Development of mHealth Applications for Pre-Eclampsia Triage

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***Abstract*—The development of mobile applications for the diagnosis and management of pregnant women with pre-eclampsia is described. These applications are designed for use by community-based health care providers (c-HCPs) in health facilities and during home visits to collect symptoms and perform clinical measurements (including pulse oximeter readings). The clinical data collected in women with pre-eclampsia are used as the inputs to a predictive model providing a risk score for the development of adverse outcomes. Based on this risk, the applications provide recommendations on treatment, referral, and reassessment. c-HCPs can access patient records across multiple visits, using multiple devices that are synchronized using a secure Research Electronic Data Capture server. A unique feature of these applications is the ability to measure oxygen saturation with a pulse oximeter connected to a smartphone (Phone Oximeter). The mobile health application development process, including challenges encountered and solutions are described.**

***Index Terms*—Decision support, mobile health (mHealth) application, oxygen saturation, pre-eclampsia, predictive model, risk score.**

I. Introduction

THE hypertensive disorders of pregnancy, and in particular pre-eclampsia (commonly defined as the presence of new hypertension and proteinuria in pregnancy) and eclampsia (commonly defined as seizures during pregnancy not from a pre-existing condition), remain one of the top two causes of global maternal mortality and morbidity [1]. The majority of these deaths occur in low- and middle-income countries (LMICs) primarily due to delays in triage (early identification of who is at risk), prompt treatment, and transportation to facilities that can provide expert care [2]. PIERS on the Move (POTM) is a low-cost, easy-to-use, mobile health (mHealth) application for accurately predicting the risk of adverse outcomes associated with pre-eclampsia in pregnant women. This application combines two separate previously successful innovations: 1) a predictive score, called the mini pre-eclampsia integrated estimate of risk (miniPIERS) score [3], and 2) the Phone Oximeter, consisting of a smartphone application and pulse oximeter sensor [4]. The application identifies the risk of adverse outcomes in pregnant women with pre-eclampsia and suggests actions to manage this risk. The prediction of adverse outcomes is based on symptoms, clinical signs, and the blood oxygen saturation (SpO_2) level, as measured with the Phone Oximeter.

This paper describes the design process of two versions of the POTM application, the original version (application referred to as POTM), and a simplified, community-based version for the Community Level Interventions for Pre-eclampsia cluster randomized controlled trial (application referred to as CLIP POTM), which is taking place in Nigeria, Mozambique, Pakistan, and India [5].

A. Application Versions

The original POTM was developed for trained nurses and midwives in South African health facilities. After three usability studies with iterative improvements to the design, a clinical study at Tygerberg Hospital in Cape Town, South Africa, has been undertaken. At the time of publication, 202 women have been assessed with the POTM application as part of the clinical study. The purpose of this study is to verify that POTM correctly identifies women who are at high or low risk of adverse maternal outcomes. Meanwhile, iterative improvements to the application have continued based on additional usability tests and feedback from the health care providers involved in the clinical study.

In the CLIP trial [5], community-based health care providers (c-HCPs) will use the CLIP POTM application during their regular antenatal visits to pregnant women. It is planned that more than 500 c-HCPs will use the application to assess over 30 000 pregnant women throughout their pregnancies. The CLIP POTM version is simplified for ease of use by the c-HCPs who have less medical training than the users of the original version of POTM. The design process of modifying POTM for CLIP included a series of rapid prototyping mockups of the application presenting the mapping of study protocols to

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application pages and individual page layouts. Prototypes of the working CLIP POTM application were then implemented. At each stage, feedback from the study leaders in the participating countries was obtained. In addition, members of our team have visited each country to provide future users with prototypes of the CLIP POTM. Their feedback led to further modifications in the design, thus ensuring the application is optimized for efficient use and acceptance among the users.

The design process described in this paper includes the specification of features and the user interface design choices made during development. Also described, are the details of the implementation, including the dynamic visit protocol and the synchronization of data across study devices. Many challenges encountered during this process are highlighted along with potential solutions.

