outcomes after implementation of the digital triage tool. The primary outcome, time to treatment initiation, will be compared to assess effectiveness of the digital health intervention.

Discussion: Smart technology has the potential to overcome the barrier of limited clinical expertise in the identification of the child at risk. This mobile health platform, with sensors and data-driven applications, will provide real-time individualized risk prediction to rapidly triage patients and facilitate timely access to life-saving treatments for children in low- and middle-income countries, where specialists are not regularly available and deaths from sepsis are common.

Trial registration: Clinical Trials.gov Identifier: NCT04304235, Registered 11 March 2020.

Keywords: Sepsis, Triage, Digital triage tool, Resource limited settings

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Background

The global burden of pediatric mortality in low- and middle-income countries (LMICs) remains high, with 4.9 million deaths in children under 5 in 2016 [1]. Most of these deaths are due to sepsis, which is defined as the body's response to an infection (such as pneumonia, diarrhea, or malaria) leading to organ damage and ultimately morbidity and mortality [2]. Sepsis is common worldwide, but countries in Africa report substantially higher case fatality rates (adjusted odds ratios: Africa, 7.89 [95% confidence interval (CI), 6.02–10.32]) as compared to the United States [3]. Recognizing the enormity of the global burden of sepsis (death, disability, social, and economic) led to a 2017 World Health Assembly resolution highlighting the need to prioritize prevention, recognition, and early treatment of sepsis [4].

Sepsis disproportionately affects socioeconomically disadvantaged populations in LMICs. Encouragingly, most deaths from sepsis are preventable by early detection and treatment. The majority of deaths occurring in health facilities happen occur as a result of delayed, inadequate, or inappropriate treatment. Every hour of delay in therapy is associated with an escalating risk of morbidity and mortality [5]. Simple, highly effective interventions to treat sepsis, including antimicrobials and intravenous (IV) fluids, are available at care facilities in LMICs. Yet availability and readiness to provide treatment is not always enough [6]—timely treatment may not occur because the sickest children are not prioritized.

The World Health Organization (WHO) advocates the use of Emergency Triage Assessment and Treatment (ETAT) guidelines to triage children in resource limited settings [7]. Although the ETAT system is widely adopted in LMICs, successful implementation of the guidelines into clinical practice is not always the case [8]. In LMICs, patients are frequently admitted and treated on a first-come, first-serve basis, leading to delayed care for children who are in need of urgent treatment. These priority children can receive faster treatment if every child is rapidly triaged upon arrival to identify danger and priority signs of sepsis [9]. However, sepsis is a syndrome that mimics many conditions and few health workers can confidently triage and diagnose sepsis. Evidence-based trigger tools and protocols may be useful in skilled hands, but require complex decision-making based on physiological, clinical, social, and laboratory parameters.

The purpose of this study is to develop and clinically evaluate a digital triage tool that can be used rapidly and reliably, without the need for extensive memorization or training, by frontline health workers (including nurses and non-physician clinicians) to identify critically ill children (including those with sepsis). The digital platform consists of a mobile application integrating a pulse oximetry sensor attached to the device, with embedded smart algorithms that predict a critically ill state, or level of risk in a child presenting at the hospital. The platform also includes an interactive dashboard located in strategic locations (e.g., laboratory, consultation rooms), which connects to the mobile application through a secure local network and displays the triage data to provide real-time monitoring for the physicians who manage the patients.

Over the past 10 years, we have developed, implemented, and evaluated the core technology of the Digital Triaging Platform including vital sign measurement devices (PhoneOx [10] and RRate [11]) and the mobile application and dashboard [12–14]. We have already identified candidate predictor variables using a modified Delphi process [15], and developed a risk prediction model based on the need for admission using predictors collected in over 1000 children at a Kenyan hospital [16].

Methods/design

This protocol was developed with adherence to Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.

Objectives

Objective 1

To develop and clinically validate a digital triage tool and dashboard for improving hospital wait times to treatment administration in critically ill children, including those with sepsis.

This will involve:

a. Collecting a pre-selected list of clinical variables (Additional file 1) from participants to develop a prediction model based on the need for hospital admission.
b. Developing digital triage tool by implementing the derived prediction model along with ETAT triage guidelines (currently followed at study hospitals) into the Digital Triaging Platform.
c. Evaluating the usability/feasibility of the digital trigger tool prior to implementation and routine use at the study hospitals.
d. Determining effectiveness of the triage tool by comparing hospital wait times to treatment administration for children before and after implementation of the digital triage tool.

Objective 2

To validate the use of an automated Radio-Frequency Identification (RFID) method to track timeliness of interventions (see RFID system section more information).

This will involve:

a. Simultaneously having trained Timekeepers track patient wait times manually, and an RFID system track patient wait times automatically.
b. Comparing time data obtained from the Timekeepers with time data obtained from the RFID system to evaluate accuracy of the RFID system.
c. Achieving routine use of a clinically evaluated RFID system to automate tracking of patient wait times in the study hospitals.

Trial design

This is a pre-post intervention study concerning pediatric patients presenting to the study hospitals in seek of medical care for an acute illness. The study will take place over a period of 24 months. Participant recruitment will be initiated in April 2020 and continue for approximately 12 months. Statistical analysis, results presentation and dissemination will be conducted in the remaining months.

Study procedures can be divided into three phases: (I) pre-intervention (baseline), (II) interphase, (III) intervention (Table 1).

