JHSPH IRB Research Plan for New Data Collection

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Study Title: ePartogram Effectiveness Study in Kenya

IRB No.: 6958

PI Version No./Date: July 14, 2017, v4

I. Aims of the Study: Describe the aims/objectives of the research and/or the project's research questions or hypotheses.

The study aim is to measure the effectiveness of use of the electronic partogram vs. the standard-of-care paper partograph on labor management outcomes and labor outcomes in maternity wards in Kenya.

Research Questions

Primary

Comparing facilities in which birth attendant/providers are using the ePartogram and facilities in which providers are using the paper partograph, are the following improved?: (partograph review)

P1) compliance with globally-recommended, labor monitoring practices and recording on the partograph of the practices performed

P2) decision-making and actions taken to maintain normal labor

P3) detection, decision-making and action to address deviations from normal labor and complications arising during labor

Complications of interest are: prolonged labor (labors over 12 hours or labor that crosses the action line, may not be over 12 hours), arrest of descent/dilation that precedes obstructed labor; obstructed labor including arrest of descent/dilation, fetal distress and maternal distress; maternal infection; severe pre-eclampsia or eclampsia; fetal distress; and maternal distress with shock-like symptoms.

Secondary

In intervention and control sites:

S1) Is facility use of ePartogam (vs. paper-partograph) associated with **lower rate of** (neonatal death <24 hours and intrapartum death (fresh stillbirth rate)? (register review)

S2) What **facility conditions** and practices enable or hinder implementation of best practices in labor monitoring and decision-making? What makes the partograph/ePartogram easy-to-use? Efficient? (qualitative inquiry, facility assessment)

S3) What is the availability, accessibility, acceptability, and quality of **supervision/support** provided with eSupervision connectivity and referral functions of the partogram? (qualitative inquiry)

This study will inform the Ministry of Health on the effectiveness of the ePartogram and whether to use it more widely in Kenya.

II. Background and Rationale: Explain why this study is being done. Summarize briefly what is already known about the issue and reference previously published research, if relevant.

Background

Public Health Problem

Globally, in 2015, the World Health Organization estimated that 303,000 maternal deaths occurred.[1] A global burden of disease study estimated that 18,789 (95% UI 16,281–21,747) women died due to obstructed labor annually out of estimated 292,982 maternal deaths (95% UI 261 017–327 792) or 6.4% in 2013 (2014 estimate).[2] Despite the majority of births occurring in health facilities currently, 1.3 million intrapartum stillbirths occurred, devastating families.[3] In addition, 904,000 newborns die from hypoxia.[4] Many of these deaths, stillbirths and disability could be prevented with timely identification and management of intrapartum complications.[3,4]

Existing Solution

The partograph is pre-printed, paper-based medical record and early warning system to assist skilled birth attendants (SBA) in monitoring fetal well-being, maternal well-being, progress of labor, and identification of obstetric and fetal complications. WHO recommends partograph use to improve decision-making in labor and decrease perinatal mortality by **reducing prolonged or obstructed labor** (which results in maternal and fetal deaths, ruptured uterus and fistula), **sepsis, fetal distress, and unnecessary operative interventions**.[5] A 2013 Cochrane review of partograph use in high- and low-resource settings found no difference comparing partograph and no partograph groups in rates of caesarean section, instrumental vaginal delivery or Apgar score less than seven at five minutes. However, the Cochrane review conceded in its conclusion, 'partograms may be useful in settings with poorer access to healthcare resources, as studies in Mexico and Africa also showed some reduction in caesarean section rates with partogram use and early intervention for delayed progress in labour.[6]

Routine use of paper partograph in low- and middle-income countries is low and inconsistent.[7, 88] In many settings, partographs are completed retrospectively for record-keeping purposes only. The MCHIP Quality of Care Study in Kenya in 2010[9] found that "the partograph was widely used during labor (in 88% of 442 cases), and when used, its use was initiated at the correct time in more than 90% of the cases. Providers were less consistent in filling in details on the partograph during labor and delivery, with all components completed in only 58% of cases." In cases where the partograph action line was reached (in 19% or 78 cases), the appropriate action was taken 78% of the time.

Innovation

The **ePartogram,** developed by Jhpiego and partners, is an Android tablet-based application based on the modified WHO paper-based partograph for use by SBAs to monitor labor. As when using the paper partograph in labor and delivery settings, SBAs using the ePartogram obtain clinical measurements from the woman and fetus according to the current standard of care. The measurements are entered into the ePartogram, which will then plot the data in the familiar modified WHO partograph format (see Appendix A and Appendix B). The ePartogram is designed to increase timely utilization of the partograph (and thus improve labor management outcomes) by addressing key challenges in paper partograph use and interpretation. These challenges include data entry not being straight-forward, and lack of real-time data collection, detection of complications, and awareness on when to take clinical action. The ePartogram electronically captures data and triggers warnings to reinforce clinical expertise and action by providers; it never touches the woman and will only be used by SBAs for recording measurements and interpretation.

The ePartogram provides reminders[1] for obtaining further routine measurements and alarms[2] for abnormal measurements. Abnormal measurements and associated alarms are defined by "clinical rules"[3] based on global guidelines published in WHO's *Managing Complications In Pregnancy And Childbirth: A Guide For midwives And doctors,* 2003[10]), augmented where necessary by opinion from Jhpiego clinicians who are experts in labor management. The clinical rules are the basis for the alarm algorithm of the application. The clinical rules have undergone a validation process by expert SBAs from a variety of geographic and clinical settings not affiliated with Jhpiego. The ePartogram is not considered a medical device.

The ePartogram has a supervision support component. The eSupervision component of the ePartogram enables real-time transmission of partograph data, enabling on-site supervisors, off-site supervisors, and SBAs at referral facilities to view patient information and provide consultation as needed. Supervisors can view daily, weekly, and monthly labor and delivery statistics in the ePartogram and through the associated online dashboard. Should a laboring client need to be referred, the partograph record is electronically shared with the referral facility for prompt care.

The ePartogram has been developed by Jhpiego over the last 4.5 years, and in collaboration with D-Tree International, a non-profit software development company, for the past 2 years. The usability and functionality of the ePartogram has been tested on the benchtop in the United States, during field validation exercises in Tanzania and Kenya, and in the "Feasibility of ePartogram Use in Zanzibar" study (JHPSH IRB# 6146). The ePartogram comprises 78 clinical rules that are programmed in the software to trigger clinical reminders for taking measurements and alerts. Over the past 6 months Jhpiego has simulated 125 scenarios, to validate that every clinical rule triggers the correct alert in ePartogram. Jhpiego, D-tree, and Sonjara, Inc., a software testing and quality assurance company, have developed a comprehensive end-to-end quality assurance testing plan to verify the functionality, performance, and clinical support of the ePartogram. The software testing aims to ensure the quality of the accuracy, stability, usability, and clinical algorithms in the ePartogram, and is further described in Appendix C.

The ePartogram intervention includes features to benefit SBAs, as well as supervisors and health officials:

<u>SBAs:</u>

- Automated plotting of clinical data
- Reminders for when to take measurements (beeps)
- Alarms for abnormal clinical measurements (red colored tabs or cells)
- Facilitates recording of medications administered and notes on client condition
- Data sharing between tablets actively used by SBAs for coordinated care on laboring woman
- Referral form and data sharing between facilities
- Ability to print paper record to remain at the facility

<u>Supervisors and Health Officials:</u>

- Supervisor function allows for viewing partograph data in real-time, facilitating supervision and communication on care
- Completed client records available for review and audits
- Online database with monthly reports and raw data for analysis
- Online dashboard with monthly summary reports and visual representations of key data

Prior ePartogram Study

[1] A reminder is an auditory and visual alert automatically triggered within the ePartogram. The reminder indicates when a specific measurement should be taken and recorded in the ePartogram.

[2] An alarm is a visual alert automatically triggered within the ePartogram to indicate when a clinical measurement is outside of the normal range, as defined by WHO guidelines and augmented by Jhpiego clinicians. Alarms can be "low-level" which is indicated as pink in the ePartogram and alerts providers to pay attention to the clinical measurement or "high-level" which is indicated in red in the application and alerts providers that clinical action may be needed. (see Appendix B for more detail)

[3] "Clinical rules" refers to a document the defines the reminders and alarms "low-level" and "high-level" that are programmed into the ePartogram

Jhpiego conducted the "Feasibility of ePartogram Use in Zanzibar" research study (JHSPH IRB number 6146) in April and May 2015 in three health facilities: Makunduchi Health Center, Chukwani Primary Health Care Unit, and Mwembeladu Maternity Home. Thirty-nine skilled birth attendants (SBAs) were trained to use the ePartogram and monitored 103 laboring women using the application. Trained clinical observers hired by the study assessed the providers' comfort and confidence in labor management using the ePartogram. In addition, there were 84 short interviews conducted with providers after the providers' first five uses of the ePartogram to gain insight on initial interactions with the application in an actual labor and delivery setting. At the conclusion of data collection, 15 in-depth interviews were conducted with SBAs to get feedback on the application and its use overall, including the possibility of scale-up. The ePartogram was used as intended by SBAs in the research setting, meaning that providers entered data into the ePartogram and mentioned in qualitative interviews that they responded to the clinical reminders and alarms.

The overall study objective was to determine the feasibility of ePartogram use in low-resource clinical settings. Jhpiego sought to achieve this through qualitative means to achieve the following specific study objectives:

1. To assess acceptability by SBAs and ease of use when managing multiple clients;
2. To describe how SBAs care for tablets, keep them charged and handover during shift change;
3. And to confirm some aspects of field refinement including time for data entry, screen flow, brightness of screen in different times of day, ability to enter data.

Results for Objective 1: Based on observations, SBAs quickly learned how to use the ePartogram: 86% accomplished all tasks with ease after five shifts, and 82% demonstrated confidence in using the application within five uses. The vast majority of SBAs observed (92%) responded to the ePartogram alerts and reminders by taking required measurements in a timely manner. Interviews revealed that SBAs felt that the ePartogram reinforced their clinical knowledge, prompting them to take measurements and closely monitor their clients. SBAs also stated that the ePartogram improved the timeliness of care, simplified work, and was easier to interpret than the paper partograph. They felt that it could conveniently integrate into labor and delivery settings in Zanzibar with a low volume of clients, but the application has not been evaluated in high-volume settings. The study also aimed to better understand how easy or difficult it is for SBAs to use the ePartogram to monitor multiple clients. Since SBAs monitored multiple clients in only one-third of the observed shifts, this was observed infrequently but no SBAs had difficulty in performing ePartogram tasks while managing multiple clients. The majority of SBAs interviewed felt that they would be able to manage 1-2 clients at a time using the ePartogram, with one stating she felt that she would be able to monitor up to 5 clients.