II. Background

A. Predictive Model

The fullPIERS [6] clinical prediction model predicts adverse maternal outcomes occurring as a result of pre-eclampsia, based on demographics, symptoms, clinical signs (including SpO_2), and laboratory tests. However, the laboratory tests are frequently not available outside of a tertiary hospital setting. The miniPIERS model [3] was developed to avoid the need for these laboratory tests and uses only simple demographics, symptoms, and clinical signs; this simplified prediction model includes parity, gestational age at presentation, systolic blood pressure, dipstick proteinuria, and the presence of the following symptoms: chest pain, shortness of breath, headache, visual disturbances, and vaginal bleeding with abdominal pain. The miniPIERS model outputs a score for the risk of an adverse outcome. This score, a probability rating, is used within a decision tree model to give treatment recommendations. In addition, the decision tree includes past maternal adverse events, the current stage of pregnancy, and SpO_2.

B. Phone Oximeter

The Phone Oximeter [4] is a smartphone application, which receives data in real time from a connected pulse oximeter.

A pulse oximeter is a noninvasive sensor that measures oxygen saturation by shining infrared and red light through a part of the body, such as a finger. The noninvasiveness and potential low cost of this sensor technology facilitates its mobility and use in low resource settings. Unfortunately, artifacts caused by improper application of the sensor or movement of the patient during recordings can limit the robustness of the measurement. The risk of recording inaccurate data can be mitigated by clearly displaying the data quality in real time. The Phone Oximeter accomplishes this within the smartphone application (see Section IV-B).

Smartphones are rapidly becoming available in many low resource settings and their small size and weight facilitate their use during home visits. The developed Phone Oximeter applications can run on existing smartphones, already owned or used by health care providers. Another advantage of using smartphones is that they can serve as communication devices to facilitate escalation of care and a 3G or Wi-Fi connection allows sending of data to a central server. GPS functionality can also be used to track data collection locations.

The Phone Oximeter was first developed as a mobile application for use in continuous monitoring of SpO_2 during anesthesia [4] and later in data collection applications for 1-min spot-checks of SpO_2 [7] in a range of studies taking place in LMICs. The applications were developed using the LambdaNative framework, which provides the ability to compile applications for Android or iOS operating systems [8]. For the POTM clinical study, the application is running on iPod Touch (fourth generation model; Apple Inc., Cupertino, CA) and iPhone (3 GS A1303 model; Apple Inc.) devices and for the CLIP trial, the application will run on Android (4.0; Google Inc., Mountain View, California) devices. These Android phones are manufactured by companies located in Asia and Africa. Mobile phone adoption in LMICs is increasing rapidly. Africa has seen an enormous growth in mobile phone usage in recent years, with 648.4 million mobile phone subscriptions in 2011, more than in the United States or the European Union [9]. This provides an ideal opportunity to embrace the use of mHealth applications.

C. Related Work

Even before smartphones, personal digital assistants (PDAs) were used as the first electronic mHealth tools. They offer a significant advantage over paper data collection even when it is necessary to train the local health care workers. Blaya *et al.* [10] demonstrated that PDAs were more efficient than paper and preferred for collecting tuberculosis bacteriology data in Peru. Data were collected over a large geographical area, much of which did not have Internet access. The CLIP trial will be performed in similar environments.

Thriemer *et al.* [11] also compared PDAs with paper data collection forms for hospital registration of feverous patients in Tanzania. Data entry by PDA was found to be much faster and cheaper despite the added cost of the devices. Direct data entry also saves the cost and time of data reentry from paper to an electronic record, and PDA data entry was greatly preferred by the users. The PDA forms included follow-up questions, which automatically appeared only if deemed appropriate based on the previous answers. The POTM applications also include this form of branching logic to show or hide the applicable fields and forms dynamically based on previous field values. Finally, Byass *et al.* [12] used PDAs successfully for household surveys in Burkina Faso, using GPS to record locations as is done in the POTM applications.

All of the aforementioned studies took advantage of mobile devices to perform data validation and inform the user of any errors. Byass *et al.* found that missing data still occurred and unfortunately often went unnoticed until the end of the study. For our applications, data are uploaded regularly and viewing of the online reports can rapidly identify these errors and missing entries. None of these studies included connecting sensors directly to the data collection device, whereas the Phone Oximeter applications connect directly to a pulse oximeter.

