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An intervention to improve the quality of emergency care during childbirth in Nigeria

Submission date
03/08/2020

Recruitment status
No longer recruiting

Registration date
14/08/2020

Overall study status
Completed

Last Edited
17/09/2024

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Along with India, Nigeria currently accounts for one-third of the annual maternal deaths in the world. Among several other factors, poor quality of care and the inadequate use of skilled care for pregnant women are the key determinants of the high rate of maternal deaths in Nigeria. The intervention was designed to improve the quality of care, and patient satisfaction and to reduce deaths of mothers and children during pregnancy and childbirth in Nigeria.

Who can participate?
Pregnant women who access maternal care in participating centers and their health care givers

What does the study involve?
Of the 8 hospitals involved in the study, the intervention was carried out in 4. The intervention activities include structured training in improving maternal outcomes, strategic planning and monitoring, and gathering patient feedback. During the study period data was collected from all 8 hospitals on maternal outcomes to compare between the hospitals that received the intervention and those that did not.

What are the possible benefits and risks of participating?
None

Where is the study run from?
The Women's Health and Research Centre, Bénin City (Nigeria)

When is the study starting and how long is it expected to run for?
July 2017 to July 2019

Who is funding the study?
World Health Organisation (Switzerland)

Who is the main contact?
Prof. Friday Okonofua, feokonofua@yahoo.co.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
A65869, NCTR91540209

Study information

Scientific Title
Intervention to improve the quality of emergency obstetric care for preventing maternal and perinatal mortality in referral hospitals in Nigeria: a quasi-experimental research study

Study objectives
1.There is no significant difference in the policies and patterns of emergency obstetric care and practices between intervention and control health facilities
2. There is no significant difference in the clinical management of the complications that lead to maternal/perinatal deaths between the intervention and control health facilities
3. There is no significant difference in the assessments of the quality of clinical care between intervention and control sites
4. There is no significant difference in case-fatality rates due to leading obstetric complications between intervention and control sites
5. There is no significant difference in the indicators of maternal and newborn outcomes (maternal, stillbirth, and neonatal death ratios) between the intervention and control health facilities

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 25/06/204, WHO Research Ethics Review Committee (20 Avenue Appia-CH-1211 Geneva 27, Switzerland; no telephone number provided; ercsec@who.int), ref: A65869.
2. Approved 16/07/2014, National Health Research Ethics Committee (NHREC) of Nigeria (Federal Ministry of Health, Federal Secretariat, Abuja, Nigeria; +234-9-523-8367; info@nhrec.net), ref: NHREC/01/01/2007 – renewed in 2015, ref: NHREC 01/01/20047-12/12/2015b

Study design
Multi-centre interventional quasi-experimental mixed-methods study

Primary study design
Interventional

Secondary study design
Quasi-experimental mixed-methods study

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Emergency obstetric care

Interventions

All the women who presented for antenatal, delivery and postnatal care within the period were eligible for inclusion in the study. Recruitment and informed consent were obtained at the time the women registered in the hospitals for antenatal care, or during admission for management of complications, or at the time of delivery. Informed consent was obtained from those presenting with pregnancy related complications when they have been clinically stabilized. For women presenting at the hospital for the first time in labour, consent is obtained after they delivered their babies. The monitoring/evaluation officer collects and enters the data into the computer system daily. Sources of data collection were hospital records, clinical case records, maternal/perinatal deaths clinical audit records, maternal/perinatal death reviews, client flow analysis, focus group discussion, in-depth interview, and exit interviews. Total duration of observation is the total time the woman spends at the facility.

Six public secondary care hospitals and two public tertiary care hospitals in both north and south of Nigeria were selected randomly for the formative phase. Thereafter the intervention was carried out in four of the initial eight hospitals, with two hospitals as intervention and two as control sites. At baseline, we assessed the providers' and facilities' readiness to provide care, patients' satisfaction and experience while accessing obstetric care, using a mixed-method which included a questionnaire on knowledge and management of obstetric complications, site inventory assessment, client flow analysis, focus group discussion and in-depth interviews.
The intervention activities which were developed based on the results in the formative research include
1. Development of a strategic plan for preventing maternal and perinatal deaths
2. Staff Training/Capacity building for healthcare providers in the facilities
3. Establishing a maternal and perinatal death surveillance and response system (MPDSR) in the health facilities
4. Development of protocols, guidelines, algorithm and reminders for clinical Emergency Obstetric Care EmOC
5. Advocacy activities for increased funding and resource mobilization
6. Computerized appointment scheduling system to reducing delays in service delivery
7. Patients education and feedback- Involving men in maternal and child health care through monthly health talk

Intervention Type

Mixed

Primary outcome measure

Measured at baseline, monthly during the intervention, and at endline using patient records:
1. Number of women attending antenatal, delivery and post-natal clinics
2. Women with moderate to severe PPH, eclampsia, and obstructed labour
3. Number of cases with PPH, eclampsia and obstructed labour where internationally accepted protocols are adhered to or breeched
4. Number of clinically managed cases of PPH, eclampsia and obstructed that died
5. Number of maternal deaths
6. Number of stillbirths and early neonatal deaths occurring in the hospitals

Secondary outcome measures

Client perception of quality and satisfaction with care measured using client flow analysis (patient records) at baseline, monthly during the intervention, and at endline and also by an exit interview questionnaire

Overall study start date
01/07/2017

Completion date
30/07/2019

Eligibility

Key inclusion criteria
1. Pregnant women that present during the intervention period
2. All the healthcare givers in the obstetric units

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
18,000 patient records reviewed and 2,400 interviewed

Total final enrolment
20439

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/10/2017

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
Nigeria

Study participating centre
Central Hospital Benin City
Benin City
Nigeria
301000

Study participating centre
Central Hospital Warri
Warri
Nigeria
-

Study participating centre
General Hospital Minna
Minna
Nigeria
-

Study participating centre
General Hospital Suleja
Suleja
Nigeria
-

Sponsor information

Organisation
World Health Organization

Sponsor details
20 Avenue Appia-CH-1211
Geneva
Switzerland
CH1211
+41 22 791 3791
ercsec@who.int

Sponsor type
Research council

Website
https://www.WHO.INT.RPC/Research_Ethics

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organization

Alternative Name(s)
, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Switzerland

Results and Publications

Publication and dissemination plan
Data repository
Publication in high impact journals
Policy document

Intention to publish date
30/10/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository.
The datasets generated during the formative phase of this study is stored on Zenodo (http://doi.org/10.5281/zenodo.161549). Users are expected to request for access from the Principal Investigator, Professor Friday Okonofua Email feokonofua@yahoo.co.uk. The intervention datasets will also be stored on Zenodo and will be available on request from the principal Investigator. The qualitative data are outputs generated from a computer-assisted qualitative data analysis software, Atlas.ti version 6.25, whereas the quantitative data are all stored in SPSS format. There are no legal issues, and no consent to share is required from the participants.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	Effects on rates of primary postpartum haemorrhage (PPH)	01/04/2022	17/08/2022	Yes	No
Results article	Results of exit interviews with mothers	26/08/2023	29/08/2023	Yes	No
Results article	improving six quality indicators	04/11/2020	17/09/2024	Yes	No