Results for Objective 2: SBAs consistently cleaned the ePartogram according to protocol, with more than 80% of SBAs correctly cleaning the tablet and tablet cover during their first shift and 100% adhered to the protocols by their fifth shift. The tablet battery lasted throughout 92% (77/84) of the shifts but it died during seven shifts. However, by the third shift no tablets ran out of battery, and only one tablet died while being used during an SBA's fourth or fifth shift. During this study, the SBA used the ePartogram and clinical observers documented measurements in real-time on the paper partograph for back up.

Results for Objective 3: Study staff documented any issues with the application or feedback provided during the qualitative interviews in order to work with D-tree to optimize the ePartogram application. The study team identified the need to include PMTCT information on the client intake form, update the software-refresh mechanism on the client list, and change display of the maternal graphs; these changes have been made.

While study results demonstrated many benefits of ePartogram use, additional needed software refinements were identified, and further research is needed to assess its use in a greater variety of clinical settings. The proposed ePartogram effectiveness aims to further test the ePartogram software and use of ePartogram on clinical decision-making and care.

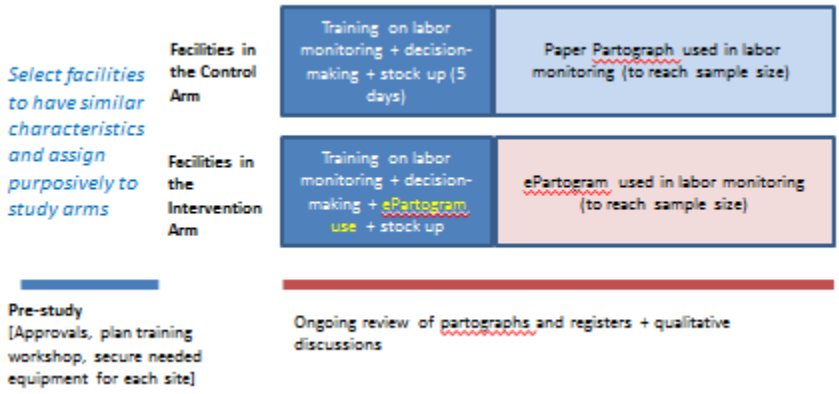
III. Study Design

A. Provide an overview of your **study design and methods**.

Study Design

The study design is a quasi-experimental design evaluation with labor management outcomes compared for the study period between two study groups, intervention and control. The study will involve mixed methods – quantitative and qualitative data. The study is depicted below.

Figure 1. Study Design and Phases



Methods

The study will be conducted in the following phases.

Phases

1) An initial group of **facilities selected** for participation will be confirmed in Kisumu County and Meru County. A rapid formative assessment of possible facilities collected data on:
    a. training needs on the paper partograph and
    b. supplies, drugs and equipment available in stock for monitoring of normal labor, management of complications and referrals (facility assessment tool; this will be repeated every 3 months) (?).
    c. percent of births recorded in the register at the facility in past 3 months that had a partograph started and used.
    d. this activity received a non-HSR determination.

2) In each region, we expect approximately 6 facilities to participate. Within each region, equal numbers of facilities that will be purposively assigned to the study groups. Each study group will have facilities that have a similar birth volume, staffing levels, and BEmONC/CEmONC status, as much as possible so the two group are similar

    a. Kisumu District Hospital and Meru Teaching and Referral Hospital must be intervention sites and will not be randomly allocated to the study group.

3) We will seek **approvals:**
    a. 2 IRB approvals (JHSPH and KEMRI in Kenya) (see section X.E of this document).
    b. Ministry of Health Approval to work in their sites
    c. County Approvals (Kisumu and Meru)
    d. Facility in-charge agreement will be sought at time of provider enrollment.

4) A similar three-day **whole-site training** will be carried out in each participating health facility in both study groups on labor management and partograph use by providers following Kenyan and WHO guidelines.
    a. The training will be on routine labor monitoring and using the partograph as a decision-making tool. Facilities will receive stocks of any supplies and drugs that are needed for monitoring or normal labor and management of complications and referrals.
    b. This training will cover how to fill out the Ministry of Health register on each woman/newborn.
    c. ePartogram sites will also receive two days of training on using the Android-based ePartogram tablet 'app', maintaining the tablet computer, and standard operating procedures for tablet use and storage to

ensure data confidentiality. SBAs passing the ePartogram post-training test will be asked use the ePartogram during clinical care.

5) In both ePartogram and paper-partograph sites, **facility readiness** will be ensured. Enough copies of standard-of-care paper partographs will be available on site at facilities in both study groups, and supplies/equipment (i.e. blood pressure apparatus).

6) In **ePartogram** facilities:
   a. Software support procedures if needed will be set up.
   b. Standard Operating Procedures (SOPs) will be created for ownership of tablets, maintenance, and what to in case of tablet malfunction or loss and Jhpiego's ongoing support.
   c. Data coordinator will be on call to troubleshoot eP software questions

7) In **ePartogram** facilities, each participating provider will use the ePartogram tablet and application on women in labor.
   a.) At ePartogram sites, all data entered into the ePartogram will automatically synch to the server when connected to the internet and saved to a secure, cloud-based, password-protected website. The partograph and outcome data will be accessed at least two times per week by the study coordinator.
   b.) A designated onsite records-management staff or, in the absence of such staff, the nurse in-charge will take photographs of the Ministry of Health **register book**, weekly--where aspects of the care to a woman/newborn(s) are written in one row. This has info on the health outcomes.
   c). If paper partographs are used at ePartogam sites, this data will still be included in the ePartogram group.

8) In the **control sites**, the paper partograph will be used for labor monitoring/management. Providers will have available paper partographs, which is the standard of care for use during service delivery.
   a. In paper-partograph sites, every day onsite records-management staff or, in the absernce of such staff, the nurse in-charge will take **scans of the partographs**. These will be scanned to password-protected study laptops and the files will be saved directly to a secure Dropbox to which only study staff will have access.
   b. At paper-partograph sites, each week onsite records-management staff or, in the absence of such staff, the nurse in-charge will take photographs the Ministry of Health approved **register.**

9) At the office, the study coordinator and data clerks will monitor ePartogram and partograph data in the ePartogram website and paper partograph Dropbox.
   a. For paper partographs, the photos or scans of partographs will be uploaded to a computer.
   b. When visiting facilities, the study coordinator will orient providers on how to record in the MOH register book, if this is not occurring to standard.
   c. The study training covers how to enter record in the partograph or ePartogram app. A Jhpiego clinical study manager will provide a one-on-one orientation to the ePartogram for any new staff . On site visits, the study coordinator will help validate the most recent register book info by comparing to the medical record if one exists and discussing any discrepancies with staff during weekly calls.
   d. Register data photographed from both study groups will be saved to the office computer. At office, a data entry clerk will follow the 'abstraction tool' to enter register data to a database.

10) Partograph reviewers who are student interns from Johns Hopkins School of Public Health and Johns Hopkins Univeristy will be hired to review each partograph and enter data from the partograph and ePartogram records to the study's Partograph Extraction Tool (Revised) (see Study Implementation section).

11) The study coordination and analysis team will conduct an analysis of data **after 20 partographs and 20 ePartograms** for each site and thereafter after every 200-400 partographs. This will be to assess for completeness of data to know whether we on track to answer the research questions.

12) To answer the secondary research questions, starting in the second month after implementation, study manager will carry out **in-depth interviews** (or small focus group discussions) with providers at sites in both study groups. We will interview providers who use the paper partograph or the ePartogram to discuss barriers and facilitators to usage, including facility conditions. The supervision for providers around the ePartogram and paper-partograph use will also be explored. The interviews will be audio-recorded to capture all contributions from participants. Participants will be informed about this during consenting. The digital recorders erased/audio tapes will be destroyed after transcription and the recordings will not be used for any other purposes.

B. Provide a **sample size and a justification** as to how you arrived at that number. If you use screening procedures to arrive at a final sample a table may be helpful.

The third study objective deals with clinical actions for complications and requires the largest sample size due to the rarity of complications. We describe inputs to sample size as shown in Table 1.

Inputs to the sample size calculation are as follows:

- *Number of sites:* The available 12 sites (6 in each study arm) have 1342 births per month, , on average. So 6 facilities have 671 births per month. We believe 80% of these will have a partograph completed during the study.
- *Prevalence:* Kenya QoC report[9] stated that "19% of labors crossed the partograph 'action line'". While this appears high, we also will look for labors with more than one abnormal measurement signaling an early complication. (A study by Orji et al in Nigeria in 2008 also found 18.5% of labors crossed the action line.) For our study, we use the 19% to indicate that up to 19% of labor may cross the action line OR may have 1+ abnormal measurement that signal need for provider action.
- *Average cluster size:* is calculated to be 17.6
- *Intraclass correlation:* ICC is expected to be high as the facilities are a heterogeneous mix of district hospitals, health centers and some private facilities, so we assume ICC of 0.15.
- *Coefficient of variation*: COV is assumed to be 90%, after calculating the standard deviation of the average monthly births in these sites. Therefore, the design effect is high at 5.3, calculated as follows: 1+ ((average cluster size 16.4-1)*(1+(COV 0.80^2))* ICC 0.15).
- Outcome indicator: The value for the outcome, 'appropriate clinical actions for complications', is unknown and thus 50% gives the most conservative estimate for the facilities in the control group using the paper partographs.
- Effect size: We expect a 30% point improvement on this indicator in facilities using ePartogram, the intervention sites, to 80%.

Adjusted for design effect, the total number of partographs or ePartograms needed are 1004 per study group, or 2009 in both groups. Due to the fact that there may be additional changes to facility selection, this number of partographs to review may increase somewhat based on the formulas. So we request the number of partographs to review to be up to **2,200 in total**. .

Table 1. Sample Size Calculation Parameters

Table 1. Sample size scenarios for ePartogram effectiveness study						
Availability of partographs in selected sites per month	536.8	Proportion of all births that have a partograph filled out	**80%**	671	1342	All 12 facilities - births monthly
Cluster size (Average) (formula based on 3 cells)	17.0					
Intra-class correlation coefficient (ICC)	**0.15**					
Number of clusters (facilities) PER ARM	6	(total 12 facilities in both study arms)				
Proportion of women whose labor crosses the Action line (a)	19%		Design effect (formula based on cells)	5.3		
Coefficient of variation (determined from numbe	**90%**					
Effective Size: Detecting difference between arms on main indicator: "Case is appropriately managed"	Comparison group	ePartogram group	Unadjusted sample size (in a simple random sample) to detect difference	Adjusted for design effect	Total no of partographs required per arm	**Total no of partographs or ePartograms: both study arms**
	50%	70%	90	482	2536	**5071**
	50%	75%	55	293	1543	**3087**
	50%	80%	36	191	1004	**2009**

Sample size for qualitative interviewing

In the exercise of completing the Health Worker Line Listing at each facility, we will document the numbers of cadres (Kenya Enrolled Community Health Nurses; Kenya Registered Community Health Nurses; Kenya Registered Nurses; Kenya Registered Nurse Midwives and Bachelor of Science in Nursing Nurses) and doctors (ObGyn and medical officers). A purposive sample of all cadres using the ePartogram or partograph will be selected. At high-volume sites, a sample of half of the providers on duty in a month and half of the supervisors will be interviewed. At lower-volume sites: all providers and supervisors will be interviewed. We will also interview each facility in-charge and district authority. So there are 4 respondent types: providers, supervisors, facility-in-charge and district authority.

The study staff will carry out the interviews when visiting the facility starting in second month. Each facility will have qualitative data collected at one point in time.

For the qualitative data, we will select 8 busy facilities: assume 2 to 8 providers per site (average 4 providers), 8*4 = 32. One supervisor from each site: 8. Up to 4 in-charges and 4 district authorities. **Total 48 participants**. Note these qualitative participants will be part of the larger group of participants who consent to be part of the in the overall study.

IV. Participants

Describe the study participants and the population from which they will be drawn. Specify the inclusion and exclusion criteria. If you plan to include children, note their ages and whether you will include children in foster care. Note if the participants are particularly vulnerable in terms of cognitive limitations, education, legal migration status, incarceration, poverty, or some combination of factors.

Facilities

The facilities will include the higher referral-level hospitals in Kisumu and Meru, as well as lower level hospitals. The facilities will include both BEmONC and CEmONC sites.

Facility Inclusion Criteria:

- In Kisumu or Meru
- BEmONC or CEmONC sites
- At least one SBA on duty in labor ward 24 hours per day
- Facility in-charge or in-charge of L&D ward available physically or remotely 24 hours per day
- Use WHO modified paper partograph
- Adequate supply of paper partographs and maternity registers
- Availability of reliable transportation for referrals (e.g. functional ambulance or other) 24 hours per day

Facility Exclusion Criteria:

- Facility not registered with MOH
- No SBA on duty in labor ward at any time during a 24 hour period
- No in-charge available at any time during a 24 hour period
- Dispensary health facilities that do not practice BEmONC

Facility in-charges

Following MOH letter approval and County approval, we will seek approval from the facility in-charge and maternity in-charge. The in-charges may serve as qualitative interviewees.

Providers – for ePartograph and paper partograph data review

Providers will give individual written consent to the study and each can voluntarily decline or opt out. All providers in a selected facility will be consented to the same study arm (ePartogram or paper partograph). The intervention will start with the training on labor management, partograph (and for intervention group, the ePartogram tablet use). Providers may be invited to participate in qualitative interviews.

Inclusion:

1) Providers meeting the WHO definition of Skilled Birth Attendant (SBA)[4] clinical provider working in care for laboring women who will be working at the facility during the study.
2) Providers completing the three-day labor management training comprised of training on partograph use and management of normal labors and labor complications, according to WHO and Kenya MOH guidelines
3) Intervention sites only: Providers passing the ePartogram post-training test will be asked to use the ePartogram during clinical care.

Exclusion:

1) Providers not meeting the WHO definition of SBA
2) Providers not completing the labor management training or (intervention sites only) not passing the ePartogram post-training test

We plan to obtain written consent from all providers prior to the training. Any provider that joins the study during the study period who is in the ePartogram group B would need to receive one-on-one orientation without study coordinator or onsite trained providers and pass the ePartogram post-training skills test, prior to being consented to join the study. We will enroll no more than 200 providers.

Providers who join the study at paper partograph sites, after the training, will be asked to consent when the study coordinator visits the sites.

[4] SBA: According to the WHO, a skilled birth attendant is a doctor, nurse or midwife "trained to proficiency in the skills needed to manage normal (uncomplicated) pregnancies, childbirth and the immediate postnatal period, and in the identification, management and referral of complications in women and newborns". ("Making pregnancy safe: the critical role of the skilled birth attendant" – joint statement by WHO, ICM, FIGO http://apps.who.int/iris/bitstream/10665/42955/1/9241591692.pdf()

We are including providers regardless of number of years in maternity ward because seasoned providers could have practices that are not consistent with labor management standards and newly trained providers may be practicing exactly according to labor management standards after their pre-service training.

At each site, we will collect the register data (via photograph or scan). Analysis of this data and data capture will be mentioned in the information sheet and agreement with the facility in-charge.

We plan to capture data from on all partographs in both study groups and analyze all partographs that are started or filled out on clients in both study groups.

Women/Clients

Women in labor will receive the recommended care according to the standard-of-care guidelines in both study groups. Women's interactions with providers will follow normal guidelines. The difference is that the intervention group facility providers will use the ePartogram instead of the paper partograph to document measurements. The ePartogram is operating as expected. Back-up paper partographs will be available at each site. Additionally, data that we analyze will not have women's names or identifiers. As such, we will not consent women clients to our study.

Qualitative interviews with in-charges and district authorities.

Inclusion criteria: supervise providers (or in-charges) who used the ePartogram or paper partograph to record care to at least 3 clients OR who supervise providers who have done this. OR facility administrators who supervise the in-charges or department heads

Providers – for qualitative data.

Qualitative Interviews will begin in the second month after the providers have had time to use the ePartogram or partograph following the training at the beginning.

Inclusion criteria: used the ePartogram or paper partograph to record care to at least 3 clients.

V. Study Procedures

In this section, provide details of your procedures, particularly as they relate to human subjects. If this is a multi-center study, make the role of JHSPH clear.

A. **Recruitment Process:**

1. Describe how you will identify, approach, and inform potential participants about your study. Include details about who will perform these activities and what their qualifications are.
2. Address any **privacy issues** associated with recruitment. If recruitment itself may put potential participants at risk (if study topic is sensitive, or study population may be stigmatized), explain how you will minimize these risks.

Once all approvals are obtained, study staff will notify facility in-charges in ePartogram sites that the training workshop will occur and that providers' participation is voluntary. Jhpiego staff will be on hand to explain and answer questions. The cooperation of in-charges will be assured before approaching any providers.

At the start of the training, for recruitment, providers will be approached individually by the Jhpiego clinical trainer or Jhpiego study coordinator (who will have a bachelor's degree in a health or relevant topic), in a space allowing for audio and visual privacy

For qualitative exercise, the study coordinator will recruit individual providers in the facility about qualitative interview. Purposive sampling will be used. We will ascertain eligibility through screening questions and recruit participants who show interest.

B. **Consent Process:**

1. Describe the following details about obtaining informed consent from study participants. If a screening process precedes study enrollment, also describe the consent for screening.
   - Who will obtain informed consent, and their qualifications.
   - How, where, and when the consent discussion(s) will occur
   - The process you will use to determine whether a potential participant meets eligibility criteria

Providers in both study arms will be asked to give written consent to be in the study at the beginning of the ePartogram training workshop, by the clinical trainers (midwives or doctors employed by Jhpiego), in a space allowing for visual and auditory privacy. Facility in-charges will not influence consent discussions and will be informed that the provider can offer voluntary consent. Providers hired during the study period may consent to be the study. The study staff will consent any new providers when visiting the facility biweekly, arrange for a the training on labor management and the partograph equivalent to the training conducted at the beginning of the study and if the site has ePartogram, give ePartogram use training and post-training test.

The provider consent form to be used in ePartogram sites will have information about the ePartogram intervention and the possibility of being selected for a qualitative interview at some point during the study period.

- Whether you will obtain a signature from the participant or will use an **oral consent** process

Please see above.

- Whether you will obtain a legally authorized representative's signature for adults lacking capacity. **N/A**
- If children are included in the study, if and how you will obtain assent from them. If children are included in the study, how you will obtain permission for them to participate from their parent, legal guardian, or other legal authority (if child is in foster care or under government supervision.) **N/A**

- If you are seeking a **waiver of informed consent** or assent, the justification for this request

Data captured on labor management

Data on labor management that women receive that is recorded in either the ePartogram or on paper partograph will be captured and analyzed by our project. The woman's name will be recorded on the ePartogram and paper partograph during routine care of the woman. The woman's name will be concealed on the paper partograph and covered up with a study ID number sticker prior to the designated and trained clinic staff scanning the partograph for data entry. the woman's name will not end up in the database at all. Actual partographs will stay at the facility since they will be scanned. Also the ePartogram tablet will be connected to a printer so partograms can be printed (study coordinator will check on this when visiting each facility). The study coordinator and facility in-charges will have access to the ePartogram via the online portal and can print remotely.
The woman will receive the standard of care in both study arms.
Ministry of Health register data on the woman and newborn outcomes will be captured by our study (without woman's names). *We are seeking a waiver of informed consent for women since our interest is in the data recorded by the provider and not the woman.*

In the event of a complication arises, providers will give care per existing facility standards. Providers will provide care as per Kenyan guidelines. Providers' clinical judgment should prevail will all cases.

- Whether you will include a witness to the consent process and why. **N/A**
- If the language is unwritten, explain how you will communicate accurate information to potential participants and whether you will use props or audio materials. **N/A**

2. Identify the countries where the research will take place, and the languages that will be used for the consent process.

Table 2.

Country	Consent Document(s) (adult consent, parental permission, youth assent, etc.)	Languages
Kenya	Group A: Providers (SBAs) in the labor ward in paper partograph (control) study arm	English (language will be English for all providers in Kenya)
	Group B: Providers (SBAs) in the labor ward in **ePartogram** study arm	English

C. Study Implementation:

Answer the following:

1. Describe the **procedures** that participants will undergo. If complex, insert a table below to help the reviewer navigate.

a) In both study arms, providers will receive training on labor management and partograph usage per national and international WHO guidelines. Providers will be encouraged to consult their supervisor available when complications arise during labor, as per the standard-of-care. In the ePartogram study group only, a two-day training on ePartogram tablet use and maintenance will be given.
b) All providers in both study arms will be consented prior to the training.
c) ePartogram facilities will have the data transmitted over a cloud database accessible only to study staff.
d) An onsite facility staff will cover client identifiers and scan partographs and photograph registers for sending to a secure cloud folder. Client identifiers will be covered up prior to transmitting information.
e) Jhpiego study clinicians will access the scanned partographs and registers or ePartogram database online, and abstract the relevant data into the Partograph ExtrationTool 4 Revised and also the Register Review Tool 6. This data will be analyzed further by Jhpiego data analysts.
f) A study coordinator will be on call for any technical or software issues with the ePartogram, and backup tablets will be stored on site.
g) Note: if any clients in the ePartogram facility group are followed with a paper partograph, we will capture this info and consider this data to belong to the ePartogram group. We believe these providers would have been influenced by the use of the ePartogram in the facility.
h) Starting in second month, the study staff will collect qualitative interviews with SBAs, audio record, and transcribe for further analysis

Table 3

Study Timeline	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov
Activity									
Ethical review by JHSPH and KEMRI	X	X	X						
Finalize training materials		X	X						
Facility and stakeholder orientation visits		X	X						
Facility stockup on supplies		X	X						
Data collector training		X	X						
Provider trainings			X	X					
Data collection			X	X	X				
Partograph Review and Data analysis			X	X	X	X	X		
Dissemination Meeting								X	

Table 4. Tools

The following are data collection or abstraction tools to be used in this study.