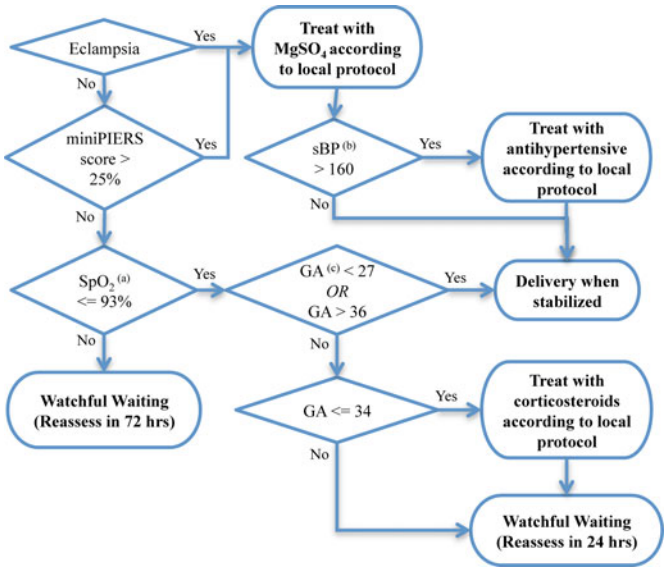

Fig. 1. Simplified diagram of the decision tree for a pregnant woman who is not in labor and is eligible for the POTM clinical study. [a]SpO_2 = blood oxygen saturation, in percent. [b]sBP = systolic blood pressure, measured in millimeters of mercury. [c]GA = gestational age of the fetus, measured in weeks.

III. Specifications

Specification documents were created to detail and define the requirements and design parameters of the applications. These documents provided guidance and documentation for the entire application development process. The requirement specifications contain a general description of the goal of the project and the specific requirements necessary to achieve this goal. The design document includes property tables and flowcharts to define the content and order of data collection application pages. The same iterative design and development cycle was used for each of the two applications, which consisted of the specifications, portable document format (PDF) mockups, and then prototypes. Throughout the process, user feedback was obtained and usability studies were performed with the prototypes.

A. Decision Support

The decision tree for determining treatment recommendations was an important component of the specification development for the application. The goal of this decision tree is to use the collected data to direct management and suggest treatments based on the risk of adverse events in the individual patient.

Even when the miniPIERS score is below a threshold of 25% (low risk), low SpO_2 (93% or below) is considered to indicate a woman at high personal risk for complications. Based on our previous research into predicting adverse maternal outcomes using pulse oximetry, the optimal threshold for the SpO_2 is 93% [13]. Preliminary data from our POTM clinical validation study have also shown that combining the SpO_2 directly into the miniPIERS predictive model increases the power of the model [14]. This adjustment may be made in future studies.

The decision tree defines which data are used in the decision making process and the order in which the data are used. Fig. 1 is a simplified (assumes patient is eligible and still pregnant) diagram of the POTM decision tree used with all women in the clinical study who have not already experienced an adverse event. To be eligible, a woman must be hypertensive (systolic blood pressure greater than 140 mmHg), or have proteinuria with severe signs or symptoms. A pregnant woman who already has eclampsia or another adverse maternal outcome does not need the miniPIERS score calculated. For those women who have experienced an adverse event, the process of fetal delivery is initiated once the patient has been medically stabilized.

To ease the workload of the c-HCP, the CLIP data collection protocol is dynamic, with only a limited dataset being required during each home visit. CLIP POTM enforces variations in the study protocol requirements for data collection based on whether it is the first visit with a patient or a subsequent visit with historical data available for the patient. This selective dynamic display of application pages ensures that the c-HCP follows a set path through the study protocol based on the clinical status of the specific woman. For example, CLIP POTM provides three methods for calculating the estimated date of delivery (EDD) of the pregnant woman. This calculation is only necessary during the first visit, unless it was previously entered using the symphysis-fundal height method with a measurement of less than 24 cm. This is due to the inaccuracy of measurements performed during early pregnancy (low fundal height). The c-HCP must measure the fundal height at each visit until it is at least 24 cm. CLIP POTM uses this logic to only display the EDD page when appropriate.

