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Quality improvement in maternity care in Nigerian tertiary hospitals using a clinical tool that aids early diagnosis and treatment

Submission date
31/08/2020

Recruitment status
No longer recruiting

Registration date
09/09/2020

Overall study status
Completed

Last Edited
07/11/2023

Condition category
Pregnancy and Childbirth

✓ Retrospectively registered
✓ Protocol added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
Background and study aims
Obstetric Early Warning Systems (EWS) use combined clinical observations on patients receiving care during pregnancy or childbirth to identify a pattern that is consistent with increased risk of deterioration and alert health workers to institute actions likely to improve outcomes. Most of the available obstetric EWS charts were designed based on clinical consensus rather than formal statistical analyses or were done in Intensive Care Units, limiting their generalisability to inpatient ward settings. Researchers previously developed and internally validated a simple obstetric diagnostic prediction model and EWS for use in resource-limited settings using secondary data from these settings. The aim of this study is to assess the effectiveness of this validated patient monitoring tool in improving health outcomes and explore the experience of health workers/managers regarding its use.

Who can participate?
Women admitted to inpatient wards at three tertiary Nigerian hospitals with medical conditions related to pregnancy and childbirth

What does the study involve?
EWS is implemented in the intervention hospital, substituting vital signs charts of all obstetric admissions, while the two control hospitals continue routine practice. Before introduction, the quality of patient monitoring and prevalence of complications are assessed through a retrospective review of case notes. This is reassessed at 4 months after EWS implementation. Outcomes are maternal death, direct obstetric complications, length of hospital stay, speed of clinical review, caesarean section and instrumental birth rates. Interviews and focus group discussions are undertaken with nurses and doctors to explore their views on the EWS' acceptability and usability.

What are the possible benefits and risks of participating?
There is no potential risk or discomfort in this research. There is no direct benefit to patients receiving care and health workers. However, participants will be contributing invaluable

feedback to be used in improving emergency obstetric care provision. Light refreshments are provided during the focus group and interview sessions, but there are no financial incentives to participants.

Where is the study run from?
Health Education England North-East (UK)

When is the study starting and how long is it expected to run for?
December 2018 to March 2019

Who is funding the study?
Nigerian Petroleum Development Trust Fund Overseas Scholarship

Who is the main contact?
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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Protocol/serial number
LSTM- Research Protocol 18-074

Study information

Scientific Title
Implementation and evaluation of obstetric early warning systems in tertiary care hospitals in Nigeria

Study hypothesis
This study tests the hypothesis that the statistically developed early warning system (EWS) reported by Umar A. et al (2020) will perform equally well in a different setting than its derivation population. The researchers also hypothesise that the EWS chart will potentially provide an easier, more convenient and efficient alternative clinical monitoring method than the routine practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 21/11/2018, Research and Ethics Committee of the Liverpool School of Tropical Medicine (Pembroke Place, Liverpool, L3 5QA, UK; +44 (0)1517053100; lstmrec@lstmed.ac.uk), ref: LSTM- Research Protocol 18-074
2. Approved 26/09/2018, ethics review committee of the National Hospital Abuja (Plot 132, Central Business District (Phase II), pmb 425, Garki FCT Abuja, Nigeria; +234 (0)8037879543; contact@nationalhospital.gov.ng), ref: NHA/OG/GC/0171
3. Approved 06/11/2018, UITH Ethical Review Committee (Old Jebba Road, pmb 1459, Ilorin Kwara, Nigeria; +234 (0)8055763942; unithilorin1980@yahoo.com), ref: UITH/CAT/189/19/167
4. Approved 24/09/2018, Research Ethics Committee of the Abubakar Tafawa Balewa University Teaching Hospital (Hospital road, off Yandoka street, PMB 0117, Bauchi, Nigeria; +234 (0) 8035044243; mails4atbuthbauchi@gmail.com), ref: ATBUTH/ADM/42/VOL1

Study design
Pilot study; mixed-method research design consisting of a controlled before-after quasi-experimental trial, qualitative interviews and focus group discussions

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Condition
Clinical monitoring of women admitted to inpatient wards with direct and indirect obstetric-related conditions to prevent the occurrence of primary outcomes

Interventions
The intervention is the use of a statistically developed obstetric EWS, details of which are published elsewhere (Umar A, 2020). The resulting EWS chart (Annex 1: EWS chart) is introduced to replace the vital signs charts of all recruited participants in the intervention site. Briefly, this is a simple score-based recording chart for vital signs. It includes seven clinical parameters (temperature, pulse rate, respiratory rate, systolic blood pressure, diastolic blood pressure, consciousness level (based on the AVPU (alert, voice, pain and unresponsive) scale) and mode of birth for post-partum women). Each parameter is scored as 0 for normal, 1 for mild and 2 for severe derangements. An escalation protocol at the top of the chart guides frequency of patient monitoring and when to trigger clinicians' review (Umar A, 2020); scores of 0 or 1 are reassuring; hence require 12-hourly monitoring or as routine for post-operative patients. A score of 2 indicates the need to repeat observations after 30 minutes; if the score remains the same or rises, doctors should be informed for review. Those with scores of 3 or more are likely to deteriorate clinically and require immediate review.