Tool No.	Tool Name	Description
1	Health Worker Line Listing	Study team will use this to assign a unique provider id to skilled birth attendants working in each facility who consented to the study and were trained by study staff. This provider study id will then be written on paper partographs, in ePartograms and on registers, when names are obscured (to account for clustering of data in the provider). We will record cadre, , years of experience, and date passed labor management and ePartogram compentency test.
2	Partograph or ePartogram file on each laboring woman (a)	The top portion of the partogram is completed on admission with information about: woman's name, gravida, parity, hospital id number, date and time of admission, and whether membranes are ruptured. At regular intervals, the following measurements are obtained by the provider: fetal heart rate, condition of amniotic fluid, moulding, descent of head, cervical dilation, contractions, oxytocin, drugs and IV fluids given, pulse, blood pressure, temperature, urine protein, acetone and volume.
3	Stamp on the paper partograph or programmed into the app (for ePartogram).	In this study, the paper partograph and ePartogram will include additional fields related to maintaining normal labor and management of abnormal conditions. The stamp will be placed on the paper partograph or programmed into the app (for ePartogram). Standard provider actions will be recorded (e.g. ambulation, nutrition, fluid intake, presence of a birth companion, oxygen administration, changing the mother's position for choice or due to fetal heart rate, presence of bleeding). *Providers will also indicate if a consultation with another provider was made for the client and if the client was transferred (reason for referral), fresh stillbirth, or early newborn death.*
4	Partograph Extraction tool (revised July 2017)	There are sections where the data extractors will enter the information on the woman and newborn conditions and outcomes that appears a) at the top of the partograph, b) at the bottom of the partograph and c) provider actions recorded on the Jhpiego stamp tool. There are repeatable sections that also allow for data entry on the actual values of the the measurements are recorded for 13 parameters (fetal heart rate, cervical dilation, systolic and diastolic blood pressure, amniotic fluid, moulding, head descent, contractions, pulse, temperature, urine protein, acetone and volume These data will be recorded for each 30 minute interval for the duration of the active stage of labor (4cm dilation to 10cm dilation).
5	Register review tool	This tool will contain the abstracter id, date and facility id, month number of deliveries, Live births (spontaneous, assisted, cesarean, breech), fresh stillbirths, macerated stillbirths, number of twins, early neonatal deaths, number referred, number of maternal deaths
6	Qualitative discussion field guide for ePartogram sites (in-depth interviews or small focus groups)	Qualitative interviews will be conducted with providers in each study arm. In the ePartogram group, qualitative interviews will be administered to to better understand the benefits and challenges of ePartogram.. Providers will be asked about their experience in using the ePartogram, opinions on various features of the application, and implementation considerations for ePartogram.
7	Qualitative discussion field guide for paper partograph sites (in-depth interviews or small focus groups)	Qualitative interviews will be conducted with providers in the paper partograph group to better understand how providers use the paper partograph in a variety of labor and delivery settings, perceived benefits and challenges in using paper partograph, and the facility conditions that enable or hinder adoption of best practices in labor management

(a) Exiting tool already in use

2. Describe the **number and type of study visits and/or contacts** between the study team and the participant, how long they will last, and where/how they will take place.

At the start of the study, the study trainers will offer a training workshop in each study group. s Thereafter, the study coordinator will visit each site monthly to collect ePartogram case information. Local staff who work in records management or the nurse in-charge will be asked to scan partographs daily and registers weekly and send the data on the study-loaned laptop to a secure cloud database. Direct interaction with study team members may occur only once per month since we will mainly collect data on paper. If a provider is having trouble with the ePartogram, then more than one interaction with study staff is possible.

A subset of providers will be asked to participate once in an in-depth interview lasting 45 minutes. These providers will have 2 contacts.

3. Describe the expected **duration** of the study from the perspective of the individual participant and duration overall.

The number of months of the use of the ePartogram at intervention sites and data collection (capture of labor information on clients) at sites in both study arms will take **up to 9 months**. We expect to collect all partograph information over 2 or 3 months, depending on volume of births and the percent covered by partographs during the actual period of study implementation.

4. Provide a **brief data analysis plan and a description of variables to be derived.**

We will compare study groups (facilities in which providers are using the ePartogram and facilities in which providers are using the paper partograph):

Table 5: Data Analysis Plan (updated July 2016; updated July 2017)

Research question	Outcome	Cases	Analysis
P1. Compliance with globally-recommended labor monitoring practices and **recording** on the partograph of the information obtained – *complete on admission* *(Tool 4)*	We will examine each parameter and enter to the database. Overall, this will be marked 'yes' if 11 of the 12 items (all except urine volume) are measured at admission (fetal heart rate, cervical dilation, systolic and diastolic blood pressure, amniotic fluid, moulding, head descent, contractions, pulse, temperature, urine protein, acetone and volume); and otherwise 'no'. Binary variable.	All labors with partograph or ePartogram Unit of analysis is each case (partograph).	First, we will examine the frequency/prevalence of each measurement recorded on admission and compare between the two study groups Second, We will examine the percent of cases marked 'yes' (defined at left). Independent variable is study group. Bivariate analysis will be an unadjusted logistic regression accounting for clustering in the facility or in the provider. In multivariable analysis, other control factors added may be facility type, client volume, region or provider variables.
- *Complete over entire labor* *(Tool 4)*	We will examine each parameter and enter to the database. Then we will see how many hours was the labor for the appropriate frequency, per the Jhpiego Clinical Rules and determine whether this was done to a large extent on time. Overall, this will be marked 'yes' if 11 of the 12 items (all except urine volume) are measured in first 4-hour period at the specified intervals (reviewer will determine for each item if occurred within the interval): fetal heart rate every 30 min, cervical	All labors with partograph or ePartogram	Same as above – except it will be for the first four hour period

	dilation every 4 hours, systolic and diastolic blood pressure every 4 hours, amniotic fluid if membranes rupture, moulding when present head descent every 2 hours, contractions every 30 min, pulse every 30 min, temperature every 2 hours, urine protein, acetone and volume, all at every 4 hours. ; and otherwise 'no'. Binary variable.		
- *Complete overl entire labor for a subset of women who arrived at 4 or 5 cm*			
P2. Decision-making and actions taken to maintain **normal labor** *(Tool 4)*	Data on each partograph parameter will be entered for each time period, as well as actions taken in labor. Jhpiego clinical rules will be applied to the data in the extraction database to determine appropriate clinical actions for a labor without any complication. This is a binary variable.	Labors in which Section 3 marked as "Normal Labor"	First, we will examine the frequency/prevalence of each clinical action taken in normal labor and compare between the two study groups. Second, we will carry out same analysis as for Objective P1.
P3. Detection, decision-making and action to address deviations from normal labor and **complications** arising during labor—*for 'slow' labor, prolonged labor, obstructed labor and cephalo-pelvic disproportion*	Data on each partograph parameter will be entered for each time period, as well as actions taken in labor. Jhpiego clinical rules will be applied to the data in the extraction database to determine appropriate clinical actions for a labor with a specific complication. This is a binary variable.	Labors in which Section 3 marked "Slow labor, prolonged labor, obstructed labor or cephalo-pelvic disproportion"	First, we will examine the frequency/prevalence of each clinical action taken in *selected complication*s and compare between the two study groups. Second, we will carry out same analysis as for Objective P1.
-- for all complications *(Tool 4)*	Same as above. A composite variable will be created for all complications. This is a binary variable.	Labors in which Section 3 marked as ANY complication	First, we will examine the frequency/prevalence of each clinical action taken in *all*

			complications and compare between the two study groups. Second, we will carry out same analysis as for Objective P1.
S1. Is facility use of ePartogram (vs. paper-partograph) associated with **lower rate of…?**			
From the Register Analysis			
Neonatal deaths <24 hours and *(Tool 5)*	Number of early neonatal deaths. This is a count variable.	All live births	We will compare means using t-tests across 2 groups. Next, we will use unadjusted regression models that account for clustering (correlation) of data within the facility. Poisson regression with offset term (or another appropriate model to be explored) will be used for bivariate and multivariable analysis.
Intrapartum death (fresh stillbirth rate) *(Tool 5)*	Number of fresh stillbirths. This is a count variable.	All live births	Same as above.
Adverse perinatal events (Neonatal deaths <24 hours+ intrapartum death (fresh stillbirth rate))	Number of neonatal deaths and fresh stillbirths	All live births	Same as above.

Statistical analysis plan

Outcomes will be dichotomous, yes/no for each measure.

In the main statistical analysis of our primary outcomes, we will focus on program effect (intervention (ePartogram) group of facilities versus comparison (paper program) group of facilities) as the main predictor of interest. The analysis will be performed at the level of the individual case (partograph). In preliminary analyses we will conduct univariable and bivariable analyses to assess the distribution of key variables and joint distributions and unadjusted relationships.
In final analyses addressing study aims, we will fit multi-level, multivariable regressions models for the outcomes with adjustment for possible confounders and account for clustering by provider and/or study clinic by the use of GEE.

While we have selected clinics roughly matched between the intervention and comparison regions, we will still evaluate confounding to attain the least biased estimate of our intervention effect. Facility level possible confounders are: monthly case load of laboring women, number of providers, key equipment availability etc. Provider-level possible confounders that may be adjusted for are years of work experience since graduation and cadre. Woman-level possible confounders are age and parity.

5. Describe whether you are collecting or storing **personal identifiers**, and if yes, why you need them, and when and how you plan to dispose of them. Signatures on consent forms are considered to be identifiers.

Identifiers of Providers

Our study will assign each facility and each provider a study id number of the Health Worker Line Listing form to be updated monthly. This will be kept separately from partograph data.

partograph review analysis: the paper partograph has a place for a provider to sign it. When we scan/photocopy paper partographs, we will obscure the provider name (cover with lose paper) but will we add/write on it the provider study id number.

ePartogram will enter the provider's study id number. There will be a drop-down menu in which the provider name and study id appears, but only provider study id will end up in the back-end database. There will be no names kept in the database of ePartogram information.

Each time the study staff visits the facility, the health worker line listing forms and database will be updated with names of new providers added to the study and for intervention sites only, who pass the post-training test for ePartogram

Written consent forms will be kept for 3 years after the study date of closing with IRB.

a. *register review analysis:* The register has a field for provider name. Prior to our taking scan/photo of registers, we will obscure the provider name and replace the provider name with the provider study id from the Health Worker Line Listing.