Another example of dynamic application flow is present on the ‘‘Signs” page. This page displays a two-by-two grid of fields for entering two readings of the blood pressure, each of which include systolic and diastolic values. If a third reading is deemed necessary (e.g., if the two systolic or diastolic readings vary by more than 10 mmHg), the grid automatically expands to include a third column. The c-HCP is trained to know that an additional confirmatory measurement should be performed; however, by automatically displaying the third column, CLIP POTM seamlessly enforces adherence to the study protocol. The mean systolic and diastolic values are calculated and a systolic blood pressure of 160 mmHg is used as a threshold for severe hypertension.

The application selectively requires the performance of additional investigations. If the woman is hypertensive, the application will suggest the need for a dipstick proteinuria measurement and ask about the symptoms the woman is experiencing. This type of flexible protocol is established within the specification as a flowchart. The protocol would be much more complex to follow if data collection was being done on paper, which would require full memorization of the flowchart by each c-HCP.

IV. Application Design

The POTM and CLIP POTM applications have been developed through an iterative process heavily influenced by our previous Phone Oximeter applications and usability studies with potential users.

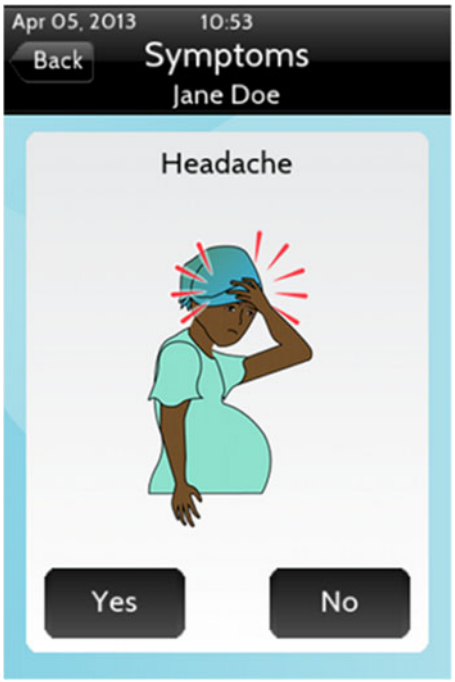

Fig. 2. Symptom page in CLIP POTM. To increase ease of use of the application by c-HCPs, the page design has been simplified and a language independent pictogram has been used.

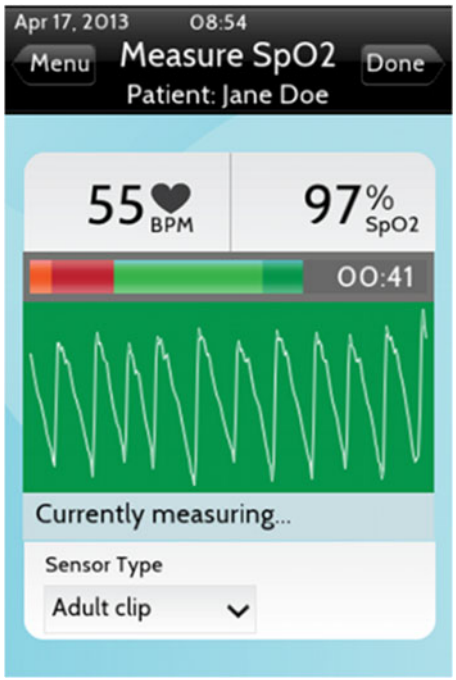

Fig. 3. Oxygen saturation spot-check page within POTM. A simple color-coding of the signal quality is used as the current waveform background color and within the progress bar to show quality over time. This example shows a recording at the 41 s mark (of 60 s). The start of the recording was poor quality data, as shown by the red section on the left, but the newest data are of excellent (green) quality.

