

Implementation and evaluation of obstetric early warning chart in a low resource tertiary healthcare setting

Research protocol

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# Title

## PhD title

Early Warning System to Improve Maternal Health in Nigeria; Design, Validation And Evaluation Of Obstetric Early Warning System For Use In Resource Limited Settings

## Phase subtitle

Implementation And Evaluation Of Obstetric Early Warning Chart In A Low Resource Tertiary Healthcare Setting

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# Signatures

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Co-Supervisor

# Collaborating Institutions

Intervention site: University of Ilorin Teaching Hospital,

Kwara State, Nigeria

Control Site 1: Ahmadu Bello University Teaching Hospital

Zaria, Nigeria

Control site 2: Abubakar Tafawa Balewa University Teaching Hospital

Bauchi, Nigeria

1. Acronyms and Glossary

**EWS:** Early Warning System

**MOEWS:** Modified Obstetric Early Warning System

**CEMACH:** Confidential Enquiry into Maternal And Child Health in the UK

**PIERS:** Preeclampsia Integrated Estimate of Risk

**CDC:** Centre for Disease Control

**WHO:** World Health Organisation

**QUADAS:** Quality Assessment of Diagnostic Accuracy Studies

**SMO**: Severe Maternal Outcome, a combination of maternal deaths and near-misses

**EmOC:** Emergency Obstetric Care

**EmONC:** Emergency Obstetric and Newborn Care

**FGD:** Focus Group Discussion

**KII:** Key Informant Interview

**LSTM:** Liverpool School of Tropical Medicine

**NVivo:** *(Qualitative analysis software)*

# Introduction

## Background

Maternal mortality, defined as the death of a woman during pregnancy, childbirth or within the 42 days after delivery, is a major challenge to health systems worldwide. Although the global burden has fallen by almost 50 percent since 1990 (UN SDG), still an estimated 830 deaths occur daily around the world, majority (approximately 99%) of which happen in developing countries (WHO 2016).

Multiple surveillance programs and research initiatives have suggested that majority of maternal deaths are potentially avoidable, especially those related to haemorrhage, hypertensive disorders of pregnancy, infection, and thromboembolic events, which are leading causes of severe maternal morbidity and mortality (Ceccati JG et al, 2016; Farquhar, 2011). Moreover, repeated analyses of maternal deaths across all settings have consistently revealed that delay in recognition of pregnancy complications is a major contributing factor to adverse pregnancy outcomes (Alkema L et al, 2016; Paternina-Caicedo et al, 2017).

Efforts are therefore focussed on developing and testing clinical tools that would enable early recognition of patients who are likely to benefit from an earlier lifesaving intervention or referral to a higher level of care (Edward SE et al, 2014; Austin DM et al, 2014; Shield LE, et al 2016). Such tools include the early warning systems, protocols, bundles or checklists, designed to improve patient safety through evidence-based interventions (Arora et al, 2016). They all aim to foster an interdisciplinary patient-centred care to achieve the goal of reduced morbidity and mortality.

## Early warning systems

These systems assign weighted values to physiological parameters, according to their degree of deviation from normal, and define a pathophysiological threshold beyond which mandatory actions must be taken to prevent irreversible morbidity or death. They range from single parameter to multi-parameter or aggregate weighted scoring systems, where a cumulative score is computed by either a medical staff (often nurse or midwife) or a computer algorithm. When a critical value or score is reached, bedside patient evaluation is triggered with the aim of achieving rapid evaluation and initiation of appropriate clinical intervention.

Early-warning systems have been devised, tested and recommended for non-obstetric patients for over 2 decades (McNeil 2013). The evaluation and triggering criteria that underlie these systems do not account for the physiologic changes of pregnancy, and this render them inadequate in obstetric populations (Lappen 2010, Zuckerwise CL 2017). Hence, a top recommendation by the UK confidential enquiries into maternal deaths in 2007 and 2011 was the use of early warning systems that are modified for obstetric populations.

## Literature review

A systematic review of peer reviewed journal articles was conducted as part of this research, to explore evidence on usefulness and overall effectiveness of obstetric early warning systems.

We searched electronic databases including Medline, Scopus, CINAHL, Science direct and Science Citation Index from January 1997 to March 2018. This time frame was chosen because the first version of early warning chart was developed in 1997. In addition, we hand searched reference lists of relevant journal articles, professional society websites including WHO, FIGO, RCOG, ACOG, CDC and SASOG to identify additional studies.

Seventeen studies of varying quality, based on an assessment tool, the Quality Assessment of Diagnostic Accuracy Studies (QUADAS 2, Whiting et al, 2011), met the inclusion criteria. These included 12 from high income and 5 from low-middle income settings, including India, Pakistan, Zimbabwe, Columbia, South Africa and Brazil. Twelve studies assessed clinical utility of early warning systems as screening tools for obstetric morbidity and 6 studies tested effectiveness of early warning systems in reducing prevalence of measured obstetric outcomes. One of the included studies assessed both clinical utility and effectiveness of obstetric early warning systems.

About 90% (n=16) of the different versions of early warning charts described in the reviewed studies included four parameters; these are the Pulse, Respiratory rate, Blood pressure and Conscious level. The charts were accurate in discriminating at least 85% of women who died (Carle et al, 2010 Paternina-Caicedo et al, 2017).

Obstetric early warning charts showed average sensitivity and specificity of 90% for predicting varying forms of morbidity, or ICU admission among all obstetric inpatients. The average positive predictive value for the two outcomes (severe morbidity or ICU admission) was relatively low (48.18%) with about 52% false positive rate. However, the overall observed test characteristics are similar to those of other non-obstetric screening tools, such as the Parent Report of Children Ability (Johnson et al, 2004; Martin et al, 2013) and the Ages and Stages Questionnaire (Skelern et al, 2001). Assessing ability to predict adverse outcomes among women with pre-eclampsia, statistically derived obstetric early warning models (Preeclampsia Integrated Estimate of Risk (PIERS)) showed accuracies of 88% (fullPIERS) and 77% (miniPIERS) in well resourced, and poor resourced settings respectively.