Identifiers of Women

a. *partograph review analysis*: The name of the client/woman is on the partograph. Prior to photographing partographs, we will make sure the partograph has the woman's 'hospital admission number'. We will verify that this is the same as recorded in the register. Once the admission number is verified, then we will scan/photocopy the partograph and obscure the woman's name by covering with a small piece of paper prior to scanning the partograph.
b. When a new client sheet is started in the ePartogram, the software will automatically assign a study-generated ID number to each laboring woman's eParotgram record. This record will also have the woman's name during the care process, for printing the ePartogram record to leave at the facility. The study ID will be the facility number (i.e. MER01 for the first facility in Meru) + date + 01 for the first woman admitted in labor.

c. *register review analysis:* The register has a field for woman's name. When we scan/photocopy the register, we can obscure women's names.

Identifiers of Providers - for Qualitative Interviews.
We may temporarily keep track of provider and supervisors names only for the purpose of setting up an interview at a convenient time. However, no names or identifiers will be collected or recorded on qualitative participants.

The names of providers receiving any payment or reimbursement as described in the consent form will be retained for financial purposes only in secure financial database at Jhpiego.

6. Answer the following **if they are relevant to your study design**:

a. If the study has **different arms,** explain the process for **assigning participants** (intervention/control, case/control), including the sequence and timing of the assignment.

This will be a cluster-randomized trial. See section on randomization under Section III Methods.

b. If human biospecimens (blood, urine, saliva, etc.) will be collected, provide details about who will collect the specimen, the volume (ml) and frequency of collection, how the specimen will be used, stored, identified, and disposed of when the study is over. If specimens will be collected for use in future research (beyond this study), complete the Biospecimen Repository section below. ***N/A***

c. If genetic/genomic analyses are planned, address whether the data will be contributed to a GWAS or other large dataset. Address returning unanticipated incidental genetic findings to study participants. ***N/A***

d. If clinical or laboratory work will be performed at JHU/JHH, provide the JH Biosafety Registration Number. ***N/A***

e. If you will perform investigational or standard diagnostic laboratory tests using human samples or data, clarify whether the tests are validated and/or the lab is certified (for example is CLIA certified in the U.S.). Explain the failure rate and under what circumstances you will repeat a test. For all human testing (biomedical, psychological, educational, etc.), clarify your plans for reporting test results to participants and/or to their families or clinicians. Address returning unanticipated incidental findings to study participants. ***N/A***

f. If your study involves medical, pharmaceutical or other therapeutic intervention, provide the following information:

- Will the study staff be **blind** to participant intervention status?

The in-charge and the providers at selected ePartorgam sites will know that their site has been selected to use this innovation, so they will not be blinded.
The in-charge and providers at the paper-partograph control sites will not be told officially about the ePartogram being used in other sites, just that their site is part of a partograph training and monitoring intervention. These individuals may find out about the ePartogram being used elsewhere, from contamination/spillover from providers in other sites or from communications with county health officials.

- Will participants receive standard care or have current therapy **stopped**?

Providers in control sites will monitor women in labor using the standard-of-care partograph. In the intervention arm, providers will use the ePartogram, an electronic version of the partograph.

- Will you use a **placebo or non-treatment group**, and is that justifiable?

Please see prior question. We plan to study the effectiveness of the ePartogram in improving labor management outcomes, which currently is unknown.

- Explain when you may **remove a participant** from the study.

All birth attendants at selected sites who meet eligibility requirements will be included and not removed unless they are transferred away from these sites.

A provider in the ePartogram facility may choose not to use the tablet and instead use the paper partograph to monitor clients, this is a voluntary choice. Or, if an ePartogram tablet is temporarily not working, the provider will use a paper partograph for labor monitoring. Paper partographs will be available at all study sites. Paper partographs used at ePartogram sites will nonetheless contribute to the data from the Intervention sites, for 'intention to treat' analysis. We will monitor this situation if this arises.

- What happens to participants on study intervention when the **study ends**?

After the study, the ePartogram facilities will return to having providers use the standard-of-care paper partograph for labor management.

- Describe the process for **referring participants** to care outside the study, if needed.

The regular referral processes currently in place at each facility will be described at the start of the study and the same procedures will apply during our study.

VI. Data Custody, Security, and Confidentiality Protections

The sections below describe types of data sources and how they will be protected. For the type(s) of data, put an "X" in the appropriate box to the left of the section that best describes how you will minimize the risk of a breach of confidentiality for your study. Note, as appropriate, how you will record/store data. These descriptions represent MINIMAL measures; you may add more stringent protections and other relevant information in B.

Confidentiality: The *LOSS OR THEFT* of 1) original/duplicate version of physical data collection instruments (forms, tapes, etc.) or 2) physical devices containing electronic data (i.e. laptop/mobile device, external flash drive(s), is a threat to subject confidentiality. Risk of such a loss/theft is increased during movement/transport of data (in any format), such as in a vehicle or other move. Be sure to train anyone (co-investigators, staff, students, etc.) who might be engaged in the oversight of data handling/storage about this problem. Some typical risk-mitigation strategies would include:

- **minimizing the physical movement of data and/or devices containing data**
- **encrypting electronic data (especially when stored on any mobile device, including flash memory tools, phones, tablets, etc, or when transferring across networks)**
- **making use of reliable courier services (FedEx, DHL, etc) when physical transport of bulk data forms is necessary**
- **minimizing the transfer of identifiable data in physical or electronic form (i.e. removing/separating/destroying identifiable data, when physical transfer of data is necessary)**

table 6

A. Data Storage

	1. Hard Copies of Data Collection Forms.
X	This activity will not involve receiving and/or accessing hard copies of data Hard copies of the partographs and ePartogram-printed partographs will remain at the facility for purposes of care. Registers are MOH documents and will remain onsite. We will not collect printed/hard copies of patient partographs or registers. Qualitative data –Paper tracking forms which temporarily have names of providers in order to schedule interviews will be kept secure and destroyed/shredded when qualitative data collection is complete.
	Data collection forms RECORD NO PERSONAL IDENTIFIERS connecting study participants, and there are no codes providing a link. Data are anonymous.
	Data collection forms INCLUDE IDENTIFIERS. The forms are locked in a secure cabinet or room with limited access by authorized individuals. Forms will be kept in study team's possession during transport and will not be left unattended in a vehicle. When possible, de-identified copies will be used for coding and analysis.

	Data collection forms ARE CODED with study participants' random study ID numbers. Codes/links between study IDs and identifiers are stored securely in a separate place (locked storage cabinet or secure electronic database.)
	Other:
2. Electronic Data	
	The data do not contain personally identifiable information
	These data are stored on a secure server protected by limited access and strong password systems. Data are coded when possible. Portable electronic devices will not contain identifiable information unless encrypted.
X	Other: Providers will be given a study id. The Health Worker Line Listing will have provider name and study id only for each facility, and this will be kept secure in electronic files with password protection of laptop computers. Partograph scans and ePartogram data will not have provider names, only study ids. ePartograms will have woman's name during use at the facility and for printing the record to leave at the facility for care purposes but the names will be removed from the database prior to analysis. ePartograms will have a study-generated ID for the woman. ePartograms data will be sent from the password protected ePartogram devices to the secure cloud server or obtained by the study coordinator on a flash drive and the devices will have passwords for study personnel only. The study coordinator or onsite nurses or records staff will have a smartphone with which will take photos of partogaphs and registers, or a portable scanner on which to load scans to the study coordinator's laptop – these will have passwords. The tablets will be kept as secure as possible while study coordinator visits facilities. Scanned and photographed partograms and registers will not show any names of clients or providers, only study ids. Qualitative data – no identifiers will be kept in electronic form.
3. Other Identifiable Data Storage, Retention, and Destruction (Audiotapes, videotapes, photographs, etc.) will be retained and stored securely (locked in cabinet or room) until:	
	Transcription is complete, then will be destroyed.
	Analysis is complete, then will be destroyed.
X	Study is complete and file is closed. Audio files will be deleted once transcription is completed. Transcripts will be kept indefinitely in electronic form, without identifiers.
	Indefinitely. Provide justification for indefinite retention:
4. Existing Biospecimens to be used in this study: n/a	

B. **Certificate of Confidentiality *N/A***

Will the study data stored in the United States be protected by a Certificate of Confidentiality? If yes, explain who will apply for and maintain the Certificate. (http://grants.nih.gov/grants/policy/coc/appl_extramural.htm)

C. Data Security and Sharing

PIs have the responsibility for responsible stewardship of data and protecting data confidentiality. This responsibility includes protecting physical custody of the data, storage and sharing with appropriate data use agreements that contain the appropriate security provisions. Describe any additional plans beyond those

identified in the table that you have for storing and sharing the study data and/or materials, and how responsibility for the data will be managed. Include the following details:

1. Where will the study data be stored?

Study data will be kept on computers at the Jhpiego Kenya office and HQ office and/or in a secure, cloud-based database. We will keep these indefinitely. If another organization requests the data once the study is complete, we will do a data sharing agreement.

2. Who controls access to the data? Jhpiego, under leadership of Dr. Harshad Sanghvi
3. Will data be shared only if de-identified? Yes
4. What additional (if any) security controls will be in place? N/A

VII. Risks of the Study

A. Describe the risks, discomforts, and inconveniences associated with the study and its procedures, including physical, psychological, emotional, social, legal, or economic risks, and the risk of a breach of confidentiality. These risks should be described in the consent documents.