A. *Mockups*

Once the specification document was approved, the next stage was the creation of application mockups. Mockups were created using Balsamiq Mockups (Balsamiq Studios, Sacramento, CA), which provides a simple drag-and-drop interface for placing common graphical elements on a page. Graphical elements, such as buttons, can also link pages together. The resulting series of mockups was exported as an interactive PDF file providing a walk-through of the application. This was much easier and faster than programming prototypes and led to rapid iterative modifications of the application design. Rapid feedback on the design could be obtained from investigators in the CLIP study countries who consulted with their team (including future users) by simply emailing them the mockup PDF. These international team members were not required to perform a software install process and the PDF could be annotated with standard document annotation tools.

B. *User Interface Design*

The user interface designs of POTM and CLIP POTM consider the user's technical abilities, the type of data being collected, and the size of the mobile device display. In CLIP POTM, the amount of data being collected has been significantly reduced as the c-HCPs have minimal medical training and minimal smartphone experience. Thus, the amount of data entry was reduced and the displays have been simplified compared to the original POTM application. Buttons have been made larger and easier to press on the smaller mobile device screen.

In CLIP POTM, language independent and culturally appropriate pictograms are used throughout the application to complement the text fields (see Fig. 2). The country specific pictogram of the symptom is displayed with the simple choice (Yes or No) for the presence or absence of the symptom in the woman being assessed. In contrast, within the POTM application, the symptoms were listed on a single screen with no pictograms, which also included follow-up questions and intensity ratings for each symptom present. Section IV-C describes other changes in the design that were motivated by usability studies and user feedback.

For both applications, multiple language support was required. Translations in the necessary languages are stored as a comma-separated value file with one column per language. Translated text was required to be within a certain length so it would fit within the application. The translation text file is the source for all static text displayed within the application. Choosing a language from the login screen specifies which column to use in the translation file. CLIP POTM can display right-to-left text such as Arabic characters.

The oxygen saturation page of POTM is used to perform spot-check measurements of SpO_2. The design of this page was influenced by previous Phone Oximeter applications and feedback received from users [4]. The Phone Oximeter has been used in five data collection studies in Uganda, Bangladesh, and India. The goal of this page is to ensure that an accurate SpO_2 recording is made. This is accomplished by clearly displaying the quality of the signal in the current recording (see Fig. 3). A pulse oximeter must be precisely applied and remain in place with minimal movement during recordings or artifacts will occur

in the signal. Artifacts will result in an inaccurate SpO_2 value, which will in turn undermine the reliability of the decision tree.

By directly connecting the pulse oximeter to a mobile device in POTM, the risk of an inadequate recording can be mitigated. The direct connection of the pulse oximeter to the mobile device provides real-time access to not only the SpO_2 and heart rate (HR) trends, but also the photoplethysmogram (PPG) waveform and a number of error flags supplied by the pulse oximeter module. For increased reliability, the application takes a 1-min-long recording, rather than an instantaneous reading. The PPG waveform is shown onscreen throughout this recording. The median values of the SpO_2 and HR trends are calculated over this minute, but all sections of the recordings with low signal quality are excluded from the calculation.

A signal quality index (SQI) algorithm rates the quality of data, in 1-s segments, in real time [7]. The output of the SQI algorithm is a rating with a range from 0 to 100, where the range from 90 to 100 is considered to be of a high quality.

The user interface clearly displays the signal quality using color and displays an explanatory message if the quality is low. The SQI value is mapped to a simple color-coded scale from dark red for an SQI of 0 to green for high quality (90–100). The SQI color is used as the background color for the waveform and is also the color added to the progress bar for each second during a recording. The progress bar shows the changes in signal quality throughout the recording (see Fig. 3). This progress bar fills from left to right with the current data quality color as the recording progresses. If the progress bar has very little green within it, the user should cancel the recording and attempt to reposition the sensor or reduce movement in the patient before attempting another measurement. Once a green background has been obtained, a new recording can be commenced. Below the waveform a short message provides the current status of the recording that explains any current problem with the signal (e.g., "No sensor: Check connection"). During the recording, the current trend values are displayed above the progress bar. At the end of the recording, the median values are shown. On some patients, it may not be possible to get a high quality signal for a full minute. In such a case, the user may choose to accept a recording that has some low quality sections within it. Only the high quality (green) sections of the recording are included in the median SpO_2 and HR trend calculations.

