

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 21/10/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/12/2020	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

England

Benin

Burkina Faso

Niger

Study participating centre

London School of Hygiene & Tropical Medicine

London

United Kingdom

WC1E 7HT

Sponsor information**Organisation**

European Commission (Belgium) - Research Directorate-General

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes