ISRCTN67206260 https://doi.org/10.1186/ISRCTN67206260

Do facility-based audits help West African hospitals to provide better care for patients with obstetric emergencies?

Submission date 29/09/2008	**Recruitment status** No longer recruiting
Registration date 21/10/2008	**Overall study status** Completed
Last Edited 30/12/2020	**Condition category** Pregnancy and Childbirth

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.lshtm.ac.uk/ideu/mp/audobem/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32336

Study information

Scientific Title
Effectiveness of facility-based audits to improve the responsiveness of West African district hospitals to obstetric emergencies: a three-country cluster randomised controlled trial

Acronym
AUDOBEM-AFRO

Study objectives
Facility-based audits improve the quality of care for obstetric emergencies, shorten the delay between decision for and start of an emergency caesarean section, and decrease peri-natal mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London School of Hygiene and Tropical Medicine Ethics Committee, 22/11/2004, ref: 2053
2. Republique du Benin, Ministere de la sante, Direction de la recherche en sante, 12/09/2007, ref: 9535/MS/DC/SGM/DRS/SRAO/SA)
3. Burkina Faso, Ministere de la sante/Ministere des enseignements secondaires superieures et de la recherche scientifique, Comite d'ethique pour la recherche en sante, 17/07/2007, ref: 2007-050
4. Republique du Niger, Ministere de la sante publique, Direction Generale de la sante publique, 14/12/2007, ref: 45/MSP/DGSP

Study design
Three-armed unmasked multicentre stratified restricted random allocation cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Major life-threatening obstetric complications: haemorrhage, uterine rupture, eclampsia, septicaemia

Interventions
Prior to the trial, a 3 - 5 day refresher course on clinical management of major obstetric complications, use of partogramme and essential clinical documentation has been given to staff of all 36 participating hospitals.

The intervention to be evaluated consists of 3 - 5 days staff training sessions on criterion-based clinical audit (CBCA) (12 hospitals) or alternatively on patient-centred case reviews (PCCR) (12 hospitals). The 12 hospitals in the control arm did not receive any training on audits. The follow-up period for all trial arms lasts 24 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Quality of care score, based on compliance with adapted WHO treatment guidelines
2. Delay between decision for and start of emergency caesarean section
3. Perinatal mortality in mature newborns without malformations and, in the case of stillbirths, without signs of maceration. Maturity defined as gestational age greater than or equal to 35 weeks or gestational age greater than or equal to 8 months or birth weight greater than or equal to 200 g or length greater than or equal to 45 cm

Comparison based on period month -6 to -1 before audit training versus period month +7 to +24 after audit training, with period month +1 to +6 considered as run-in period.

Secondary outcome measures
Secondary analyses will be used to generate hypotheses only, not to judge the success of the audit interventions.

Overall study start date
01/11/2008

Completion date
31/10/2010

Eligibility

Key inclusion criteria
1. District hospitals, supplemented by regional hospitals where number of eligible district hospitals was insufficient
2. Minimum number of births/year: 500 in Benin, 600 in Burkina Faso, 1000 in Niger
3. Minimum 50 caesarean sections/year

Participant type(s)

Patient

Age group
Adult

Sex
Female

Target number of participants
36 hospitals

Total final enrolment
51

Key exclusion criteria
1. Audits of obstetric near-miss morbidity already underway
2. Insecurity (Niger, desert region)
3. Unclear status as in health system (certain confessional hospitals in Benin)
4. Inability of key staff to communicate in French (Hospital in Burkina Faso run by Chinese Cooperation)

Date of first enrolment
01/11/2008

Date of final enrolment
31/10/2010

Locations

Countries of recruitment
Benin

Burkina Faso

England

Niger

United Kingdom

Study participating centre
London School of Hygiene & Tropical Medicine
London
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Sponsor information

Organisation
European Commission (Belgium) - Research Directorate-General

Sponsor details
c/o Albrecht Jahn, MD, PhD
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Sponsor type
Government

Website
http://ec.europa.eu/dgs/research/index_en.html

ROR
https://ror.org/00k4n6c32

Funder(s)

Funder type
Government

Funder Name
European Commission (Belgium) - Research Directorate-General, INCO programme (Contract no.: 032336)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/05/2014	30/12/2020	Yes	No