C. Usability Studies

The inclusion of health care personnel in the countries that are anticipated to use the application in the development of the specifications, design, and usability studies has been essential to the creation of an easy-to-use application. A total of 37 nurses and midwives evaluated the user interface through three usability studies from November 2011 to January 2013. Each usability study demonstrated improvements in the ease of use of the application, and also provided valuable information on how to further improve the interface and information flow. All tasks within the usability studies were timed and carefully monitored. Any errors in normal use of the app were recorded and then categorized by severity (from problematic to critical) and section of the application (keypad, navigation, etc.). Options to prevent these errors in the future were then devised, discussed and implemented before the next usability study.

The first usability study revealed that entering patient contact details was the most time-consuming task. This task only occurs when first creating a patient record and the difficulty in completing it quickly was due to user inexperience with a small onscreen keypad. The keypad size was expanded for the next usability study, resulting in a decrease in mean task completion time from 10:24 (minutes:seconds) to 5:46. The POTM application tasks during an evaluation are much faster than the entering of contact details, with the mean time for an entire evaluation being reduced from 16:38 to 14:34 between usability studies.

Although the use of mobile devices is becoming widespread in the CLIP trial countries, many of our potential users have not had prior experience with smartphones or at least have not used any smartphone applications involving data collection. For example, many of the users did not know how to scroll on a touchscreen device. To address this problem, the amount of information on one screen has been kept to a minimum and if scrolling is necessary, the application auto-advances the scrolling as the user enters data. Some users were unaware of the purpose or use of a dropdown list. The interface now avoids the use of dropdown lists, and instead shows all options simultaneously with checkboxes or radio buttons. This makes navigation more intuitive for novice users as it more closely resembles the paper data collection forms familiar to them.

For all three usability studies, users completed the poststudy system usability questionnaire [15]. Overall, users were pleased with the application, and believed it would improve their ability to care for hypertensive women.

D. Data Security

As with any clinical study, collected data must be stored securely. Security is a challenge when data are collected on mobile devices used by the c-HCP during their home visits to pregnant women. If unencrypted data were stored on a device and this mobile device was stolen or misplaced, unauthorized parties could access the data.

Strategies have been developed to ensure data are only accessible to those authorized to access the data. First, all of the data stored by CLIP POTM are encrypted using the Blowfish algorithm [16], a symmetric Feistel cipher using a 128-bit key. The only access to this data is through using the application, which requires a username and password. No effective cryptanalysis has been developed for breaking the full 16-round Blowfish algorithm used in these applications [17]. Second, to deter the theft of devices, all devices are clearly marked as being used for medical research purposes.

E. Data Tracking

Within the CLIP trial, c-HCPs will perform their visits without supervision therefore a method was needed to verify that these visits were actually performed. In addition, if inconsistencies in data are discovered, a method to determine which steps led to poor data quality was required to ensure more accurate

data collection in the future. For these reasons, CLIP POTM uses GPS-based location information and includes an audit trail of each c-HCP's modifications to the data on the device.

The c-HCP must login to the application using secure user-specific credentials to initiate data entry. Each time a c-HCP logs into the device the audit trail file is amended. This file initially contains the user name, time, and the version of the application being used. Each time the user creates a new record; adds, edits, or deletes field values; or has values calculated by the application, the action is added to the audit file. Thus, if a team leader needs to view a record of all the actions taken by a c-HCP, they can retrieve this file from the device. Additionally, the application uses the GPS coordinates provided by the device to track usage. The application records the current GPS location each time a new visit begins.

To enable recording of complete audit trails, it is necessary that each c-HCP have their own username and password credentials. It is not possible, nor should it be necessary to setup in advance a master list of all users who will use all the devices involved in a study. Instead, the task of user control is delegated to local data managers who will be more knowledgeable about individual users than any higher level investigator. Initially, an instance of the CLIP application has a single default administrator password. These credentials are shared only with the data managers at each study cluster center. The administrator credentials allow them to login to the setup pages of CLIP POTM. The administrator can then add, edit, or remove individual c-HCP users and setup their passwords. These newly created credentials can then be used to login to the main application functions on the specific device. This protocol allows flexibility for adapting the user list when c-HCPs leave or join the study, and it also maintains security, as only the administrator password will work on all devices. This type of credentials organization is much simpler than centrally administering all usernames and passwords, which would require extensive communication with study sites and a synchronization process for the credentials.