Phase I: pre-intervention (baseline)

This will be a period of baseline data collection at Mbagathi County Hospital, Jinja Regional Referral Hospital, and Kiambu County Referral Hospital. There will be no changes to healthcare delivery procedures in the hospitals. Triage in the pediatric outpatient department will continue as per usual by hospital nurses using ETAT guidelines [7]. Research nurses will consent participants and collect health data (see Additional file 1) in the triage waiting area, where patients are waiting to be seen by the hospital triage nurses. The control site, Kiambu County Referral Hospital will participate in Phase I for an elongated period of time (see Table 1) and will not participate in Phase II or Phase III.

Phase II: interphase

Model derivation and technology development A risk prediction model will be derived using the data collected in Phase I and implemented in a Digital Triaging Platform, along with a digitized version of the ETAT+ guidelines. The Digital Triaging Platform, including vital sign measurement devices (PhoneOx [10] and RRate [11]) and the mobile application and clinical dashboard [12–14] has already been developed and evaluated. Once the digital triage tool has been developed, it will be evaluated in potential users using simulated patient scenarios and a 'Think Aloud' method.

Usability testing and training The digital triage tool will be evaluated for ease of interface navigation, functionality and basic workflow. A sample of 15 health workers in the study hospitals to represent the primary user groups will be selected for participation in the 60-min-long usability testing initiatives. Participants will be recruited through word of mouth as there is a very small cadre of potential participants. The objective of the training is to (1) ensure healthcare workers understand how to correctly collect and interpret patient information, and (2) to obtain feedback on the digitization of the tool. Training will use a framework that meets key international norms for testing digital tools, including, the think-aloud method and a questionnaire. Each training session will be conducted by a moderator and observer. During the evaluation, the observer will be seated next to the participant and will record user interaction with each interface, comments, errors, and duration of each task. Participants will be given 3–5 patient scenarios which will list hypothetical information to be entered into the app. This information will be designed to represent routine data collected during triage examination at the study hospitals. The moderator will provide the fictional charts to participants and instruct them throughout the tasks. During the simulated patient

Table 1 Study Schema

Experimental Sites:	Phase I Baseline (3–5 months)	Phase II Interphase (1–3 months)	Phase III Intervention (5–6 months)	Post-Data Collection (9–14 months)
1. Mbagathi County Hospital, Nairobi 2. Jinja Regional Referral Hospital, Jinja	Data collection of predictors and outcomes by **study** nurses.	Model derivation, technology development, usability testing.	Data collection continues as done in Phase I by **study** nurses. Routine use of digital triage tool by **hospital** nurses.	Analysis, results presentation and dissemination.
Control Site:	**Phase I (12 months)**			
1. Kiambu County Hospital, Nairobi	Ongoing baseline data collection.			

scenarios, participants will be asked to think aloud, in order to assess their thought process as they used the app. Participants will be specifically instructed to comment on the layout of the app screen, the dialogue on each interface, the order of tasks, and any additional observations or opinions. After learning the basics of the digital platform, the participants will be read the think aloud instructions and asked to perform the list of tasks and answer questions. The observer will complete a checklist to ensure that all tasks were completed, questions will be asked to evaluate task comprehension, and notes will be taken about whether help was needed in completing each task. At the end of the training session, participants will complete a triage tool training questionnaire to provide an understanding of the practical benefits and drawbacks of incorporating the digital triage tool into a clinical context. The questionnaire will utilize open ended questions and comment responses. From this evaluation. Responses from the survey will be anonymous. The data generated from the training phase is fictitious and will not be linked to any individual subject. Transcriptions and Think Aloud observations will be analyzed using the Framework Method [17] to assess attitudes of health workers. Responses will be transcribed and coded using NVivo [18], for the identification, examination and interpretation of emerging themes and patterns. Results from the analysis, feedback from the questionnaires, and comments on the observer checklists will be used to generate a report with suggested improvements to be shared with the quality improvement implementation team prior to Phase III.

Phase III: intervention

Phase III will be an interventional period involving routine use of the digital triage tool by the **hospital triage nurses** at Mbagathi County Hospital in Nairobi, Kenya, and Jinja Regional Referral Hospital in Jinja, Uganda. The digital triage tool will not replace triage policies in place at the study hospitals, but rather it will strengthen existing systems by integrating ETAT guidelines and a data-driven risk prediction model into the application. As done in Phase I, **study nurses** will consent participants and collect health data in the triage waiting area while patients are waiting to be seen by **the hospital triage nurses** (who will be using the digital triage tool). Continued collection of predictor variables will allow comparison of participant characteristics in the pre-intervention cohort and the post-intervention cohort.

Methods: participants, interventions, and outcomes

Study setting

This multi-site study will take place at one hospital in Uganda, and two hospitals in Kenya. In Uganda, the study will be conducted at Jinja Regional Referral Hospital in Jinja. Jinja, a city of approximately 90,000 people, is located in the Eastern region of Uganda. The Jinja Regional Referral Hospital pediatric ward admits approximately 5000 patients per year and the outpatient department sees approximately 100 patients per day. In Kenya, the study will be conducted at Mbagathi County Hospital and Kiambu County Referral Hospital, both located in Nairobi. A typical outpatient department (OPD) in the Kenyan study hospitals serves approximately 20,000 children per year and is staffed by one or two nurses who conduct triage and administer treatment, two or three clinicians who review patients and issue prescriptions, and one additional nurse who administers treatment and provides counselling to caregivers of children. The Kenyan hospitals admit approximately 2000 pediatric patients per year.