The review also identified emerging evidence on effectiveness of obstetric early warning systems in improving measured outcomes. Improved vital signs monitoring, and recording was reported after implementation of the Irish maternity early warning system (Maguire PJ et al, 2015). Also, a quasi-experimental study reported significant reduction in the prevalence of Centre for Disease Control (CDC)-defined severe and composite maternal morbidity in 6 intervention sites compared to 19 control sites in the USA (Shield et al, 2016). Other outcomes reported include pre-operative stabilization among women going for caesarean section, need for specialist review, external referral rate, and critical care admission. However, considering the heterogeneity of the investigated outcomes, it was not feasible to pool the overall effect estimates in a meta-analysis. Hence, our review identified the need to standardize outcomes of EWS effectiveness studies for clinical and research purposes.

# Rationale

Sufficient evidence on the usefulness of obstetric EWS was established, based on an already completed systematic review of the literature, conducted as part of this research (briefly described above). The EWS systems were rapidly adopted by UK hospitals and maternities following the 2005 CEMACH report, adoption rate reaching 100% in 2014 (Isaac RA, 2014). They are also widely used in other settings including well-resourced and low-middle income countries as discussed in the systematic review in 1.4 above. However, performance of early warning charts has been shown to vary with settings; in a prospective cohort study, charts developed in well-resourced settings were found to perform poorly in a resource limited setting, hence the need for contextualization and local validation to ensure high diagnostic accuracy (Prince C et al, 2013).

Nigeria was ranked fourth highest in maternal mortality ratio (MMR) in the world in 2016 with an estimated MMR of 814 per 100,000 live births (WHO 2016); considering its population size, Nigeria had even more maternal deaths (58,000) than two of the three countries with highest MMR in the world in 2016 (Chad, 54000 and Central African Republic, 1400). To date however, there is no published work on the use of obstetric/non-obstetric early warning systems for maternity care in Nigeria.

This PhD research therefore sets out to design, validate, introduce and evaluate the use of early warning system in Nigerian tertiary hospitals. We conducted a baseline feasibility study (phase 1) where we identified gross man-power shortages and insufficient monitoring equipment in the three feasibility study sites. However, basic vital signs are monitored and recorded at least twice in a day despite these challenges. The systematic review findings were also reassuring, considering that the five parameters included in almost 95% of the reviewed charts (systolic blood pressure, diastolic blood pressure, pulse rate, respiratory rate and conscious level) require only one monitoring tool (BP Machine) to achieve. These parameters are currently being validated statistically using a secondary data on women who suffered death or near-miss across 42 tertiary hospitals in Nigeria (Phase 2) to ensure good diagnostic accuracy (Prince et al, 2013).

In the last phase for which this protocol applies, we are going to implement the validated early warning chart and assess its usefulness using mixed method research methodology, presented below.

# Aim and objectives

## Study aim

The research aims to introduce and evaluate the usefulness of obstetric early warning system in a tertiary hospital in northern Nigeria.

## Objectives

The specific objectives of the project are as follows

1. To assess effectiveness of obstetric early warning chart in improving measured patient outcomes
2. To explore usefulness of the early warning chart to healthcare staff using qualitative interviews and focus group discussions

# Methodology

## Study design

The study is a mixed design consisting of a controlled before and after quasi-experimental trial and qualitative interviews and focus group discussions.

## Setting

The study will be conducted in three tertiary hospitals in the northeast, north-central and north-western parts of Nigeria, where burden of adverse maternal outcomes is highest. One teaching hospital (University of Ilorin Teaching Hospital) is to be used for the intervention and two other teaching hospitals, National hospital Abuja and Abubakar Tafawa Balewa University Teaching Hospital Bauchi (ATBUTH) are to be recruited as control facilities.

## Participants and recruitment

Pregnant and postpartum women admitted to all inpatient wards due to pregnancy complications, delivery or for any condition within the puerperium (42 days post-partum) are eligible for inclusion. Women are excluded if they have met any of the three near-miss criteria before hospital admission (clinical, management-based and organ dysfunction; Say L et al, 2009), or they are admitted straight to intensive care unit without going through any of the inpatient wards. All eligible participants in the intervention will be recruited by trained nurses/midwife undertaking patient monitoring in the respective wards. Eligible participants for the qualitative interviews and focus group discussions are discussed under the relevant scoping activities (4.7 below).

## Intervention

The intervention is obstetric early warning chart which will consist of routinely collected patient vital signs scored according to degree of deterioration from normal (attached to the protocol). This will substitute the vital signs chart in the routine nursing observation records in the intervention site. The two control sites will continue with their routine practice of patient observation

## Sample size

Baseline data for the intervention site indicates that the monthly number of obstetric admissions is around 190, and around 25 to 30% of them experience a severe maternal outcome (SMO = death or near-miss). The table below indicates reduction detectable with 80 % or 90% power for follow up period of between 3 and 6 months. Initial SMO rates of 25 and 30% are considered.

**Table 1: Sample size estimate in the intervention arm**

| **Number in pre-intervention** | **Number in follow-up period** | **Reduction from 25% detectable** | | **Reduction from 30% detectable** | |
| --- | --- | --- | --- | --- | --- |
| **80% power** | **90% power** | **80% power** | **90% power** |
| 380 (2 months) | 570 (3 months) | 8.0% | 9.1% | 8.6% | 9.8% |
|  | 760 (4 months) | 7.6% | 8.7% | 8.1% | 9.3% |
|  | 950 (5 month) | 7.3% | 8.4% | 7.8% | 9.0% |
|  | 1,140 (6 months) | 7.1% | 8.2% | 7.6% | 8.8% |
| 570 (3 months) | 570 (3 months) | 7.2% | 8.2% | 7.7% | 8.8% |

The additional month pre-intervention increased the power to detect a specified difference and reduces the total number of months for which data need to be collected for a given reduction to be detectable. We therefore considered 3 months period each for the pre and post-intervention follow ups. Factoring in possible exclusion rate of around 10%, the sample size considered is around 1000 in the intervention site (500 each in the pre and post intervention). Same number of participants will be recruited in the control sites as illustrated in table 2 below.