The local administrator setup pages allow the entry of the cluster ID associated with their location. This ID is used at the start of each patient's ID within that study cluster and is used to enable targeted data synchronization as described in the next section.

F. Data Synchronization

Datasets collected during the POTM clinical study and CLIP trial are each stored on Research Electronic Data Capture (REDCap) [18] servers. Synchronization with the online REDCap project uses the REDCap application programming interface (API) and maximizes the advantages of data collection on a mobile device. It provides easy data transfer from each device to a central location and allows data to be synchronized between multiple devices. Data synchronization is required to allow women to be seen by a different c-HCP or with a different device at subsequent visits. The historical visit data and basic demographic data should be available on each device within a study cluster. This is accomplished by using the REDCap API upload and download record functions.

TABLE I
SYNCHRONIZATION STEPS

REDCap transaction	Processing
Download All record IDs	Filter IDs to only include those in the cluster.
Download Form timestamps for all cluster records	Compare downloaded timestamps to local timestamps to determine data to upload and data to download.
Upload Cluster data newer on mobile device	Upload demographic data and then visit data. If either set is larger than 1MB, separate into smaller uploads. New records may be created on REDCap.
Download Cluster data newer on REDCap server	Only download one set of REDCap forms (across all patients) at a time: Demographic, Visit 1, Visit 2, etc. Save data by adding new records, overwriting old visit data, and adding new visits to existing records.

In the synchronization process, each device uploads all of its new data to REDCap and downloads all new relevant data (collected by other devices) from REDCap.

There are numerous technical challenges to this data synchronization process. First, there is the potential for conflicting data and data loss. Establishing clear rules regulating data editing minimizes this risk. Second, the REDCap project does not allow access to a normalized database or provide SQL query procedures; instead the API treats the entire data collection as one large table. The synchronization process (see Table I) uses multiple steps to work around this problem. Third, Internet connections within the countries targeted for the study have limited speed and connectivity. Thus, the synchronization algorithm limits the transfer of data to only new and necessary data.

Conflicts with data synchronization were likely to occur if a patient's record was edited on two different devices and then these devices were both synchronized with REDCap. Each patient record consists of a set of demographics and zero or more assessment visits. The CLIP POTM conflict resolution strategy consists of always using the newest values when changes are made to the demographic baseline data and restricting changes of visit data to the single device that initiated the visit.

Each visit is identified by a start timestamp and universal unique identifier (UUID) for the device. The first time CLIP POTM is run on a device, a UUID is generated to identify the device based on version 4 of the UUID specification [19]. The UUID of the device is saved with a visit when it is started.

Historical visit data for a patient are available within CLIP POTM during the subsequent c-HCP visits but these data cannot be edited on a different device. Editing of historical visits is allowed to remedy data entry errors, but only within 24 h of a visit and on the same device. Deleting a visit is also possible, but only within 24 h and only for incomplete visits. New (less than 24 h old) incomplete visits are not uploaded to REDCap. These rules ensure the maintenance of records on the devices. As visits can only be edited in one location, there is no possibility of conflicts in their values.

To assist with synchronization, CLIP POTM has an additional timestamp field for each REDCap form with the last updated time. Demographic data for a patient can be updated on any device. The form timestamps are specifically used to determine which instance of a form is newer, the local copy or the one on REDCap. Additionally, demographic data should never be deleted, only updated. By default, the REDCap API upload ignores blank values so none of the field values will be overwritten with blank values.

Local Internet connectivity for CLIP POTM is not typically available during home visits. Thus, no live search of records can happen during a c-HCP's home visit. The historical data must already be present on the device. For this reason, the synchronization process (see Table I) ensures that all the newest data from all women within a study cluster are present on all the devices within that cluster.