Study sites

1. Jinja Regional Referral Hospital, Jinja, Uganda (experimental site)
2. Mbagathi County Hospital, Nairobi, Kenya (experimental site)
3. Kiambu County Referral Hospital, Nairobi, Kenya (control site)

Eligibility criteria

Inclusion Criteria:

1. All pediatric outpatients seeking medical treatment of an acute illness. The lower age limit will include children aged from 0 days, and the upper age limit will be in accordance to respective hospitals' practice for pediatric admissions (this may be 12, 15 or 19 years).
2. Informed parental/guardian consent provided.
3. Assent from children older than 8 years (Uganda site) or 13 years (Kenya sites) in addition to parental/guardian consent provided.

Exclusion Criteria:

1. Patients presenting to the outpatient department for elective cases (e.g. elective surgery or change of dressing) or for clinical review appointment.
2. Informed consent or assent (when applicable) not provided.

Interventions

PRST (digital triage tool)

The PRST is a triage tool hosted on a digital platform that will enable frontline health workers in LMICs to identify critically ill children (i.e. severe infections, sepsis) early, so that life-saving treatment can be

administered in a timely manner. The digital platform will consist of a mobile application hosted on an Android tablet integrating a pulse oximetry sensor attached to the tablet, with embedded smart algorithms that predict a critically ill state, or level of risk in a child presenting to the hospital. The platform will also include an interactive dashboard which will display the triage data to provide real-time monitoring for the clinicians who manage the patients. The dashboard will be implemented as a password protected website accessible by registered medical staff on any computer or tablet on the local network, allowing for easy and non-disruptive integration into health systems with existing electronic health records. ETAT+ criteria for triage will be incorporated as part of the digital platform (in addition to model identified from data obtained in Phase I).

RFID system

Timing tracking will be automated using customised RFID. RFID uses radio-frequency electromagnetic fields to identify the location of patients carrying special tags, with the help of readers located in key locations around the hospital, including the registration area, triage examination rooms, and treatment rooms. We intend to use Low Energy Bluetooth (BLE) tags that have a diameter of approximately 3 cm and weigh < 20 g. These tags will be inserted into a custom, washable arm, wrist or leg band. The tag could also be retained by the caregiver if the child was not willing to have the tag attached to them. When in close vicinity to a reader (for example, in the same room), the tag (location beacon) sends a message to a strategically located receiver to track the time at which the patient was in that precise location. The Bluetooth frequency is no different to that used by mobile phones and is not expected to interfere with other processes in the hospital. The RFID system will allow health workers to keep track of patients with ease and has the potential to increase organization in fast-paced, overburdened healthcare facilities.

Outcomes

Primary outcomes

For model development Hospital admission (within 5 days of assessment) status determined from hospital records, and a follow up call 7 days post discharge. This will inform development of a clinical prediction model based on need for hospital admission.

For effectiveness evaluation of digital triage tool An increase of at least 20% in the proportion of critically ill children (emergency and priority cases) receiving an appropriate bundle of care within 60 min of arrival at the hospital. An appropriate bundle of care is defined as at least one of antibiotics, intravenous fluids, or oxygen as appropriate for age and clinical syndrome as determined and administered by **hospital staff**.

Secondary outcomes

1. Length of hospitalization determined from hospital records, and a follow up call 7 days post-discharge.
2. Final diagnosis determined from hospital records.
3. 7-day post-discharge mortality status determined from a follow up call 7 days post-discharge.
4. 7-day readmission status determined from a follow up call 7 days post-discharge.
   a. Facility of readmission.
   b. Treatment received during readmission.

Participant involvement

Total study participation time is estimated to be a maximum of 60 min per participant in both the baseline (phase I) and intervention (phase III) periods.

Participant involvement in phase I and phase III

Potential participants will be recruited by study nurses while they are waiting in line to be seen by the hospital triage nurses. Participants can anticipate study procedures (including consent, clinical examination, and interview) to take between 35 to 50 min. The study nurses will conduct study procedures in the triage waiting area, while the participant is waiting in line to be seen by the hospital triage nurses. If it is the participant's turn to be seen by the hospital triage nurses, study procedures will stop and there will be no interference or delays in accessing standard care. Participants will also engage in a short (10 min) follow up call 7-days post-discharge.

Additional procedures in phase III

In the intervention period, the hospital triage nurses will be conducting triage using the digital triage tool (which will include a digitized version of the triage guidelines in already place at the study hospitals). It is important to understand that the digital triage tool will NOT be replacing standard care, but rather it will be integrated into standard care to supplement and strengthen existing triage systems.

To reiterate, the study nurses will conduct the same study procedures (consent, clinical examination, and interview) in both the baseline (Phase I) and intervention (Phase III) periods. These procedures are conducted while the participants are waiting in line to be seen by the hospital triage nurses. The difference in Phase III is that the hospital triage nurses (that the participants are waiting in line to see) will be using the digital triage tool to triage participants.

Sampling and recruitment

Sample size

Model development considerations The sample size for model development is based on two components: the number of predictors expected in the final model (effective variables), n, and the outcome event rate, I. We employ the typical minimum standard of 10 events per effective variable and calculate the sample size as $N = (n \times 10)/I$. Based on our previous study at a Kenyan hospital [16], we estimate the admission rate as $I = 12\%$, and thus, to allow for a model with 10 predictors we require a minimum sample of 833 children.