**Table 2: Breakdown of sample size by study arms**

|  |  |  |  |
| --- | --- | --- | --- |
| **Study arm** | **Before** | **After** | **Total** |
| Intervention | 600 | 600 | 1200 |
| Control 1 | 300 | 300 | 600 |
| Control 2 | 300 | 300 | 600 |
| Total | 1000 | 1000 | 2400 |

Intervention = UITH Ilorin, Control 1 = National hospital Abuja, Control 2 = ATBUTH Bauchi

## Quantitative method

### Trial procedure

A controlled before-and-after quasi-experimental study design will be employed to address the first research objective. the first stage will involve implementation of the chart in the intervention hospital. Implementation team will be constituted which will consist of the primary researcher, the co-PI in the intervention site, a resident doctor and an experienced/senior nurse in administrative position. All staff involved in monitoring of obstetric patients will be trained on how to use the chart to trigger response and inform plan for further monitoring; however, management of specific complications will be according to hospital-specific protocol or usual practice as appropriate. All subsequent queries related to the chart are to be directed to the implementation team.

The implementation of obstetric early warning system in the intervention hospital is part of the extended emergency obstetric care (EmOC) training (assisted vaginal delivery, caesarean section and peri-operative care), which is a department-wide initiative for quality improvement. Routinely collected patient information will be collected for the quasi-experimental study, thus, no individual-level consent was deemed necessary as was done in similar studies (Merriel A et al, 2017; Sheikh S et al, 2017; Singh A et al, 2016).

The chart will be incorporated into the medical files of the eligible obstetric patients and the patients will be prospectively followed until the end of their stay in the hospital. To assess any change in practice and prevalence of outcomes (listed below) following the implementation, notes of all eligible women will be reviewed retrospectively pre-implementation (1st August to 31st October) and post implementation (1ST December to 28th February). This task will be undertaken by the principal investigator and a research assistant in each of the three study sites. Data will be extracted from patients’ case notes onto a data abstraction sheet for analysis.

### Primary outcomes

The primary outcome measures are maternal death (based on the ICD-10 definition, Say L et al, 2009), maternal near-miss (based on the three near-miss criteria, clinical, management-based and organ dysfunction; Say L et al, 2009) or admission to intensive care unit (ICU).

### Secondary outcomes

Secondary outcome measures will include rate of vital signs monitoring and recording (respiratory rate, pulse, blood pressure and temperature), duration of hospital stay, speed of post-trigger specialist review, caesarean section rate and rate of instrumental delivery.

The details of primary and secondary outcomes are clearly defined on table 3 below.

**Table 3: Outcome measures and definitions**

|  |  |
| --- | --- |
| **Outcomes** | **Definition** |
| **Maternal death** | Death of a woman while pregnant or within 42 days of termination of pregnancy from causes related to or aggravated by the pregnancy or its management and not from accidental or incidental causes |
| **Near-miss** | A woman who nearly died but survived a complication hat occurred during pregnancy, childbirth or within 42 days of termination of pregnancy. This will be identified based on the clinical based, intervention-based and organ system dysfunction-based criteria as defined by Say et al (Say et al, 2009). Data collectors will be trained to correctly identify maternal near-miss cases based on these. |
| **ICU admission** | Number of admissions to intensive care or high dependency care units that are due to direct obstetric conditions. |
| **Vital signs recording** | Rate of recording of respiratory rate, pulse, blood pressure and temperature computed as ratio of the observed to expected in percentage. |
| **Duration of hospital stay** | This is the average number of days spent between hospital admission and discharge. |
| **Speed of specialist review** | This will be average time interval between trigger and specialist review |
| **C/S delivery rate** | This will be proportion of deliveries that are conducted via caesarean section |
| **Instrumental delivery rate** | This will be proportion of deliveries that are conducted via assisted vaginal delivery methods using vacuum or forceps |

## Qualitative interviews and focus group discussions

Semi structured key informant interviews (KII) and focus group discussions (FGD) will be conducted in the intervention site at the end of the follow up period. These activities will be employed to explore experience of health workers on use of early warning chart.

The KII aims to collect an in-depth information on the perception of key informants on the usefulness or otherwise, of obstetric early warning chart and challenges that might have been experienced from use of the implemented system and how these might have been addressed. The targets are purposefully selected but very experienced midwives/nurses in administrative positions, doctors in the obstetric department including residents and consultants. standardized open ended interview approach will be employed in the early part of all interviews. Open ended questions will be designed to respond to the interview aims, and all the interviewees will be asked the same questions. However, the interviewer will be free to pursue any subject of interest deemed relevant during the latter parts of the interviews.

The FGD target staff nurses/midwives and, where applicable, other cadres of staff who undertake monitoring of studied participants using the early warning charts. By conducting the FGD, we aim to explore and understand exactly the experience of using the chart and challenges encountered from view point of those using the chart. Such rich data will also allow for triangulation with data from key informant interviews.

Once identified, participants will be oriented about the research and participant information sheet will be issued by the principal researcher. All KIIs and FGDs will be facilitated by the principal researcher (and a research assistant in case of the FGDs) who has been trained on how to moderate sessions and have significant experience in conducting qualitative research. An informed consent, including consent to audio-record interview/focus group discussion sessions will be obtained. If any participant refuse consent to audio record, the facilitator (or research assistant in the case of FGDs) will try his best to take notes during those interviews or focus group sessions. Although we aim to conduct about 10 KIIs and 4-7 FGDs, data collection will continue until saturation is reached.

## Quality control

The term quality control refers to “the efforts and procedures that researchers put in place to ensure the quality and accuracy of data being collected using the methodologies chosen for a particular study” (Roe 2008). Quality control will be maintained throughout the research, by monitoring of the process, both for the quantitative and qualitative components of the research. The strategies to achieve this monitoring process include:

For the quantitative study (quasi-experimental trial), compliance will be audited by the principal researcher during the immediate post implementation period daily for 2 weeks to ensure that the chart is correctly used on all eligible participants. Subsequently, a monthly audit will be performed by the implementation team to monitor use of the chart and any ongoing change in practice. A quality indicator will be adopted (adopted tool attached: Merriel et al, 2017) to provide the implementation team with a simple way to achieve this. This indicator will incorporate the notes of the patients on one ward on a particular day in a month. It will capture the usage rate of charts (number of cases with correctly completed MOEWS charts/number of cases reviewed), whether healthcare staff took appropriate action to abnormal observations (number of cases in which action was taken/total number of charts requiring action), and the timeliness of the action if one was required (total number where action was taken within the required timeframe/total number where action was taken).

For the FGDs and KIIs, a comprehensive and detailed standardised operating procedure manual, which aligns with the research protocol, will guide data collection. Topic guides will be pretested before its use in the full KIIs and FGDs and will only inquire relevant questions and avoid redundancy to ensure data efficiency.

Emphasis will be placed on trustworthiness of the research. The research will aim to ensure that participants feel comfortable and that they are able to express themselves or behave naturally (credibility), by ensuring that sufficient rapport is established between the researcher and the researched. Efforts will be made to ensure that the sample is representative of the study population and data collection will continue up to the point when no new information is being retrieved during the FGDs and KIIs (i.e. saturation is achieved). In addition, key findings collected from the focus groups will be repeated to the participants to verify that they recognise them, and they convey their intended meaning (confirmability).

All these quality control activities would potentially contribute to improving data quality and thus the results.

## Data management and analysis

### Quantitative data

Data collected will be entered into computer and cleaned for analysis. All data will be managed in accordance with the Liverpool School of Tropical Medicine (LSTM)’s policy for data management. Data will be stored for a maximum of five years and will be destroyed afterward. Analysis will be conducted using IBM SPSS version 23. Descriptive statistics will be calculated to evaluate the number of women with correctly completed observation charts, the number with observations that should trigger action, and the number with action taken per month. Descriptive statistics, χ2 test, and poisson regression analysis will be used to evaluate whether primary and secondary outcomes occurred less frequently in the intervention site after early warning chart implementation. Prevalence of outcomes will also be computed during the same period in the control site to check for trend effect or effects of other quality improvement programs during the study period. Data from the pre-implementation and post-implementation periods in all study arms will be compared by χ2 test. *P<*0.05 will be taken as statistically significant. Results will be presented in tables and charts.

### Qualitative data

KIIs and FGDs will be conducted in English language, scripts will be transcribed verbatim, ensuring all identifying information are removed and transcripts are anonymized. Thematic framework approach will be employed to analyse the qualitative data. This method was chosen because of its systematic approach to data management, and its emphasis on transparency in analysis (Richie and Lewis, 2003).

Familiarization will be carried out by repeated listening on the audio recordings. Transcripts will have large margins and adequate line spacing for coding and note making. A thorough review of the raw data will be carried out to identify important themes and concepts. These recurring themes will then be sorted and grouped under a smaller number of broader categories of main themes and placed within an overall framework.

Having developed a preliminary contextual framework, ‘indexing’ will be performed, which entails applying the initial framework to the raw data to check how categories fit. Modification of the framework will then be performed where necessary, such as addition of missing categories, and the framework will be appropriately labelled. These will be done electronically with the aid of Computer Assisted Qualitative Data Analysis Software (CAQDAS), NVivo 11.

Following these, we will sort the data by themes, and subsequently reduce it through summarization and synthesis (Richie and Lewis, 2003). A set of thematic matrices/charts will be created, and each main theme and its associated subtopics will be plotted on a separate thematic chart. Each respondent will be allocated a row in the matrix, while each subtopic will be displayed in a separate column. Key parts of each piece of data will be summarized and placed appropriately in the thematic matrix (charting). Throughout the charting process, a balance will be maintained between reducing the data and preserving the context, and the language in which it was expressed.

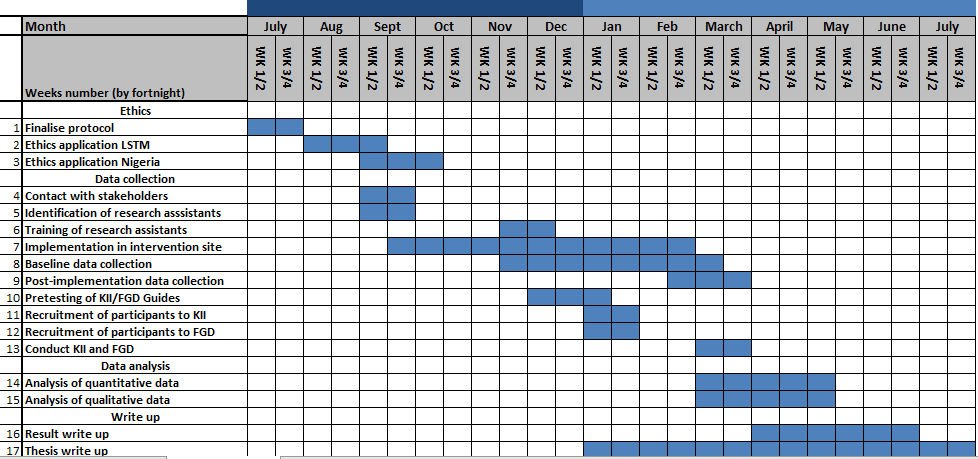
Having finished the qualitative data management steps of the framework analysis, we will try to make sense out of the synthesized evidence using descriptive accounts (Richie and Lewis, 2003). Emerging understandings will be tested, alternative explanations will be sought, and data analysis will be written up. Results will be presented using different NVivo data presentation tools including charts, tree maps and graphs.

# Ethical issues

The study requires both primary and secondary data. Ethical approval will be sought from the Research Ethics Committee (REC) of the Liverpool School of Tropical Medicine, and the local ethics committees of the selected hospitals. Recordings of interviews and FGDs will be stored on password protected data devices and will be destroyed once data is transcribed and analysed. Potential ethical issues we anticipate and how we intend to address them are discussed below;

* *Evidence exist for usefulness of early warning charts, it could therefore be argued that having control sites will be denying the participants of benefit of the intervention: We aim to minimize this by collecting only secondary data in the control sites, and also by disseminating our findings to the two control sites and possibly introducing the charts after data collection.*
* *Interviewees and participants of FGD may have problem in taking time from work to participate in study:* We aim to minimize the above ethical issue by being flexible with the timings of KII and FGD to meet the needs of research participants.
* *FGD participants may be reluctant to openly express their views or criticize others’ views for fear of negative consequences from their superiors or line managers:*We will ensure that confidentiality of participants is guaranteed before commencement of data collection. FGDs will comprise of same cohorts of participants, midwife/nurses in charge or other appropriate line managers will be excluded from participating.