Table 7

Risk	Description	Mitigation	Anticipated frequency
Physical	Patient care decisions will be made based on data recorded on the ePartogram. Therefore, if the battery dies, screen freezes or any other tablet or software failure occurs, there is a potential impact on care	Each study site will have at least 2 back up tablets. Since ePartogram data automatically syncs, a provider can continue to care for the client using another tablet. Providers will be trained in ePartogram use and maintenance, and a selected provider will check the battery level of tablets each day. The study coordinator will be on-call 24 hours/day to troubleshoot issues. D-tree, the software development company, and Jhpiego have tested all aspects of the ePartogram software. Blank paper partographs will also be available at ePartogram sites in case they are needed, and this will be checked by the study coordinator at each visit.	<5% of cases
Physical	Providers may consider the ePartogram reminders and alerts when making clinical decisions during labor and delivery. The ePartogram could trigger a "false positive" alert that may cause a provider to consider taking an action when it is not warranted. Conversely, the ePartogram could trigger a "false negative" alert that may indicate that a clinical measurement is normal when in fact a provider may need to take action.	The providers will be instructed to use their own clinical knowledge should they disagree with any reminders or alerts in ePartogram. The provider consent form states that a provider will use his/her clinical judgement in interpreting the reminders and alerts in the ePartogram and provide care per Kenya clinical guidelines. ePartogram providers receive a labor management training on the Kenya and global standards for partograph use, managing normal labor and managing complicated labors and in use of and maintenance of the ePartogram. ePartogram sites will have a facility in-charge or labor and delivery in-charge available 24 hours per day to consult on any labor and delivery complications. The study coordinator will be available or reachable by phone to provide support on ePartogram use.	<1% of cases

		The 78 clinical rules in the ePartogram have been validated with Jhpiego clinicians and external experts. The ePartogram algorithms comprised of these rules that are programmed in the software to trigger clinical reminders for taking measurements and alerts have been tested in the software. Over the past 6 months Jhpiego has simulated 125 scenarios, to validate that every clinical rule triggers the correct alert in ePartogram. These tests have been repeated numerous times.	
Psychological or emotional	Providers may not be comfortable using the ePartogram in a clinical setting, or when monitoring multiple clients	Providers in the ePartogram group will be trained at the start of the study on ePartogram use and maintenance to ensure their comfort. Also each provider to use the ePartogram in care will pass the post-training test Providers can freely choose to use the paper partograph instead of the ePartogram. The data from the paper partograph will be analyzed.	<1% of providers; this did not occur in previous study
Psychological or emotional	Providers may view the study with suspicion if they do not understand the study purpose and procedures, and may be concerned that their decision to participate or their participation in the study will affect their job.	Providers in the ePartogram sites will be consented to the study and this will include an explanation of study aims. Participants can withdraw from the study at any time. Data will be aggregated by facility, not by provider, so performance will not be assessed. We do not believe the qualitative interviews will result in any psychological or emotional risk; there are no sensitive topics. The interviews will be conducted in private. Participants will be reminded of their right to not respond to any question they are uncomfortable with.	<1% of providers, did not occur in previous study
	Providers may not be comfortable with audio recording of the interviews.	We will remind participants that the interview will be conducted in a private space and the data kept confidential. There will be no identifiers on the audio files or electronic files. We will destroy the audio files once the transcripts are confirmed.	<1% of providers, did not occur in previous study
Social / Legal / Economic	Breach of confidentiality of the data	Study ID numbers will be assigned to each provider. Any client information will be de-identified. In the case of breach of confidentiality however, there are no anticipated social, legal or economic consequences for either clients or SBAs. We will ensure that in-charges, through discussion and the information sheet, know that the partograph assessment data is for study personnel only and study information will not be shared with the provider's supervisor or anyone outside the study.	<1% of cases, did not occur in previous study

		Before transcription, audio recorded data will be kept under lock and key and accessed by authorized staff only.	

B. Describe the anticipated frequency and severity of the harms associated with the risks identified above; for example, if you are performing "x" test/assessment, or dispensing "y" drug, how often do you expect an "anticipated" adverse reaction to occur in a study participant, and how severe do you expect that reaction to be? See table
C. Describe steps to be taken to minimize risks. Include a description of your efforts to arrange for care or referral for participants who may need it. See table
D. Describe the **research burden** for participants, including time, inconvenience, out-of pocket costs, etc.

Consenting providers in each study arm will attend a training workshop on labor management. Providers from ePartogram sites will attend an additional training on use of ePartogram. The trainings will be held on-site, where possible, or near the facility. Throughout study implementation, providers will administer care per the current standard-of-care, using either the paper partograph or ePartogram. Providers may opt in to participate in qualitative interviews when not attending to a laboring client. These will take a maximum of 45 minutes.

E. Describe how participant privacy will be protected during data collection if sensitive questions are included in interviews.
We do not plan to ask any sensitive questions. Interviews will be done in a space allowing for visual and audio privacy.

VIII. Direct Personal and Social Benefits

A. Describe any potential direct benefits the study offers to participants ("payment" for participation is not a direct personal benefit).

There is no direct benefit to participants for participating in the study, but providers' actions during labor may be improved by use of the ePartogam—this is what the study is designed to assess.

Providers may be satisfied to know that the Ministry of Health and Jhpiego are concerned about improving the usefulness of the partograph for improved clinical decision-making and labor management in diverse health facility settings, intrapartum maternal health care delivery, and ultimately, birth outcomes.

Providers will benefit from the training, which will include a refresher on the use of the standard paper partograph and will gain a better appreciation and competency for this tool. Providers will gain competency with the ePartogram, and could be considered early adopters of the innovation if it is introduced in Kenya. Providers will also be provided tea breaks and lunch during the training days and during interviews, and will receive a certificate of completion.

Clients may feel satisfied that the Ministry of Health and Jhpiego are concerned about improving the usefulness of the partograph by using it in an electronic form to monitor labor.

B. Describe potential societal benefits likely to derive from the research, including value of knowledge learned.

The ePartogram has the potential to improve appropriate use of the partograph and ultimately to improve intrapartum maternal and fetal outcomes. If this study demonstrates ePartogram effectiveness in a clinical setting, it could contribute to efforts to make the ePartogram available widely in resource-challenged settings.

IX. Payment:

A. Describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not "payment," and if the study will reimburse, explain.

- We tell providers in consent script: "As a SBA, you will receive a per diem of 1750 Kenyan Shillings for each day that you take part in the training workshop. You will also receive 2000 Kenyan Shillings transportation allowance for each round trip to the training site.
- Accommodation and lunch will be provided for the duration of the training.
- If you are selected for and complete the interview, you will receive an additional 500 Kenyan Shillings for your time."

B. Include the possible total remuneration and any consequences for not completing all phases of the research.

SBAs would receive a maximum of 10750 Kenyan Shillings (~ US$108) remuneration comprised of 1750 Kenyan Shillings per diem for each of five training days and 2000 Kenyan Shillings for roundtrip ground transportation to the training. Accommodation and lunch will be provided during the trainings. An additional 500 Shillings will be offered to participants completing a qualitative interview; providers can participate in a maximum of 2 qualitative interviews. There are no consequences for providers if they choose to withdraw or not participate in the study at any time.

Facility records management staff person or, in the absence of such a person, the nurse in-charge selected to scan partograph data at the control sites and to photograph maternity registers will receive 2000 Kenyan Shillings (~US$20) per day worked. Nurse in-charges will work at most 2 hours per day for 5 days in a week, equivalent to 1 day worked per week. Study implementation will take up to 3 months (or 12 weeks). The possible total remuneration for a nurse in-charge is 24,000 Kenyan Shillings (~ US$240).

In Kenya, Jhpiego has instituted a policy of electronic compensation for study participants, with the aim of minimizing the risk of carrying money while in the field for the purpose of reimbursing participants. This system uses mobile electronic money transfer (M-PESA) as an alternative to the cash advance system. To receive reimbursement, the system collects each participant's name, phone number, national identification number, and thumbprint. During reimbursement the registered participant is asked to place their thumb on the biometric reader, this information is sent to the Jhpiego Nairobi finance servers, and this is reviewed against the budgeted amount, and the money released through Mpesa into the participants Mpesa account. The finance department will retain these digital records indefinitely for future audit. This information will not be used for any other purpose other than audits. In addition it will not be accessible to the research team or any other person after the research activity. Security measures are maintained to protect the data stored on the Jhpiego servers.

X. Study Management

A. Oversight Plan:

1. Describe how the study will be managed.

The study will be managed by a multi-disciplinary team of OB/GYNs, clinicians, public health practitioners and expert researchers based in the U.S. and Kenya. The PI for the study, Dr. Harshad Sanghvi, will be responsible for overseeing the activities and research staff and ensuring compliance with approved study protocols and practices. The PI will work

closely with co-investigators to facilitate trainings of data collectors and providers in the paper partograph and ePartogram group, oversee partograph review, research ethics, and ensure data quality and confidentiality.

To ensure study activities are carried out ethically and within the allotted study period, the PI and co-investigators will carry out roles as outlined below:

Table 8. Management plan:

Role	Responsibilities
Study Manager (co-investigator)	• Provide day-to-day management and oversight for study implementation at facilities • Conduct site orientations and stockups • Oversee research team and data collection, and liaise with study sites • Conduct qualitative interviews • Share weekly progress updates and facilitate bi-weekly study team calls during data collection
Study Clinical Advisors (PI and co-investigators)	• Provide technical and clinical advising for the ePartogram study • Advise on any severe adverse events (SAEs) • Lead a team of clinicians to evaluate partograms for study endpoints • Develop SOPs for partograph review and clinical use of ePartogram • Contribute to labor management training materials and/or conduct trainings
Study Coordinator (co-investigator)	• Verify collected data and ensure confidentiality of study documents • Conduct ePartogram training and support sites on use of the ePartogram • Facilitate study logistics, including procurement and hiring
Co-investigators, including Data management /analysis team	• Develop SOPs • Contribute to development of training materials and/or conduct trainings • Develop databases and data extraction tools • Perform statistical analyses • Ensure processes for confidentiality and IRB compliance are communicated to all members of the study team, and quality of data • Assist study manger and study coordinator with tasks as required

2. What are the qualifications of study personnel managing the project?

Table 9

Name	Role	Institution	Background	Study Responsibilities
Dr. Harshadkumar Chandulal Sanghvi	Principal Investigator	Jhpiego, USA	Dr. Sanghvi is the Vice President of Innovations and Jhpiego Medical Director. For more than 25 years, Dr. Sanghvi has made invaluable contributions to the field of obstetrics, gynecology and clinical epidemiology. He has extensive experience assisting more than 25 low-resource countries to adopt evidence-based guidelines, design training systems, develop health trainers and leaders, scale up training programs, and seek innovative solutions to improve the performance of health services for women. For the last 10 years, he has led the global effort in expanding emergency obstetric care as well as seeking solutions for preventing postpartum hemorrhage and cervical cancer in low-resource settings.	Responsible for oversight of study implementation and management, and communication with study team. Dr. Sanghvi will provide leadership for development of articles, presentations and other publications.
Patricia Gomez	Co-Investigator	Jhpiego, USA	Patricia Gomez, CNM, MPH, is a certified nurse-midwife with over 30 years of experience in the development of maternal, newborn and reproductive health curricula; use and expansion of innovative best practices for MNH; assessment of quality of MNH care and health service delivery; and pre-service and in-service education of nurse-midwives and physicians in Central America, Asia, Africa and the United States. She is a senior technical advisor for maternal and newborn health at Jhpiego. **Ms. Gomez was PI on the ePartogram feasibility study IRB 6146.**	Patricia Gomez will provide overall technical guidance and clinical advising for the study. She is the lead writer for the training materials, and will lead a team of Jhpiego master trainers in training study participants from the ePartogram and paper partograph study groups. She will contribute to reports and publications related to the study.
Dr. Zahida Qureshi	Co-Investigator	University of Nairobi	Zahida Qureshi is a Senior Lecturer and Consultant, respectively, at the Department of Obstetrics and Gynaecology, University of Nairobi, Nairobi, Kenya, and Kenyatta National Hospital, Nairobi, Kenya. Her main research interests are maternal and neonatal health and evidence-based medical care.	Dr. Qureshi will primarily oversee the partograph review activities, including pilot testing of data collection tools, training of reviews, and managing the review process. She will also provide technical guidance and clinical advising for the study, and participate in stakeholder meetings and dissemination activities.