Power to detect difference considerations Based on an assumed pre-intervention rate of 27% of children who receive a bundle of care within 1 h, an assumed 20% relative increase due to the intervention, and an alpha of 0.05, an estimate of 750 children per group is needed for 80% power. The assumed pre-intervention rate is consistent with previous studies [19] and confirmed in our feasibility trial of the application and dashboard in Uganda.

Selected sample size Based on the uncertainty commonly present in these smaller sample sizes [20], the desire to include the possibly of modelling non-linearities in our models (using machine learning methods) and the clinical feasibility (large case load) we plan to target a larger sample of 4000 at each site, with a minimum sample size of 1000 participants enrolled in Phase I. Based on the activity at our selected sites this would require no more than a 60% recruitment rate during a six-month period.

Sampling strategy

A systematic method for participant selection based on time cut-offs will be adopted to minimize sampling bias. The study nurses will be instructed to screen the first patient arriving after each time cut-off (i.e. first patient to arrive after every 30-min cut-off). If the patient is not eligible, the next patient arriving after the time cut-off will be selected, and so on. The interval between time cut-offs will reflect the time a study nurse spends with each participant (35–50 min) to maximize efficiency. When there is more than one study nurse on a given shift, the time intervals will be staggered.

Methods: data collection, management, and analysis

Data collection

Predictors, hospital outcomes, 7-day follow-up calls

All study nurses will be trained and well versed on the standard operating procedures to facilitate standardization of all measurements. Study nurses will collect data using a custom-built Android application on a Samsung Galaxy Tablet A8. The list of predictors to be collected include clinical signs and symptoms, demographic/sociodemographic data, and pregnancy/birth information (see Additional file 1). Similarly, designated study nurses will obtain hospital outcomes (see Additional file 1) from patient records and enter them into the application on the Samsung Galaxy Tablet. Study nurses will conduct 7-day follow up calls in accordance with the standard operating procedures and enter the data into the application on the Samsung Galaxy Tablet.

Time outcomes

Timing tracking will be automated using customised RFID (see RFID system section for details).

Usability testing data

Think Aloud transcriptions and observer checklists will be entered into a computer and uploaded to REDCap. The Triage Tool Training Questionnaire (Additional file 2) will be captured on paper and stored in a locked cabinet, in a locked room in our research spaces nearby the study sites.

Post-study healthcare worker satisfaction survey

After completion of Phase III of the study, healthcare workers that participated in the usability testing initiative will be invited to complete a Healthcare Worker Satisfaction Survey (Additional file 3). This will be used to generate a report that provides insight on the overall perception of health worker's experiences with the digital triage tool.

Data management

Data collection infrastructure

Study Nurses will collect data using a custom-built Android application, created using LambdaNative (lambdanative.org), the open-source cross-platform toolkit developed internally at BC Children's Hospital Research institute. All data entered into the mobile application is stored in an encrypted database using the encryption cipher Rabbit. Access to the tablet and application is secured by passwords; without using the application, the encrypted files are not readable. The Masimo iSpO2® Pulse Oximeter with Micro USB Connector will be used to collect pulse oximetry and heart rate (including 30 s of raw plethysmographic data) and the Masimo Caregiver™ non-contact thermometer will be used to measure core temperature. The data collection application also contains complex error checking specific to the survey questions such as date inconsistency checks and ensures only relevant data items are collected, by dynamically hiding redundant questions.

Due to the complex nature of a large multi-center study, data will be uploaded directly from the Android tablets to REDCap (Research Electronic Data Capture, https://projectredcap.org/). REDCap is a secure web-based application designed to support data capture for research studies and it has been used for over 300,000 projects, in over 100 countries, including prior studies in Uganda [13]. Encrypted data will be stored for less than 14 days after completion of data collection on the tablets. In Kenya, the data will be directly uploaded weekly (depending on internet availability) over a secured internet connection to KTWRP servers, where it will be stored. A deidentified copy will be sent to the central study server at the BC Children's Hospital Research institute where data will be checked for completeness and consistency with data definitions. In Uganda, the data will be sent to the central study server at the BC Children's Hospital Research Institute. After this upload, the data on the tablets will be deleted. Each subject will be given a unique number and all data will be connected to this unique number. Using REDCap limits the amount of paper-based data, further ensuring data integrity and safety. The uploaded data will be accessible to only study team members with secure access to the server.

Data collected during follow-up interviews conducted by phone or in person will also be collected electronically and shared in the same secured manner. Personal identifiers are required for the collection of admission data and follow-up data. The data collection application contains several forms. All identifiers are collected on a single form, separate from the other forms containing non-identifying information, and stored in a separate and restricted REDCap form. Access to identifiers will be limited to those requiring this data for follow-up (i.e. only study personnel involved in follow-up or data verification). No analysts, co-investigators or principal investigators not directly involved in the follow-up or data verification will have access to this data. Access to REDCap will require 2-way authentication: in addition to the normal password process, a secure code (sent via SMS to the user) will be required for access to this data.

Paper based data collection items include consent forms and research assistant field notes (which do not contain identifiers). These will be stored in a locked cabinet, in a locked at our research spaces next to each study site.