# Timeline



# Budget

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S/No** | **Item (unit description)** | **Unit cost (£)** | **Number** | **Cost (£)** | **Cost (N)** |
|  | **Research** |  |  |  |  |
| 1 | Ethics application (LSTM) | 50 | 1 | 50 | 23300 |
| 2 | Pay for research assistants | 150 | 3 | 450 | 209700 |
| 3 | Refreshment for FGD Participants | 3 | 25 | 75 | 34950 |
|  | **Logistics** |  |  |  |  |
| 4 | Air travel to Nigeria | 500 | 3 | 1500 | 699,000 |
| 5 | Local flights (Ilorin, Bauchi) | 70 | 9 | 630 | 293,580 |
| 6 | Land travel (Zaria, Bauchi) | 60 | 3 | 180 | 55920 |
| 7 | Accommodation and feeding  (Ilorin, Bauchi) \* | 30 | 30 | 900 | 419400 |
| 8 | Transcription fee for KII and FGD | 20 | 15 | 300 | 139800 |
|  | Total |  |  | 4,085 | 1,903,610 |
|  | Miscellaneous (10% of total) | 10% |  | 408.5 | 190,361 |
|  | Grand total (total + miscellaneous) |  |  | 4493 | 2,093,971 |

\*Accommodation and feeding in Zaria not included as my family lives in Zaria

# Reference list

1. Cecatti JG, Costa ML, Haddad SM, Parpinelli MA, Souza JP, Sousa MH, Surita FG, Pinto e Silva JL, Pacagnella RC, Passini Jr R, Brazilian Network for Surveillance of Severe Maternal Morbidity study Group. Network for Surveillance of Severe Maternal Morbidity: a powerful national collaboration generating data on maternal health outcomes and care. BJOG: An International Journal of Obstetrics & Gynaecology. 2016 May;123(6):946-53.

2. Farquhar C, Sadler L, Masson V, Bohm G, Haslam A. Beyond the numbers: classifying contributory factors and potentially avoidable maternal deaths in New Zealand, 2006–2009. Am J Obstet Gynecol 2011; 205:331.e1–8.

3. Alkema L, Chou D, Hogan D, et al. Global, regional, and national levels and trends in maternal mortality between 1990 and 2015, with scenario-based projections to 2030: a systematic analysis by the UN Maternal Mortality Estimation Inter-Agency Group. Lancet 2016;387:462-74.

4. Paternina-Caicedo A, Miranda J, Bourjeily G, et al. Performance of the Obstetric Early Warning Score in critically ill patients for the prediction of maternal death. Am J Obstet Gynecol;216(1):58-e1.

5. Edwards SE, Grobman WA, Lappen JR, et al. Modified obstetric early warning scoring systems (MOEWS): validating the diagnostic performance for severe sepsis in women with chorioamnionitis. Am J Obstet Gynecol 2015; 212:536. e1-8

6. Austin DM, Sadler L, McLintock C, McArthur C, Masson V, Farquhar C, Rhodes S. Early detection of severe maternal morbidity: a retrospective assessment of the role of an early warning score system. Aust N Z J Obstet Gynaecol. 2014 ;54(2):152-5.

7. Shields LE, Wiesner S, Klein C, Pelletreau B, Hedriana HL. Use of maternal early warning trigger tool reduces maternal morbidity. Ame J Obstet Gynecol. 2016;214(4):527-e1.

8. Arora KS, ShieldsLE, Grobman WA, D’Alton ME, LappenJR, Mercer BM. Triggers, bundles, protocols, and checklists-what every maternal care provider needs to know. Am J Obstet Gynecol. 2016;214(4):444–451.

9. McNeill G, BrydenD. Do either early warning systems or emergency response teams improve hospital patient survival? A systematic review. Resuscitation. 2013;84(12): 1652–1667.

10. Lappen JR, Keene M, Lore M, Grobman WA, Gossett DR, et al. Existing models fail to predict sepsis in an obstetric population with intrauterine infection. Am J Obstet Gynecol. 2010; 203(6): 573.e1-5.

11. Zuckerwise LC, Lipkind HS. Maternal early warning systems—Towards reducing preventable maternal mortality and severe maternal morbidity through improved clinical surveillance and responsiveness. In Seminars in perinatology 2017 Apr 1 (Vol. 41, No. 3, pp. 161-165). WB Saunders.

12. Whiting PF, Rutjes AW, Westwood ME, Mallett S, Deeks JJ, Reitsma JB, Leeflang MM, Sterne JA, Bossuyt PM. QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies. Annals of internal medicine. 2011 Oct 18;155(8):529-36.

13. Carle C, Alexander P, Columb M, Johal J. Design and internal validation of an obstetric early warning score: secondary analysis of the Intensive Care National Audit and Research Centre Case Mix Programme database. Anaesthesia. 2013;68(4):354-67.

14. Johnson S, Marlow N, Wolke D, Davidson L, Marston L, O'Hare A, et al. Validation of a parent report measure of cognitive development in very preterm infants. Dev Med Child Neurol. 2004; 46(6):389-397.

15.Skellern CY, Rogers Y, O'Callaghan MJ. A parent‐completed developmental questionnaire: follow up of ex‐premature infants. J Pediatr. 2001 10; 37(2):125-129.

16.Martin AJ, Darlow BA, Salt A, Hague W, Sebastian L, McNeill N, et al. Performance of the Parent Report of Children's Abilities–Revised (PARCA-R) versus the Bayley Scales of Infant Development III. Arch Dis Child 2013; 98 (12):955-958.

17. Maguire PJ, O'higgins AC, Power KA, Daly N, McKeating A, Turner MJ. Maternal bacteremia and the Irish maternity early warning system. International Journal of Gynecology & Obstetrics. 2015 May 1;129(2):142-5.

18. Isaacs RA, Wee MY, Bick DE, et al, Modified Obstetric Early Warning Systems Research Group. A National Survey of Obstetric Early Warning Systems in the United Kingdom: 5 Years On. Obstetric Anesthesia Digest. 2015 35(3):121

19. Price C, Sitch A, Banda P, et al. Early warning scores generated in developed healthcare settings are not sufficient at predicting early mortality in Blantyre, Malawi: a prospective cohort study. PloS one. 2013 Mar 29;8(3):e59830

21.Merriel A, Murove BT, Merriel SW, Sibanda T, Moyo S, Crofts J. Implementation of a modified obstetric early warning system to improve the quality of obstetric care in Zimbabwe. International Journal of Gynecology & Obstetrics. 2017 Feb 1;136(2):175-9.