Dr. Anthony Gichangi	Co-Investigator	Jhpiego, Kenya	Dr. Gichangi is the acting Monitoring, Evaluation and Research (MER) Director for Jhpiego in Kenya. Dr. Gichangi, a Kenyan, has a Ph.D. in biostatistics and over 10 years of experience in applied statistics, statistical consulting, leading research, surveillance and programmatic activities in public health. Dr. Gichagi recently oversaw two studied in Kenya as Principal Investigator.	Dr. Gichangi with manage the data collection and analysis team, providing overall coordination and oversight for data analyses and development of databases. He will lead site selection and randomization. He will lead conceptualization of publications, and writing of articles, presentations and other publications.
Dr. Eva Bazant	Co-Investigator	Jhpiego, USA	Eva Bazant, DrPH, is a health services evaluator and researcher with more than 15 years of experience in international maternal and reproductive health, using both quantitative and qualitative methods. Dr. Bazant leads the Research Team and has served as Principal Investigator or Co-investigator of studies in maternal and newborn health, HIV-related care and disability services in African and Asian countries. Dr. Bazant will ensure the data systems are set up to collect and analyze data and protect human subjects. Dr. Bazant recently oversaw two studies in Kenya as PI, IRB 6159 and IRB 5839.	Dr. Bazant will contribute to study design, training of data collectors and reviewers, development of data analysis and validation plans, quantitative and qualitative analyses, and writing and dissemination.
Lindsay Litwin	Co-Investigator	Jhpiego, USA	Lindsay Litwin is a master of science in public health (MSPH) and the Program Officer for the Innovations Unit at Jhpiego and has been involved with development of the ePartogram for the past two years. She has six years of experience in international development and public health research, as well as experience in south and east Africa. She was a co-investigator on the ePartogram feasibility study IRB 6146.	Lindsay works closely with local staff and travels to the field during study implementation. She will provide overall oversight of study staff and activities. She is responsible for developing ePartogram training materials, SOPs, and troubleshooting device-related issues.
Dr. Lynn Kanyuuru,	Co-Investigator	Jhpiego, Kenya	Dr. Kanyuuru is a medical officer with many years' experience in public health. She is the Maternal and Newborn Health Advisor for Maternal Child Survival Program in Kenya and Innovations Advisor for Jhpiego Kenya. She has been a principal investigator in multiple studies in Kenya.	Dr. Kanyuuru will provide overall technical guidance and clinical advising for the study. She will assist in site selection and randomization and oversight of local study staff.

Levis Onsase	Co-Investigator	Jhpiego, Kenya	Levis Onsase is Public Health specialist with vast experience in MNH, HIV/AIDS and NCDs. He is a program Associate for the Innovations unit and also Healthy Heart Africa project in Kenya. He was the field supervisor for the recently completed Wheelchair study.	Levis Onsase will coordinate the study. He will be responsible for data validation and communications with study sites. He will contribute to development of SOPs and training materials.
Dr. Dickens Onyango,	Co-Investigator	Ministry of Health, Kisumu County	Dr. Dickens is the County Director for Health in Kisumu County. He is a medical officer specializing in epidemiology and has over 10years experience in the medical field. He has been involved in various studies as a co-investigator. These include Maternal Morbidity Measurement Pilot Tool Study, integrated bio-behavioral surveillance of HIV among the fisher-folk in Kenya, HIV case based surveillance and mortality surveillance among others.	Dr. Dickens will coordinate study activities in Kisumu and conduct site visits with the study manager. He will participate in stakeholder meetings.
Valentino Wabwile	Co-Investigator	Jhpiego, Kenya	Valentino Wabwile, BScN, is a service delivery officer for the Tupange project and AphiaPlus Kamili program, coordinating RHMNCH and FP activities. He currently supervises the contraceptive implant failure study among women on ARTs in Nyanza Region, Kenya.	Valentino Wabwile is the study manager. He will be responsible for day-to-day management of study activities. He will lead site orientation and stakeholder meetings. Valentino will contribute to dissemination activities and developing publications.
Timothy Kibidi	Co-Investigator (Jhpiego, Kenya)	Timothy is an Information Systems professional with Jhpiego. He is currently in-charge of the data systems for the contraceptive implant failure study among women on ARTs in Nyanza Region, Kenya, being implemented by Jhpiego.	Timothy will be the data systems support person for the study. He will monitor the flow of data sequentially as it is being submitted for analysis.	Timothy Kibidi

Ruth Muia	Co-Investigator	Ruth is currently working with the Ministry of Health in Reproductive and maternal health services unit. She holds a MSc. Reproductive health. She is also an EmONC trainer.	Ruth will coordinate and contribute to study implementation activities in Kisumu and Meru Counties. She will participate in national and local stakeholder engagement activities.	Ruth Muia
Dr. James Gitonga	Co-Investigator	Dr. Gitonga is currently working with the Meru County as the Chief Officer of Health. He holds a MPH from the University of Nairobi	Dr. Gitonga will coordinate study activities in Meru and conduct site visits with the study manager. He will participate in stakeholder meetings.	Dr. James Gitonga

3. How will personnel involved with the data collection and analysis be trained in human subjects research protections? (Use the JHSPH Ethics Field Training Guide on our website.)

   The principal investigators and all co-investigators have CITI certification in protection of human subjects in research. All additional study team members will sign off on their understanding of the research protocol, data collection tools and recruitment/consent scripts.

   The study manager and study data coordinators and all co-investigators will read and acknowledge having read Jhpiego's IRB Policy and be trained on protection of human subjects using *JHSPH IRB Research Ethics Training Guide*.

4. If the PI will not personally be on-site throughout the data collection process, provide details about PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team.
   Dr. Sanghvi is based in Baltimore, USA. During implementation, he will visit the sites at least one time. He will oversee study staff and ensure ethical study implementation. Dr. Sanghvi as PI will have bi-weekly calls with the study manager and co-investigators. He will have direct access to all collected data via Dropbox, and will be immediately contacted in the unlikely case of an adverse event during the study.

B. **Recordkeeping:**

Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation. For assistance, contact housecall@jhsph.edu.

C. **Safety Monitoring**

1. Describe how participant safety will be monitored as the study progresses, by whom, and how often. Will there be a medical monitor on site? If yes, who will serve in that role?

Services will be provided to clients as part of routine MOH service provision. No adverse events as a result of this study are anticipated. If complications arise during routine service provision, the regular mechanisms will be followed, such as contacting senior providers and initiating referrals.

2. If a Data Safety Monitoring Board (DSMB), or equivalent will be established, describe the following:
   a. The DSMB membership, affiliation and expertise.
   b. The charge or charter to the DSMB.
   c. Plans for providing DSMB reports to the IRB.
3. Describe plans for interim analysis and stopping rules, if any.

D. **Reporting unanticipated problems/adverse events (AE's) to the IRB** (***all studies must complete this section***):
Describe your plan for reporting to the IRB and (if applicable) to the sponsor. Include your plan for government-mandated reporting of abuse or illegal activity.
NOTE: The IRB does not require submission for all AEs, only those that are **unanticipated, pose risk of harm to participants or others, and are related to the study**.

ADVERSE EVENTS EXPECTED & UNEXPECTED

- At baseline, study staff (or a designated provider onsite) will visit the study sites to scan registers for the three previous months to establish the baseline rate for maternal and early newborn deaths and fresh stillbirths. . .
- Every 2 weeks, the study team will obtain the maternity register scan from each facility. We will determine the number of deliveries, number of live births, and the number of maternal and early newborn deaths and fresh stillbirths. We will determine the appropriate rates and whether any are more than 10% above the expected/normal rate.
- A summary log will be created for recording the number of deliveries, births, and adverse maternal or newborn outcomes for each 2 week period. This log will have the woman's facility admission number id on it obtained from the register. If this log indicates that normal levels have occurred, this summary AE log will be submitted to IRB along with progress report.
- If the normal level is exceeded (>10% higher than the average monthly total from 3 months prior to the intervention), Jhpiego will prepare a severe adverse events (SAE) report and the SAE policy will take effect with expedited reporting to IRB.

REPORTING

- If any unanticipated problems or adverse events occur, the study team will follow JHSPH IRB policy no. 103.06, "Reports of Unanticipated Problems Involving Risks to Participants or to Others".
- Should any adverse event occur in relation to or at the time of the data collection, the data collectors will be trained to notify their team leader immediately by phone, who will notify the co-investigators in Kenya and the PI and headquarters co-investigators within 2 business days.

- If a **severe adverse event (SAE)** occurs, the study team will immediately inform the principal investigator and follow Jhpiego's SAE Policy. The SAE policy requires immediate notification of the Kenya Country Director, local PI and overall study PI and completion and submission of Jhpiego's SAE Report Form. The Country Director will then send the relevant documentation to the Jhpiego headquarters-based Medical Director and Contracts Administrative Manager. Advice will then be provided to the Country Director for next steps.
- A summary of unanticipated problems and AEs will be reported to JHSPH IRB in the annual progress report.
- Severe unanticipated problems will be reported to JHSPH IRB as soon as possible after the PI learns of the event, but not later than 10 days.

E. **Other IRBs/Ethics Review Boards:**
If other IRBs will review the research, provide the name and contact information for each IRB/ethics review board and its Federal Wide Assurance, if it has one (available on OHRP's website at http://www.hhs.gov/ohrp/assurances).