Health intervention infrastructure

The bundle of care during the intervention will include triage in the OPD using an additional custom Android web-app, running locally on the device with no required Internet connection. As with the data collection app, this application will be password protected and data will be stored encrypted on the device. Following each triage, the triage data will be sent to a local low-cost Unix server Soekris box based in a secure room at each site. Data will be sent through encrypted HTTPS requests to server-side PHP scripts, which insert it within MySQL tables.

The clinician dashboard that will be used to clinically manage all children in the OPD who have been triaged will be implemented as a password protected website accessible by registered medical staff on any computer or tablet on the local network. As with the triage app, this website runs completely locally, independent of an outside Internet connection and is not accessible from offsite. The dashboard is implemented using the Laravel (https://laravel.com), a PHP web framework, which queries the MySQL server tables securely. Personal identifiers will be collected in the triage app and sent to the server for display on the dashboard as is necessary for correct identification of patients, but such information will never leave the hospital site. As the study hospitals already have computers in their OPDs, use of the clinical dashboard will not be extra work for the hospital staff or interfere with other tasks.

Statistical analysis

Model development

The predictive model for severe infection and sepsis in children will be developed based on the need for hospital admission of 24 h or longer. To find the best performing, and most parsimonious model, a variety of model building techniques will be compared. These will include but are not limited to: stepwise regression based on Akaike's Information Criterion (AIC), penalized regression via elastic net, and random forest [21]. Models will be compared based on the area under the receiver operating curve, and the specificity achieved at high (80–90%) sensitivity thresholds. Models within 10% of the best performing model will be considered. Final model selection will depend on parsimony, availability of predictors across sites (based on resources, cost and feasibility of collection), discrimination and calibration. All model comparisons will take place within an internal validation resampling framework such as cross validation or bootstrapping. Risk thresholds to stratify participants into triage categories (emergency, priority, and queue) be selected based on sensitivity analysis and expert opinion. To account for geographical differences and disparities in disease prevalence (high malaria prevalence in Jinja, Uganda), we will use net reclassification improvement to optimize and re-calibrate (if required) the prediction model [22].

RFID system validation

We will validate the RFID technology against a human timekeeper control for the time to bundle of care outcome by investigating bias and accuracy using a Bland

Altman analysis. The RFID technology will be considered as interchangeable with a human timekeeper if the 95% limits of agreement fall within +/− 5 min. We chose this cut off as delays in bundle of care delivery below this threshold is unlikely to be of clinical significance. We will use the first 100 pairs of RFID and human measurements to calculate a mean difference and standard deviation of difference between the two measurements. Using these two values and a clinically acceptable limit of 5 min, with an alpha of 0.05 and beta of 0.2, we will calculate the sample size required for the Bland Altmann analysis by methods previously described [23]. If the 95% limits of agreement fall outside of 5 min, the same Bland Altman analysis will be done for the patient arrival time and time of bundle of care delivery; these comprise of the start and end time components of the time to bundle of care outcome. These secondary analyses serve to ascertain which of the two components contains the larger discrepancy between RFID and human measurement. Should these secondary analyses be necessary, implementation issues in the RFID technology will be brainstormed in focus groups with the technology team and addressed on the ground, and we will repeat the same validation process as described. After successful logistical improvements and validation of the RFID technology to within 5 min of a human timekeeper, we will utilize the RFID technology for data collection with a human timekeeper as backup as needed.

Outcomes analysis

We will be conducting our primary analysis using a difference in differences method. For our primary analysis, a logistic regression model for receipt of bundle of care within 1 h will be fit including: 1) phase of study (pre vs. post PRST) and 2) group (intervention versus control) as independent dummy variables and 3) their interaction. The interaction term corresponds to the difference in log-odds between groups in baseline vs intervention and it's exponent as the ratio of odds ratios. We will summarise this difference by estimating the marginal effect (risk difference) of phase in both the control and intervention groups. The difference of these marginal effects is the so-called 'difference in difference' for a binary outcome [24]. Confidence intervals will be based on the delta-method, or bootstrapping, where appropriate. A similar approach will be used for binary secondary outcomes (mortality, readmission), or quantile regression for median time to bundle of care, a non-parametric outcome.

Subgroup analyses specified a priori include Ugandan vs. Kenyan intervention site, young infant (under 2 months old) vs. children under 5 vs. older children, and presentation during day-shift hours versus night-shift hours (if applicable). We will also perform subgroup analyses on each triage category (emergency, priority, queue); patients from the pre-intervention phase will be retroactively categorized into these subgroups for this analysis. These subgroup analyses will be conducted with the inclusion of a three-way interaction between said variable, phase, and group. Statistical significance will be based on a likelihood ratio test comparing models with and without this term. This three-way interaction term would represent potential interactions between different subgroups and our difference in odds ratio obtained in our primary analysis, and results will again be presented on the risk difference scale based on marginal effects. This method of subgroup analysis sometimes termed a difference in difference in differences method.

Although none are expected, if there are any time varying confounders identified during the study that differ between intervention and control (health system or policy changes, natural events, changes in patient populations etc.) they will be included in above models as sensitivity analyses.