22. Sheikh S, Qureshi R, Nausheen S, Sultanali RS. Implementation of warning tool to improve maternal newborn health outcomes in a developing country. Journal of the Pakistan Medical Association: JPMA. 2017;67(1):111.

23. Singh A, Guleria K, Vaid NB, et al. Evaluation of maternal early obstetric warning system (MEOWS chart) as a predictor of obstetric morbidity: a prospective observational study. Eur J Obstet Gynecol Reprod Biol. 2016; 207:11-7

24. Say L, Souza JP, Pattinson RC. Maternal near miss–towards a standard tool for monitoring quality of maternal health care. Best Practice & Research Clinical Obstetrics & Gynaecology. 2009 Jun 1;23(3):287-96.

25. Richie J, Lewis J, Nichols C, Ormston R. Qualitative research practice. A guide for social science students and. 2003.

Month: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Year: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Total number of admissions/inpatients: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Number of research eligible patients reviewed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# APPENDIX A: MONTHLY DATA ABSTRACTION SHEET

Testing effectiveness of obstetric early warning charts in improving measured outcomes

**Baseline characteristics**

1. Mean (Q1-Q3) 2. Number (%)

* Age \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ - Booked cases\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Weight \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ -Live birth \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Height \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ -Still birth \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Booking GA \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ -Spontaneous abortion \_\_\_\_\_\_\_\_\_\_\_\_\_
* Parity \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ -Induced abortion \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* GA at delivery \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ -Birth weight \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Number ANC visit\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Primary outcomes

3. Number of maternal deaths\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 4. ICU Admissions\_\_\_\_\_\_\_\_\_\_\_\_ 5. Near-misses \_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Condition | ICU/HDU Admission | Near-miss | Death | Total |
| Obstetric haemorrhage |  |  |  |  |
| Pregnancy related infections |  |  |  |  |
| Hypertensive disorders |  |  |  |  |
| Prolonged labour |  |  |  |  |
| Obstructed labour |  |  |  |  |
| Thromboembolism |  |  |  |  |
| Abortion complications |  |  |  |  |
| Others, please specify  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Secondary outcomes**

**6.** Rate of vital signs recording = (charts with completed vital sign / charts reviewed) in %

- Respiratory rate \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

- Pulse rate \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

-Systolic Blood pressure \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

-Diastolic blood pressure \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

-Temperature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**7**. Mean (Q1-Q3) duration of hospital stay in days \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**8**. Mean (Q1-Q3) time interval between trigger and specialist review in minutes \_\_\_\_\_\_\_\_\_\_\_\_\_\_

9. Number (%) elective caesarean section \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

10. Number (%) elective caesarean section \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

11. Number (%) of instrumental deliveries

- Forceps \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

- Vacuum \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

-Destructive delivery \_\_\_\_\_\_\_\_\_\_\_\_

-Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# APPENDIX B: KEY INFORMANT INTERVIEW TOPIC GUIDE

**CHARACTERISTICS OF THE INTERVIEWEE**

**ID No \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Hospital \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Designation\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Duration of experience\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Interviewer**: The principal researcher will be responsible for coordination of the discussion, audio-recording and making notes, including context of the discussion. He is also responsible for general logistics and planning of all sessions.

**Introduction**

Thank you very much for sparing time to partake in this interview. We are meeting to discuss your experience in relation to obstetric early warning chart which was introduced to this facility some time ago. What we discuss here will remain confidential. I will start by asking you to identify and describe your role(s) regarding monitoring and care of obstetric inpatients. I will continue by asking what you feel are the advantages and downsides of the intervention, and what is your perception of its net usefulness in patient monitoring and care. If you happen to be one of the staffs using the chart for monitoring (nurse or midwife), Then I would ask you to describe very briefly some of the challenges experienced after implementation of the tool. I will then go on to ask about some of these challenges in more details and review your opinion on how they were (or can be) surmounted. The entire session will take about 45 minutes. I will audio-record the sessions but nothing you said will be linked to you during or after analysis.

**Specific interview questions**

1. Can you please describe your role (s) in regards to monitoring and care of obstetric inpatients admitted to all hospital wards (or ICU as the case may be).

**Probe:** ask for general roles, link to the early warning chart use, or response to trigger (as appropriate)

*If the interviewee does not use the chart primarily for patient monitoring (is a doctor), skip 2 and 3.*

1. Can you please describe your experience of the use of obstetric early warning chart

**Probe;** ease of use, compare to earlier practice, accuracy in identifying deterioration

1. What challenges did you encounter while using the obstetric early warning chart?

**Probe:** Ask in depth and explore specific challenges

1. What, from your experience, do you consider as advantages of the obstetric early warning charts

**Probe:** Ask in depth and explore specific advantages

1. What, from your experience, do you consider as the downsides of using obstetric early warning charts?

**Probe:** Ask in depth and explore specific disadvantages

1. What is your perception of the net usefulness of obstetric early warning charts?

**Probe:** Ask how participant will prioritize merits and demerits? which ones do you think outweighs the other?

1. Do you think the disadvantages can be remedied? if yes, what measures in your opinion can be taken to address them?

**Probe:** Explore measures taken (that can be taken) to address each challenge (disadvantage) mentioned in 5 above.

1. How sustainable do you think this intervention (obstetric early warning chart) can be in this facility?

**Probe:** Ask how long interviewee thinks adherence to use of the chart can last for, ask what factors can affect sustainability, explore factors/reasons

1. How do you think sustainability can be improved?

**Probe:** Ask what measures can be taken to address factors mentioned in 8, ask what could have been done differently, how can the implementation program be improved.

1. Is there anything that you think is important and can add to this discussion?



# APPENDIX C: FOCUS GROUP DISCUSSION TOPIC GUIDE

**CHARACTERISTICS OF PARTICIPANTS WILL BE COLLECTED IN THE FOCUS GROUP DISCUSSION LOG**

**Moderator:** The principal researcher is responsible for coordination of the discussion

**Assistant:** A research assistant will be responsible for audio-recording and making notes, including context of the discussion. He is also responsible for general logistics and planning of all sessions.