The synchronization process is designed to transfer only new data specific to the research cluster (geographical region). All IDs within a cluster begin with the same digits, but the REDCap API does not provide SQL queries, so the application must perform the filtering on a list of all IDs and then use the filtered list to download the specific cluster data. Initially, downloading only the timestamp fields of records in the cluster greatly reduces the data download requirements when compared to downloading all data. The timestamps from the local records are compared to the downloaded timestamps and new information overrides old information. If the REDCap timestamp is older or does not exist, then the local data are uploaded. If the local timestamp is older or does not exist, then the REDCap data are downloaded. No action is performed if the timestamps are identical.

The aforementioned process enables each device to stay up to date with all the data from across the cluster, provided that the device is synchronized on a regular basis.

V. Discussion

The miniPIERS model integrated into an mHealth application combined with a pulse oximeter and used within clinical studies is a large step forward in reducing adverse events related to pre-eclampsia and eclampsia. The decision making for this complex disease has many challenges in settings that lack medical expertise.

The successful development of an mHealth tool, as with any application, must consider the user and the setting in which it is deployed. Achieving the acceptance of the mobile application by investigators in the countries involved in the CLIP trial has been an ongoing process and a learning experience for all involved. This effort involves introducing new processes and new technology to users with very little relevant technology experience. The users required significant amounts of training, but they also provided valuable feedback that led to new ideas on how to simplify the information presented in the application. An mHealth application for use in a hospital setting will be very different from an mHealth application for use in the community, even if they have a similar desired outcome.

CLIP POTM began with a single specification document, but we discovered differing requests from the different countries with their cultural differences, leading to modified application versions for each country. In addition to different pictograms and languages, some of the data fields and recommendations for treatment were specific to users and locations. For example, in India, an Accredited Social Health Activist (ASHA) performs the home visit, but must bring the woman to an Auxiliary Nurse Midwife (ANM) if they require treatment. The CLIP POTM for India was altered to advise the ASHA to refer to an ANM when necessary rather than directly recommending the treatment. In India, the CLIP study will also be using the Maternal Newborn Health numbers that already exist as unique identifiers of women, instead of creating a new CLIP ID number for each woman.

In addition, use cases of real world scenarios must be considered. In certain circumstances, such as when the patient is having a seizure, the data collection must be cut short to provide rapid life saving treatment. Based on feedback from a site visit to India, first aid information was added to the application for managing an adverse outcome. While waiting for transport, the c-HCP is given the option of continuing data collection.

The development of an mHealth application requires considerations of data security and synchronization, but above all, the application must be developed with input from users. This is necessary to design a flexible application that considers the users training and limitations and anticipates possible scenarios that will be encountered.

VI. Future Work

The POTM and CLIP POTM applications apply the power of mobile devices and pulse oximetry to the task of pre-eclampsia adverse outcome prediction, monitoring, triage, and treatment, but there is much more that can be done. Mobile device use is growing in many LMICs, where health management is also in great need of improvement. mHealth tools are perfectly positioned to fit this need. We plan to extend our current applications to a comprehensive perinatal health record, reduce the cost of pulse oximetry, and add new sensor measurements.

Our future applications will include a full health record for pregnant women during antenatal, intrapartum, and postnatal care including the identification and management of postpartum hemorrhage. In addition, sepsis and pneumonia diagnostic applications are being developed for children under 5 years of age. These can be used for assessment of children and combined with pregnancy tools for assessment of women with septic complications of pregnancy.

Finally, the Audio Phone Oximeter [20], which consists of a pulse oximeter sensor connected directly to the audio port of a phone, is an innovative solution to pulse oximetry on a mobile device. This eliminates the pulse oximeter processing module, which is an expensive piece of hardware that performs the processing of the pulse oximeter signals. Instead the processing required to extract the HR and SpO_2 from the PPG waveform will be done directly on the phone. Additional sensors such as a semiautomated blood pressure cuff and a temperature sensor, which also connect to the audio port of any mobile device, are being developed. The combination of sensors with decision

support algorithms, all managed by a mobile phone, is a path to decreasing adverse health events globally at an affordable cost.

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