As we are continually collecting data regarding predictors for admission alongside the clinical team, there is the possibility that our research activities may interact with the efficiency of delivering the sepsis bundle of care. Although the possibility of such interaction is minimized by our use of dedicated research personnel who would not approach patients who are actively receiving clinical care, any such interactions could potentially limit the external validity of our study to non-research-controlled settings. Therefore, to assess this potential interaction, we will pause the collection of predictor data 1 month before and after implementation of the PRST program. This pause will also occur in the control group in order to replicate any bias caused by changes in our primary outcome attributable to the pause rather than the PRST program. To investigate the potential for this bias, we will treat the collection or non-collection of predictors as a dummy variable for subgroup analysis using the difference in difference in differences method described above.

All analyses will be conducted using R statistical software [25], and an alpha level of 0.05 will be considered statistically significant for all outcome analyses.

Methods: monitoring

Data monitoring

Internal monitoring of study processes will be done regularly by the study coordinators at each hospital site. During monitoring, data and consent forms for 10% of enrolled participants will be reviewed for compliance. Retraining of study staff will be done to correct for any inconsistencies noted during monitoring and follow-up will be subsequently done by the study coordinator to ensure compliance. Given that the digital triage tool is

community and health system level intervention, a data monitoring committee was not deemed necessary.

Data completeness will be continuously monitored using daily, weekly and monthly reports. Accuracy of data will be verified using an audit of 5% of cases by a data manager who will not be involved in enrolling subjects. Preliminary data quality checks and analysis will be performed throughout the data collection stage to ensure that data collected is valid and secure. These data quality checks will include checking the quality of pulse oximetry waveform data via implementing a Signal Quality Index (SQI) algorithm and checking for completeness and validity of input data. Further data quality checks will inspect the number of patients enrolled, the number of patients admitted, and the timed outcome data. Upon completion of data collection, a summary of the data collected will be compiled and will be discussed by the investigators and the study nurses to ensure that data is clean, correct and useful.

Ethics and dissemination

Research ethics approval/protocol amendments

Ethical approval has been obtained from Makerere University School of Public Health (MUSPH) Higher Degrees, Research and Ethics Committee, Kenya Medical Research Institute (KEMRI) Scientific & Ethics Review Unit (SERU), and The University of British Columbia/ Children's and Women's Health Centre of British Columbia Research Ethics Board (UBC C&W REB). MUSPH provided approval for the study to be conducted at Jinja Reginal Referral Hospital in Jinja, Uganda. KEMRI SERU provided approval for the study to be conducted on behalf of both Mbagathi County Hospital and Kiambu County Referral Hospital in Nairobi, Kenya. A copy of the protocol proposed informed consent forms, other written participation information, and any proposed advertising material will be submitted for written approval. The investigators will submit and, where necessary, obtain approval from the Institutional Review Board (IRB) for any major protocol amendments and changes to the informed consent document. The study team are responsible for assuring that this protocol and the associated informed consent documents and study-related documents are approved prior to implementation of the protocol. Any major amendments to the protocol, informed consents, or other study- related documents must be approved by the IRB prior to implementation.

Informed consent and assent

All consent materials will be approved by all three IRBs listed in the section above prior to use.

The study nurses will be responsible for screening and consenting participants. This would be the norm in Kenya and Uganda. The study nurses will be certified and trained to ensure that the caregiver has a complete understanding of the consent processes, the consent form, and that the caregiver is of legal age (18 years old) and competent to provide consent.

In obtaining and documenting informed consent, the site investigators and their designees will comply with applicable local and domestic regulatory requirements. This clinical study will have a paper-based informed consent form (ICF) for enrollment developed for local use that are in accordance with applicable guidelines. The consent form will include the purpose of the study, a description of the procedures to be followed and the risks and benefits of participation. The informed consent process will give individuals all of the relevant information they need to decide whether to participate, or to continue participation, in this study. Potential research participants' caregivers will be encouraged to ask questions and to exchange information freely with the study team. Participants will be informed on who to contact (Principal Investigator) should they have any questions during, or after the study period. If the caregiver providing consent is illiterate, an independent witness will be present to verify to the caregiver that all the information read aloud is contained in the ICF. In this instance, both the caregiver and witness will sign the ICF. The caregiver will voluntarily sign, thumbprint and date (thumbprint acceptable if illiterate who will also require a witness) the consent form if they wish to participate in the study and will be provided with a copy of the consent form. A signed and dated copy of the consent form will be kept in the documentation file at all times.

There will be consent forms specific to Phase I and Phase III. Assent will be sought for children aged 13 and older in Kenya, and for children aged 8 and older in Uganda. The lower age limit for assent was selected based on site-specific requirements, which differ in Kenya and Uganda. Consent will also be sought for participation in usability testing initiatives, the Triage Tool Training Questionnaire, and the Healthcare Worker Satisfaction Survey. Consent forms will be made available in English and the local language of the catchment population at each study site, which is Kiswahili in Kenya and Luganda in Uganda.

In emergency cases, consent will be deferred until the child is stable and study procedures will only begin after initiation of emergency treatment. Study procedures will not delay or interfere with access to standard care. If consent is not granted, the data will be deleted. This deferred consent procedure is to avoid introduction of bias by neglecting to obtain data from the most severely ill children while avoiding delays in providing care to the child. This procedure has been used in previous studies

involving children with severe illness, including use by the Fluid Expansion As Supportive Therapy (FEAST) study [26].