**Introduction**

Thank you all for agreeing and sparing time to partake in this exercise. We are meeting to discuss your experience in relation to obstetric early warning chart which was introduced to this facility 3 months ago, as part of the emergency obstetric care training by the Centre for Maternal and Newborn Health, Liverpool School of Tropical Medicine. What we discuss here will remain confidential. I will start by asking you to identify and describe your role(s) regarding monitoring and care of obstetric inpatients. I will then ask you to discuss exhaustively your experience of patient monitoring with early warning chart and how that was different from the earlier practice of vital signs monitoring on nurses’ chart. I will continue by asking what you feel are the advantages and downsides of the intervention, and what is your perception of its net usefulness in patient monitoring and care. This session will take about one hour. As you would have consented, I will audio-record the sessions to have accurate findings but can assure you that nothing you said will be linked to you during or after analysis.

*Can we set our ground rules to foster good discussions?*

Questions to be discussed

1. Can you please describe your role (s) in regard to monitoring and care of obstetric inpatients admitted to all hospital wards (or ICU as the case may be)?

**Probe:** ask for general roles, link to the early warning chart use and triggering response based on the chart

1. Can you describe your experience of patient monitoring using obstetric early warning chart?

**Probe;** ease of use, compare to earlier practice, accuracy in identifying deterioration

1. What do you consider as positive outcomes of implementing obstetric early warning chart on you or your practice?
2. What do you consider as Negative outcomes of implementing obstetric early warning chart on you or your practice?
3. On the piece of paper in front of you, jot down four of these items that you consider most important, separating the positives from negatives (two each).

**Probe:** Collect the sheet and guide discussion using identified factors as guides

1. What is your perception of the net usefulness of obstetric early warning charts?

**Probe:** Ask how you will prioritize merits and demerits, which ones do you think outweighs the other

1. Do you think the aforementioned negative outcomes can be remedied? if yes, what measures in your opinion can be taken to address them?

**Probe:** Explore measures taken (that can be taken) to address each outcome (disadvantage) mentioned in 5 above

1. How sustainable do you think this intervention (obstetric early warning chart) can be in this facility?

**Probe:** Ask how long participants thinks adherence to use of the chart can last for, ask what factors can affect sustainability, explore factors/reasons

1. How do you think sustainability can be improved?

**Probe:** Ask what measures can be taken to address factors mentioned in 8, ask what could have been done differently, how can the implementation program be improved.

1. Is there anything that you think is important and can add to this discussion?



# APPENDIX D: TRIAL QUALITY ASSESSMENT CHECKLIST

Day and Month: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Year: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Total number of admissions/inpatients: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Number of research eligible patients reviewed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Number of patients in 2 above with correctly completed obstetric early warning chart: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Compute the usage rate of Obstetric early warning chart: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**NB**

Usage rate = (result of number 3 / results of number 2 above) expressed in %

1. Total number of charts requiring action based on the escalation guideline: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Number of cases in which action was taken: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Number of cases in whom action was required: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Compute an index (X) of whether healthcare staff took appropriate action to abnormal observation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**NB**

X = (Findings in number 6 / Findings in number 7) expressed in %

1. Number of triggered patients in whom review was done within one hour of trigger \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Compute index of timeliness of action taken (Y): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**NB**

Y = total number where action was taken within the required timeframe/total number where action was taken

Y = (Findings in 9 / findings in 6 above) expressed in %

# APPENDIX E: INFORMED CONSENT AND INFORMATION SHEET (KII)

**Name of Principal Researcher:** Dr Aminu Aliyu Umar

**Name of Organisation:** Liverpool School of Tropical Medicine

**Scoping activity: Key Informant Interview**

This informed consent form has two parts:

• Information Sheet (to share information about the research with you)

• Certificate of Consent (for signatures if you agree to take part)

**INFORMATION SHEET**

**BACKGROUND**

You are invited to participate in this research project, which is part of a doctoral thesis, which is aimed at improving maternal and newborn outcomes through early detection of features of maternal deterioration with the aid of obstetric early warning chart. Before you decide, it is important for you to understand why the research is being done and what it entails. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you want more information. Take time to decide whether to participate.

You were chosen because you meet certain criteria for participation, which are: you provide care to (doctors), and or undertake monitoring of, women in labour, sick pregnant and recently delivered women (within puerperium) and might have been using the recently introduced obstetric early warning chart.

Ethical approval for this research was received from the research and ethics committee of the Liverpool School of Tropical Medicine and the Ethics and Research Committee of the University of Ilorin Teaching Hospital.

**PURPOSE OF THE RESEARCH**

The research is being conducted to understand the impact of the obstetric early warning chart on obstetric outcomes in the UITH and explore its usefulness among healthcare staff. The intervention was implemented as part of the EmONC training by the Centre for Maternal and Newborn Health, Liverpool School of Tropical Medicine. We want to understand how you feel about the tool, the challenges that might have been encountered while using it, and how best you think this could be addressed.

**PROCEDURE**

You are being invited to take part in an interview. For this interview, the principal researcher (myself) will be guiding the discussion. Questions that you might have about the research can be answered at this point.

I will start by asking you to identify and describe your role(s) regarding monitoring and care of obstetric inpatients. I will continue by asking what you feel are the advantages and downsides of the intervention, and what is your perception of its net usefulness in patient monitoring and care. If you happen to be one of the staffs using the chart for monitoring (nurse or midwife), Then I would ask you to describe very briefly some of the challenges experienced after implementation of the tool. I will then go on to ask about some of these challenges in more details and review your opinion on how they were (or can be) surmounted.

The interview session will take place in [location of the interview], and no one else but myself and you will be present. The entire session will be recorded, with your permission, but no identifying information will be collected on the recording. Recordings will be stored on a secure drive and will be in possession of the principal researcher only. Information recorded is confidential. The recordings will be destroyed after 5 years.

**DURATION**

The interview session will be held once and will last about 45 minutes.

**RISKS**

There is a risk that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the interview if you feel the question(s) are too personal or if talking about them makes you uncomfortable.

**POTENTIAL IMPACT ON PARTICIPANTS**

There is no potential risk or discomfort in this research.

**EXPECTED BENEFITS FOR PARTICIPANTS AND SOCIETY**

By participating, you would be contributing invaluable feedback to be used in improving emergency obstetric care provision. There is no direct benefit to participant.

**REIMBURSEMENTS**

There will be no financial incentives to participants.

**CONFIDENTIALITY**

We will ask each of you to keep what was said in this session confidential. Any information obtained from you will be anonymised. All data will be entered into the database and securely stored. Data will be transported out of the country for analysis in the United Kingdom. Data will only be used for the purposes of this research.