IORG0006771 - Kenya Medical Research Institute (KEMRI) , IRB00008118

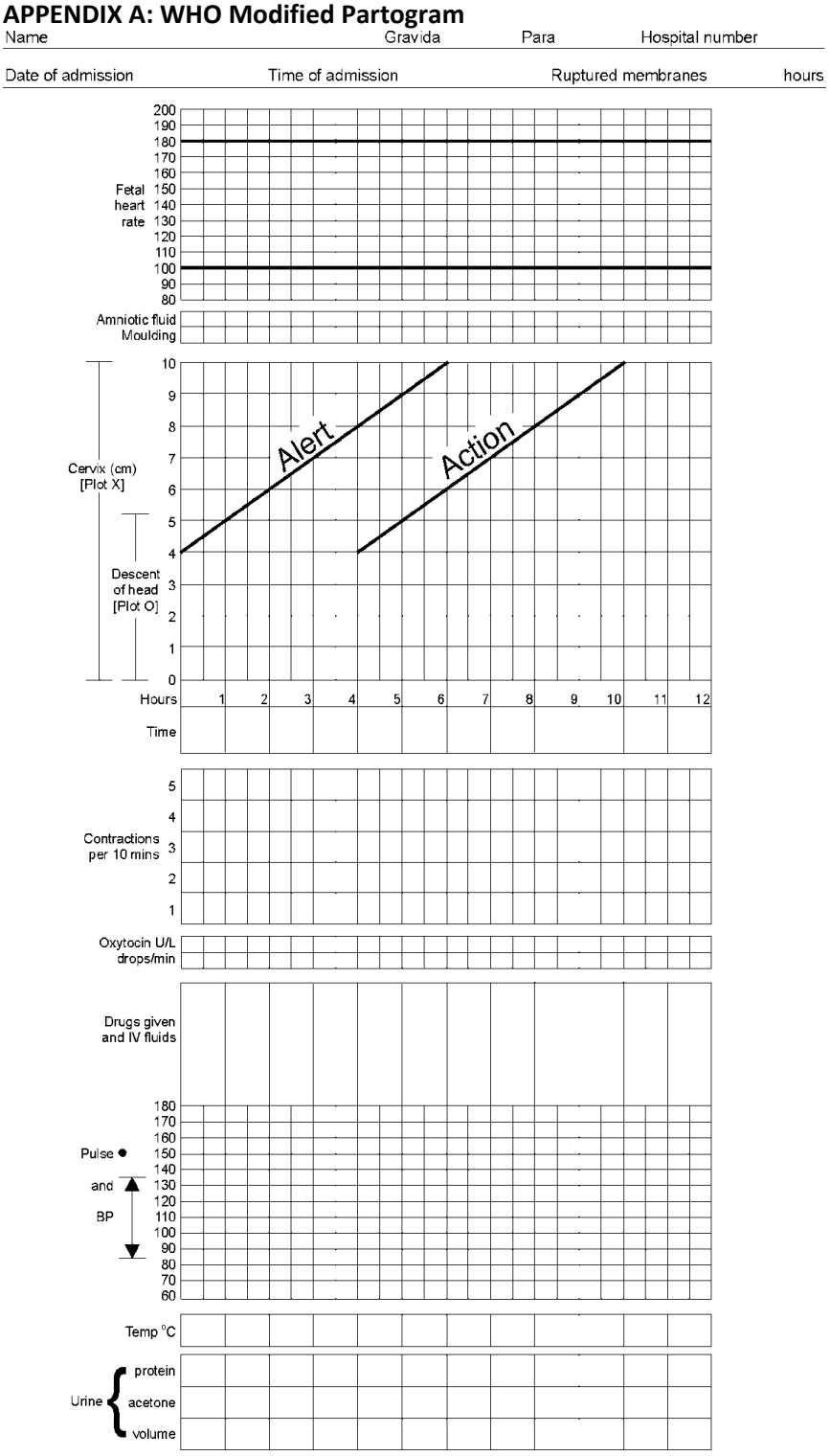
Kenya Medical Research Institute (KEMRI)
KEMRI IRB00008118
P.O. Box 54840-0020, Nairobi, Kenya
Tel#(254)(020)2722541, Email: director@kemri.org http://www.kemri.org

(for reporting of adverse events): The Secretary, KEMRI Ethics Review Committee, P. 0. Box 54840-00200, Nairobi; Telephone numbers: 020-2722541, 0722205901, 0733400003; Email address: ERCadmin@kemri .org

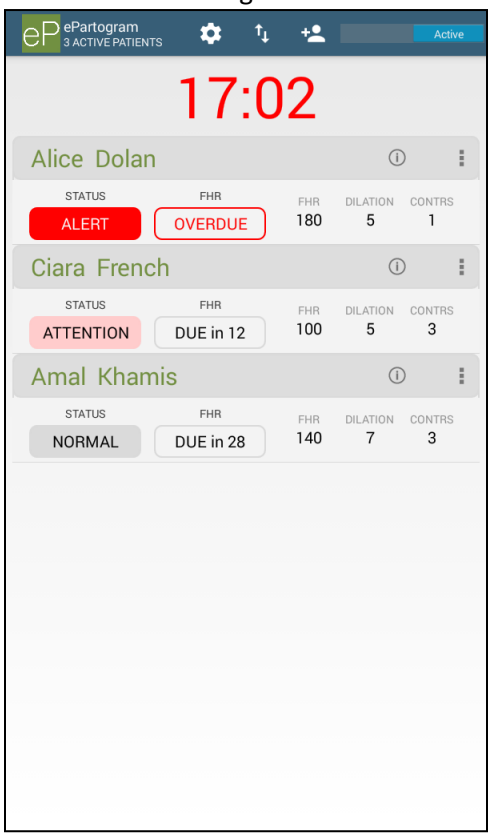
ALL SECTIONS AFTER THIS ARE NOT APPLICABLE.

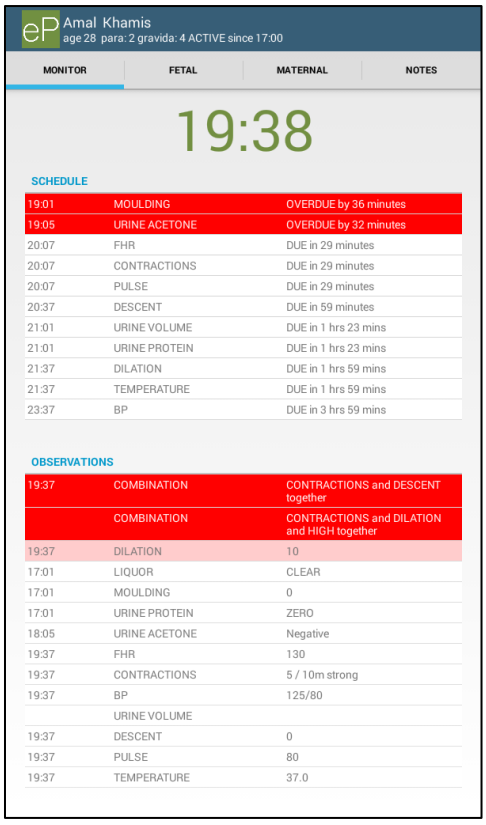
F.

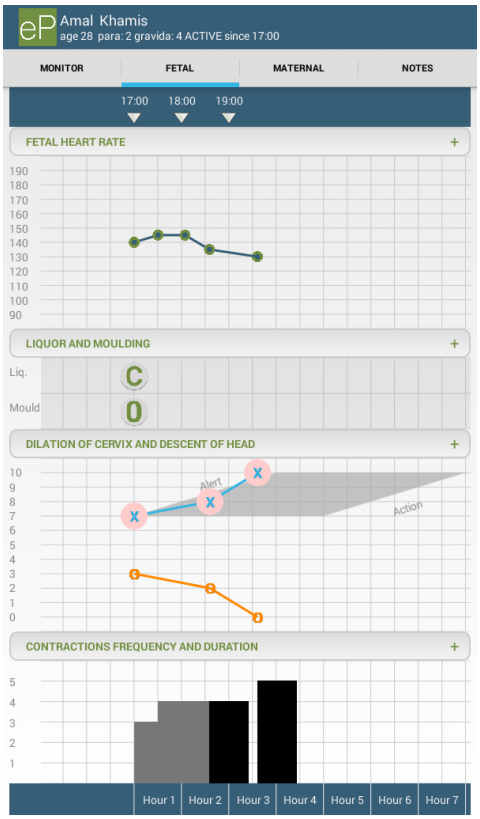
APPENDIX A: WHO Modified Partogram



APPENDIX B: ePartogram







Appendix C: ePartogram testing

Functional testing

- Navigation testing scripts to confirm that users can navigate between screens and the software responds correctly to user inputs
- Quality assurance testing scripts to prove accurate data output on all screens of the ePartogram
- Entry of test scenarios in the ePartogram to ensure that data fields populate correctly, data constraints function correctly, and alarm cutoffs are accurate
- Testing will be repeated by 3 individual testers for quality control
- Functional testing conducted in the United States, Tanzania and Kenya

Performance testing of the system

- Load testing to confirm the ePartogram performs as intended with varying numbers of simultaneous users
- Testing performance metrics for 0-250 users
- Testing will be repeated by 3 individual testers for quality control
- Functional testing conducted in the United States, Tanzania and Kenya

Clinical rules testing

- Front-end input of partograph cases into the ePartogram to verify that ePartogram reminders and alarms fire consistently and correctly
- Excel-based simulations to test the clinical reminders and alerts against the ePartogram code to ensure 100% accuracy
- 125 scenarios used to test 78 clinical rules

Field refinements

- User feedback sessions to verify software design choices and features
- Testing of connectivity at facilities to facilitate optimal data connection for ePartogram

REFERENCES

[1] World Health Organization (WHO), UNICEF, UNFPA, World Bank Group and the United Nations Population Division. (2015). Trends in Maternal Mortality: 1990 to 2015. Estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. Geneva, Switzerland. Accessed in March 2016 at http://apps.who.int/iris/bitstream/10665/194254/1/9789241565141_eng.pdf

[2] Kassebaum NJ, Bertozzi-Villa A, Coggeshall MS (2014). Global, regional, and national levels and causes of maternal mortality during 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet; 384: 980–1004

[3] Lawn J, Blencowe H, Waiswa P et al (2016) Ending preventable stillbirths 2. Stillbirths: rates, risk factors, and acceleration towards 2030. *Lancet.* January 18, 2016. http://dx.doi.org/10.1016/S0140-6736(15)00837-5

[4] Lawn et al, 2010 Two million intrapartum-related stillbirths and neonatal deaths: Where, why, and what can be done? And G. Justus Hofmeyr et al. 2010. Obstetric care in low-resource settings: What, who, and how to overcome challenges to scale up?

[5] Obstetric care in low-resource settings: What, who, and how to overcome challenges to scale up? Hofmeyer et al. *International Journal of Gynecology & Obstetrics*. Volume 107, Supplement , Pages S21–S45, October 2009

[6] Lavender T, Hart A, Smyth RMD. Effect of partogram use on outcomes for women in spontaneous labour at term. Cochrane Database of Systematic Reviews 2008, Issue 7. Art. No.: CD005461. DOI: 10.1002/14651858.CD005461.pub4

[7]Windrim R, Seaward PG, Hodnett E, Akoury H, Kingdom J, Salenieks ME, Fallah S, Ryan G. (2007). A Randomized controlled trial of a bedside partogram in the active management of primiparous labour. *J Obstet Gynaecol Can.* Jan; 29(1): 27-34.

[8] USAID. Quality of Antenatal and Delivery Care Services in Six Countries in Sub-Saharan Africa. Accessed in March 2016 at http://www.mchip.net/sites/default/files/Quality%20of%20ANC%20in%206%20African%20Countries.pdf.

[9] Kagema F, Ricca J, Rawlins B, Rosen H, Mukhwana W, Lynam P, et al. Quality of care for prevention and management of common maternal and newborn complications: findings from a National Health Facility Survey in Kenya—are services provided according to international standards? Baltimore: Jhpiego; 2011. Accessed in January 2016 at http://www.mchip.net/search/apachesolr_search/Kenya%20QoC

[10] World Health Organization. (2003). Management Complications in Pregnancy and Childbirth. Accessed in March 2016 at http://hetv.org/resources/reproductive-health/impac/mcpc.pdf.