Confidentiality

Data will be stored and distributed using password protected locations and secure data transfer. All data entered into the digital triage tool is stored in an encrypted database using the encryption cipher Rabbit. Access to the digital tool is secured by passwords and without using the application, the encrypted files are not readable. Encrypted data will be stored for a maximum of 2 weeks on the tablets before being directly uploaded and stored stored in a secure research server at MUSPH (Uganda), or KEMRI (Kenya), and UBC. After this upload, the data on the devices will be deleted. Data will be entered into the digital triage tool using a REDCap electronic data collection form. REDCap is a secure, web-based application designed to support data capture for research studies. Each subject will be given a unique number and data will be connected to this unique number. Using REDCap limits the amount of paper-based data; further ensuring data integrity and safety. The uploaded data will be accessible to any team member with secure access to the server, including investigators from MUSPH, KEMRI, and UBC. Standard operating procedures will be implemented for the security of data, physical devices and networks. All research staff will be well trained and understand that privacy and confidentiality are imperative. All paper forms used for consent will not contain the study number. These forms will be stored in our research spaces near the study sites under lock and key, for the duration of the study and for any additional time required by the local and/or national guidelines at the time.

Risks/adverse events

We do not anticipate any adverse events directly attributable to the study. The most significant risk in this study is a small delay in treatment administration due to inappropriate triage by the digital triage tool. This delay would not be significantly different from the baseline standard of care. The risk of an adverse event is minimal as the digital triage tool will only be used to guide the frontline health workers in identifying critically ill children in need of prompt assessment. All subjects will still be assessed by a healthcare provider regardless of triage status assigned by the digital tool.

All children enrolled into this study will receive standard care according to local, regional and national guidelines. No study procedures will take place which in any way interfere with the prescribed care. Study procedures will be delayed, when necessary, to ensure that these procedures will not impact recommended care.

Other potential risks include:

RFID tagging

The RFID tag is a new and unfamiliar piece of technology that needs to be worn or attached to participants who may not feel comfortable with it. We will ensure that participants/caregivers are fully aware of the purpose of wearing the RFID tag and how the system works. Further, the tag is a tiny piece of plastic that can be easily concealed and will not cause any discomfort to participants. This has been discussed with our local PI's and local ethics committees in Kenya and Uganda. This has been approved by both the local and national ethics committees.

Blood sampling

Blood sampling will only be conducted when clinically indicated are already routine hospital procedures. This will not be done by research staff for research purposes, but rather we will be ensuring the resources are available to the hospital nurses to do this testing if indicated. These will be communicated by the consultant during the consultation that follows the triage process.

Coercion

Caregivers may feel coerced to enroll in the study in order to receive care for their child within a research setting, which may be perceived as of a higher quality than the standard of care. This will be minimized by ensuring that study nurses emphasize that the child will receive medical care whether enrolled in the study or not.

Access to data

After the study period, a de-identified copy of the data will be prepared for deposition in a repository with open access with proper governance mechanisms. We will make every effort to prevent re-identification of subjects by coding data that has the potential of being identifiable. For example, we will convert all dates into meaningful decimal numbers (date of birth into days since birth and date of recruitment will be reduced to month of recruitment) and all locations will coded into data that is useful but not specific (such as address converted to distance and direction from facility). We will ensure that data elements with small numbers of subjects (less than 10) will be coded or lumped to avoid identification. The de-identified study data will be made publicly available using the Harvard Dataverse (https://dataverse.harvard.edu/), which is the data repository for KWTRP, and a URL will be made accessible. To enhance visibility, sharing and collating datasets with other collaborating sites for increased usability/re-use, de-identified will also be shared availed to reputable data hosting service such as the INDEPTH Data Repository (http://www.indepth-

ishare.org/index.php/home), or through the newly established Pediatric Sepsis CoLab (sponsored by the World Federation of Pediatric Critical and Intensive care Societies). Sharing and access will be managed and subject to institutional agreements (KEMRI and UBC) that will set terms for how requests and access will be managed. We will ensure that a rigorous data governance structure is used by the data hosting service. The distribution will only occur with agreement from Principal Investigators and the investigators at all of the study sites. Data will also be shared through peer reviewed publications and through the Wellcome Trust open data initiatives. Data will be made available within 12 months following completion of the study.

Presentation and dissemination of results

Results presentation

The results of this research will be primarily presented through at least one published manuscript with detailed description of the background, methods, results, and conclusion. The specific format and details of this manuscript will be in accordance with the requirements of the publishing journal. All usage of data for publications and other forms of data dissemination will occur jointly between collaborative institutions and include authors from both sites in all publications.

Dissemination

Results will be disseminated to local hospital teams and key stakeholders such as at the annual conference held by the Kenya Pediatric Association (KPA). A robust knowledge translation approach is a key aspect of our transition and scale-up. An integrated equity-oriented cascade approach [27] will be used to guide knowledge translation across the duration of the project. We will engage the "6 Ps" stakeholder groups (public, patients/caregivers, policymakers, practitioners, press, and private sector), all of which are critical to the successful outcome of our project. Our key knowledge translation activities will employ a rich range of communication channels and will be multifaceted: academic, governmental, policy-driven, and public-facing. Methods of dissemination will include social media, radio, websites, progress reports, workshops, community meetings, executive summaries, technical reports, verbal presentations to key stakeholders, peer-reviewed scientific publications and conference presentations. All relevant reports, publications and data will be freely available online.