**DISSEMINATION OF RESULTS**

Results will be published in peer-reviewed journals and in print and e-thesis format.

**PARTICIPATION AND WITHDRAWAL**

Choice to participate in this study relies solely on you. At any time during the research, you can choose to withdraw without consequence to you. You can refuse to answer any question you do not want to answer and still be part of the study.

**RIGHTS OF PARTICIPANTS**

You do not lose legal rights while participating in this study.

**CONTACT**

Please contact the principal researcher on the email address [aminu.umar@lstmed.ac.uk](mailto:aminu.umar@lstmed.ac.uk) , if you have questions or concerns about this study, or by mail to the undermentioned address.

Dr Aminu Umar

First Floor Wolfson building

Centre for Maternal and Newborn Health

Liverpool School of Tropical Medicine

Pembroke Place, L3 5QA, Liverpool, UK

+441517029389

**CERTIFICATE OF CONSENT**

The above information was clearly explained to me in English by the administrator of the instrument and I understand the language. I was given the opportunity to ask questions which were answered satisfactorily.

I hereby voluntarily consent to participate and have received a copy of this form.

I am also aware that the discussion will be recorded, and I consent to this.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of participant / Date

For administrator,

I certify that all information concerning the research was accurately provided to the participant.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of administrator / Date

A copy of this information will be given when you return the completed form.

**THANK YOU**

# APPENDIX F: INFORMED CONSENT AND INFORMATION SHEET (FGD)

**Name of Principal Researcher:** Dr Aminu Aliyu Umar

**Name of Organisation:** Liverpool School of Tropical Medicine

**Scoping activity: Focus Group Discussion**

This informed consent form has two parts:

• Information Sheet (to share information about the research with you)

• Certificate of Consent (for signatures if you agree to take part)

**INFORMATION SHEET**

**BACKGROUND**

You are invited to participate in this research project, which is part of a doctoral thesis, which is aimed at improving maternal and newborn outcomes through early detection of features of maternal deterioration with the aid of obstetric early warning chart. Before you decide, it is important for you to understand why the research is being done and what it entails. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you want more information. Take time to decide whether to participate.

You were chosen because you meet certain criteria for participation, which are: you provide the care to, and undertake monitoring of, women in labour, sick pregnant and recently delivered women (within puerperium) and have been using the recently introduced obstetric early warning chart in the course of discharging your clinical duties.

Ethical approval for this research was received from the research and ethics committee of the Liverpool School of Tropical Medicine and the Ethics and Research Committee of the University of Ilorin Teaching Hospital.

**PURPOSE OF THE RESEARCH**

The research is being conducted to understand the impact of the obstetric early warning chart on obstetric outcomes in the UITH and explore its usefulness among healthcare staff. The intervention was implemented as part of the EmONC training by the Centre for Maternal and Newborn Health, Liverpool School of Tropical Medicine. We want to understand how you feel about the tool, the challenges that might have been encountered while using it, and how best you think this could be addressed.

**PROCEDURE**

You are being invited to take part in a discussion with 5-7 other persons with similar backgrounds. For the focus group discussion, a member of the research team will guide the discussion. The focus group will start with the focus group moderator, making sure that you are comfortable. Questions that you might have about the research can be answered at this point.

We will start by asking you to identify and describe your role(s) regarding monitoring and care of obstetric inpatients. We will then ask you to discuss exhaustively your experience of patient monitoring with early warning chart and how that was different from the earlier practice of vital signs monitoring on nurses’ chart. We will continue by asking what you feel are the advantages and downsides of the intervention, and what is your perception of its net usefulness in patient monitoring and care.

The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion, the note taker and I will be present. The entire discussion will be recorded, with your permission, but no one will be identified by name on the recording. Recordings will be stored on a secure drive and will be in possession of the principal researcher only. Information recorded is confidential. The recordings will be destroyed after 5 years.

**DURATION**

The focus group discussion will be held once and will last about one hour.

**RISKS**

There is a risk that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion if you feel the question(s) are too personal or if talking about them makes you uncomfortable.

**POTENTIAL IMPACT ON PARTICIPANTS**

There is no potential risk or discomfort in this research.

**EXPECTED BENEFITS FOR PARTICIPANTS AND SOCIETY**

By participating, you would be contributing invaluable feedback to be used in improving emergency obstetric care provision. There is no direct benefit to participant.

**REIMBURSEMENTS**

Light refreshments will be provided during the focus group sessions, but there will be no financial incentives to participants.

**CONFIDENTIALITY**

We will ask each of you to keep what was said in the group confidential. You should know, however, that we cannot prevent participants who were in the group from sharing things that should be confidential.

Any information obtained from you during the discussion will be anonymised. All data will be entered into the database and securely stored. Data will be transported out of the country for analysis in the United Kingdom. Data will only be used for the purposes of this research.

**DISSEMINATION OF RESULTS**

Results will be published in peer-reviewed journals and in print and e-thesis format.

**PARTICIPATION AND WITHDRAWAL**

Choice to participate in this study relies solely on you. At any time during the research, you can choose to withdraw without consequence to you. You can refuse to answer any question you do not want to answer and still be part of the study.

**RIGHTS OF PARTICIPANTS**

You do not lose legal rights while participating in this study.

**CONTACT**

Please contact the principal researcher on the email address [aminu.umar@lstmed.ac.uk](mailto:aminu.umar@lstmed.ac.uk) , if you have questions or concerns about this study, or by mail to the undermentioned address.

Dr Aminu Umar

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**CERTIFICATE OF CONSENT**

The above information was clearly explained to me in English by the administrator of the instrument and I understand the language. I was given the opportunity to ask questions which were answered satisfactorily.

I hereby voluntarily consent to participate and have received a copy of this form.

I am also aware that the discussion will be recorded, and I consent to this.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of participant / Date

For administrator,

I certify that all information concerning the research was accurately provided to the participant.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of administrator / Date

A copy of this information will be given when you return the completed form.

**THANK YOU**

# Appendix G: SAMPLE OF UNVALIDATED OBSTETRIC EARLY WARNING CHART

**Note:** The below chart is attached to the research protocol to illustrate how the system works for clarity, parameters will however, be modified based on a statistical validation process which is still ongoing.