EWS is implemented in the intervention hospital, substituting vital signs charts of all obstetric admissions, while the two control hospitals continue with the existing practices of clinical monitoring.

Prior to introduction, the quality of patient monitoring and prevalence of complications (outcome measures) are assessed through retrospective review of case notes. This is reassessed at 4 months' post EWS implementation. Outcomes are maternal death, direct obstetric complications (pre-eclampsia/eclampsia, antepartum haemorrhage, postpartum haemorrhage, sepsis, prolonged/obstructed labour, abortions complications, and thromboembolism), length of hospital stay, speed of clinical review, caesarean section (CS) and instrumental birth rates. Qualitative interviews and focus group discussions are undertaken with nurses and doctors to explore their views on EWS' acceptability and usability.

Intervention Type
Other

Primary outcome measure
Measured at the end of hospital stay (discharge or demise):
1. 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
2. Direct obstetric complications (pre-eclampsia/eclampsia, antepartum haemorrhage, postpartum haemorrhage, sepsis, prolonged/obstructed labour, abortions complications, and thromboembolism), as defined by healthcare providers

Secondary outcome measures
Measured at the end of hospital stay (discharge or demise):
1. Caesarean section delivery rate: proportion of deliveries that are conducted via caesarean section
2. Instrumental delivery rate: proportion of deliveries that are conducted via assisted vaginal delivery methods using vacuum or forceps
3. ICU admission: number of admissions to intensive care or high dependency care units that are due to direct obstetric conditions
4. The frequency of vital signs monitoring and recording: rate of recording of respiratory rate, pulse, blood pressure and temperature, assessed using the patient monitoring index (PMI), defined as the ratio of the observed to the expected frequency of vital signs monitoring over 24 hours.
Measured using registers and summary sheets in labour wards, lying-in wards, antenatal wards, obstetric gynae emergency ward and High Dependency or Intensive Care Units (HDU/ICU); reviews of completed EWS charts at the end of hospital stay and patient case notes
5. Duration of hospital stay measured through review of completed EWS charts
6. Speed of post-EWS trigger specialist review measured through review of completed EWS charts

Overall study start date
10/05/2018

Overall study end date
19/04/2019

Eligibility

Participant inclusion criteria
1. Pregnant and postpartum women admitted to all inpatient wards due to complications developing antepartum or during the puerperium (42 days' postpartum)
2. The KIIs participants (n=12) purposively selected senior midwives/nurses in administrative positions and doctors in the Obstetrics department
3. FGDs (n=6) conducted with junior nurses/midwives who undertake monitoring of obstetric patients using the EWS

Participant type(s)
Mixed

Age group
Adult

Sex
Female

Target number of participants
600

Total final enrolment
1200

Participant exclusion criteria
1. In active labour
2. Discharged within 24 hours of normal vaginal birth
3. Meet any of the three maternal near-miss criteria before hospital admission (clinical, management-based and organ dysfunction-based criteria (Say, 2009))
4. Women admitted directly to the intensive care unit without going through any of the inpatient wards

Recruitment start date
01/12/2018

Recruitment end date
31/03/2019

Locations

Countries of recruitment
Nigeria

Study participating centre
University of Ilorin Teaching Hospital
Ilorin
Kwara State
Nigeria
-

Study participating centre
National Hospital Abuja
Central Area
Abuja
FCT Abuja
Nigeria
-

Study participating centre

Abubakar Tafwa Balewa University Teaching Hospital
ATBUTH Bauchi
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-

Sponsor information

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Sponsor type
University/education

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https://ror.org/03svjbs84

Funder(s)

Funder type
Other

Funder Name
Nigerian Petroleum Development Trust Fund Overseas Scholarship

Results and Publications

Publication and dissemination plan

The findings of the study were drafted into a manuscript for publication in peer-reviewed journals and presented at academic conferences. Results will be published in peer-reviewed journals and in print and e-thesis format.

Intention to publish date
01/10/2020

Individual participant data (IPD) sharing plan
Both the quantitative data and qualitative interview/FGD transcripts are stored on the University of Liverpool M-drive. All data will be managed in accordance with the Liverpool School of Tropical Medicine (LSTM)'s policy for data management, as the sponsor of the study. All data can be made available from the corresponding author Amin Umar (amin.umar@nhs.net) within 2 weeks of a reasonable request.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		07/09/2020	08/10/2020	No	No
Protocol file			08/10/2020	No	No
Results article		20/07/2022	07/11/2023	Yes	No