Discussion

Our team has demonstrated that simple and affordable technology can circumvent the lack of training and assist in identification and follow-up of high-risk children following treatment for infections [28]. Our technology aims to improve the quality of care, defined as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Quality of care is suboptimal in many LMICs, where more than 8 million people die yearly from conditions that should be treatable by the health system [9]. Nearly 60% of these deaths are from conditions that should respond to appropriate health care but occur due to poor-quality care [29].

The PRST will facilitate data-driven and evidence-based improvements to the quality of care provided to children with critical illness (i.e., sepsis). The digital platform consists of a mobile application integrating a pulse oximetry sensor attached to the device, with embedded smart algorithms (which include ETAT guidelines) that predict a critically ill state, or level of risk for children presenting to the outpatient department. The platform also includes an interactive dashboard located in strategic locations (e.g., laboratory, consultation rooms), which connects to the mobile application through a secure local network and displays the triage data to provide real-time monitoring for the physicians who manage the patients. Additionally, an RFID method for tracking patients will be used to automatically collect data on the timeliness of interventions. The dashboard and RFID tracking system will increase data accuracy and completion, enhance communication and empower health workers, and improve resource allocation.

Using the PRST, each child presenting to the healthcare facility is rapidly triaged based on clinical symptoms, signs, and vital signs, which are captured by frontline health worker in less than 5 min. Based on these data, smart algorithms in the mobile application assign a level of risk (emergency, priority, queue) to each child. Following identification of risk, we target the expedited administration of evidence-based, low-cost interventions such as antibiotic, fluid, and oxygen therapy. The timely administration of this life-saving bundle of care is driven by the triage data displayed on the dashboard.

The main objective of the PRST is to enable frontline health workers to recognize the most urgent children more rapidly and allocate necessary resources more efficiently. We designed the PRST specifically for use in low-resource settings. The mobile application, integrated pulse oximetry sensors, and dashboard are easily accessible, affordable, robust to internet and power interruptions (system includes a secure local network that does not require an active internet connection) and do not rely on sophisticated expertise to operate.

Performance of the PRST may vary depending on geographical location, season, and with different disease prevalence and severity. Standardized measurements will

be collected at sites in both Kenya and Uganda in order to explore these differences and optimize performance of the PRST at each site. External validation will be necessary to determine generalizability in other LMICs.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s12913-020-05344-w.

Additional file 1. Smart Triage Data Dictionary.

Additional file 2. Triage Tool Training Questionnaire.

Additional file 3. Healthcare Worker Satisfaction Survey.

Abbreviations

AIC: Akaike's Information Criterion; BC: British Columbia; BLE: Low-energy Bluetooth; CI: Confidence interval; ETAT: Emergency Triage and Treatment; FEAST: Fluid Expansion As Supportive Therapy; HTTPS: Hypertext Transfer Protocol Secure; ICF: Informed consent form; IEC : Independent Ethics Committee; INDEPTH: The International Network for the Demographic Evaluation of Populations and Their Health; IRB: Institutional Review Board; IV : Intravenous; KEMRI : Kenya Medical Research Institute; KPA: Kenya Pediatric Association; KWTRP: KEMRI-Wellcome Trust Research Programme; LMIC: Low- and middle-income countries; MUSPH: Makerere University School of Public Health; OPD: Outpatient Department; PHP: Hypertext Preprocessor; PRST : Pediatric Rapid Sepsis Trigger; REDCap: Research Electronic Data Capture; RFID: Radio-Frequency Identification; SERU: Scientific & Ethics Review Unit; SMS: Short Message Service; SQI: Signal Quality Index; UBC: University of British Columbia; UBC C&W REB: University of British Columbia/ Children's and Women's Health Centre of British Columbia Research Ethics Board; URL: Uniform Resource Locator; USB: Universal Serial Bus; WHO: World Health Organization

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Authors' contributions

UBC affiliated investigators AM, EL, JMA, NK, MOW, and GD conceived and designed this study with significant contributions from investigators in Kenya, SA and DK, and in Uganda, CK, AT, and NKM. EL, JNB, and AM developed the analytic approach. DD was responsible for software development, data collection systems, and data management. AM led the principal drafting of the protocol. All authors read, reviewed, and approved the final protocol.

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Availability of data and materials

Within 12 months of study completion, de-identified study data will be made publicly available. The de-identified study data will be made publicly available using the Harvard Dataverse (https://dataverse.harvard.edu/), which is the data repository for KWTRP, and a URL will be made accessible. To enhance visibility, sharing and collating datasets with other collaborating sites for increased usability/re-use, de-identified will also be shared availed to reputable data hosting service such as the INDEPTH Data Repository (http://www.indepth-ishare.org/index.php/home), or through the newly established Pediatric Sepsis CoLab (sponsored by the World Federation of Pediatric Critical and Intensive care Societies).

Ethics approval and consent to participate

Ethical approval has been obtained from Makerere University School of Public Health (MUSPH) Higher Degrees, Research and Ethics Committee, Kenya Medical Research Institute (KEMRI) Scientific & Ethics Review Unit (SERU), and The University of British Columbia/ Children's and Women's Health Centre of British Columbia Research Ethics Board (UBC C&W REB). MUSPH provided approval for the study to be conducted at Jinja Reginal Referral Hospital in Jinja, Uganda. KEMRI SERU provided approval for the study to be conducted on behalf of both Mbagathi County Hospital and Kiambu County Referral Hospital in Nairobi, Kenya. Written informed consent will be obtained from all caregivers/participants prior to enrollment.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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