ISRCTN12212410 https://doi.org/10.1186/ISRCTN12212410

An evaluation of the impact of standards-based audit and healthcare provider training on the availability and quality of antenatal (ANC) and postnatal care (PNC) in Togo

Submission date
17/07/2019

Recruitment status
No longer recruiting

Registration date
25/07/2019

Overall study status
Completed

Last Edited
03/03/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Maternal and perinatal deaths and morbidities remain a challenge, especially in Togo. Antenatal and postnatal care (ANC-PNC) offered in healthcare facilities (HCFs) by trained healthcare providers (HCPs) is a useful platform for addressing the health needs of women and babies at the time of pregnancy and the immediate period after the baby is born. In practice, however, many women do not receive all the necessary components of care. Both the content and the quality of care are at times insufficient, at least to a degree, because of a lack of knowledge, skills and confidence among HCPs. To improve the quality and availability of care, a common strategy in LMIC is to provide HCPs with in-service competency-based practical training workshops. It may also be beneficial to introduce a process for improving the quality of care called standards-based audit. This improves compliance with agreed standards of care and helps HCP make changes to their practice if compliance is poor. Standards-based audit can be done in 3-month cycles. Once standards of care are agreed, the compliance with one or more agreed standards are measured, HCPs review what could be done to improve compliance, take the appropriate action, and, this should result in improved compliance and thus a measurably improved quality of that aspect of care. The aim of this study is to find out whether training of HCPs will improve the availability and quality of integrated ANC and PNC, and whether the introduction of standards-based audit will improve the quality and availability of integrated ANC and PNC.

Who can participate?
Women who have received ANC or PNC and healthcare providers involved in ANC and PNC

What does the study involve?
Participating HCFs are randomly allocated to receive the two interventions (standards-based audit and training in ANC and PNC) at different times. Monthly measurements of the availability of ANC-PNC before training of the HCPS are compared to monthly measurements after training. Compliance to standards is also measured before and after action is taken for improvement.

What are the possible benefits and risks of participating?
In addition to training being provided for healthcare providers, the benefits of the assessment include making available to the facility data on the quality of care provided, including recommendations for improvement. There are no immediate risks to healthcare facilities and healthcare providers in participating, except for the potential increase in workload related to data collection for the study. The assessment will generate data on quality of care and highlight areas of care that may need to improve. However, none of the findings will be linked to individual staff and there will be no negative repercussions for the staff in the facility.
There are no direct benefits to patients, but the information provided will help to identify what aspects of care need to improve and the intention is that the facility will then make improvements to the quality of care provided; this means other women and their babies, would benefit in the future. There are no immediate risks to patients from taking part; however, exit interviews may stir up distressing memories of poor care being recalled as part of the assessment.

Where is the study run from?
18 healthcare facilities from the 3 regions Lomé, Plateaux and Savanes in Togo ; all work is coordinated by the Centre for Maternal and Newborn Care at the Liverpool School of Tropical Medicine, in partnership with the Ministry of Health in Togo and the University of Lomé.

When is study starting and how long is it expected to run for?
May 2019 to November 2020

Who is the main contact?
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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
Nil known

Study information

Scientific Title
Crossed randomised stepped wedge trial to assess the effectiveness of standards-based audit and healthcare provider training on the availability and quality of Antenatal (ANC) and Postnatal Care (PNC) in Togo

Study objectives
For this implementation research study there are two hypotheses:
1. Training of HCPs will improve the availability and quality of integrated ANC and PNC
2. The introduction of standards-based audit will improve the quality and availability of integrated ANC and PNC

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 16/05/2019, Bioethics Committee for Health Research (Comité Bioéthique pour la Recherche en Santé – CBRS, Togo; Tel: +228(0) 22 21 38 01; Email: cbrstogo@gmail.com), ref: 021 /2019/CBRS

2. Approved 13/08/2019, Research Governance and Ethics Office (Room 221, 2nd Floor LLSA, Daulby Street, Liverpool; Tel: +44 (0)151 705 9396; Email: lstmrec@lstmed.ac.uk)

Study design
Interventional multi-centre crossed randomised stepped-wedge clustered controlled study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Maternal and neonatal health and quality of care

Interventions
Two randomised stepped wedge trial designs (SWD) will be crossed and used to assess the effects of the two interventions (Standards-based Audit and Training in ANC and PNC). Thus each HCF will receive both of the interventions, and in the case of standards-based audit the impact will be assessed using six different standards.

To assess the impact of training in ANC and PNC, an incomplete closed cohort SWD will be used. This means that the participants are the same HCFs, for which assessments are obtained each month. Availability of each signal function will be assessed in each calendar month.

To assess the effect of the implementation of standards-based audit, a multi-dimensional incomplete stepped wedge (SW) cluster randomised trial with cross-sectional sampling will be used. Within each participating HCF standards-based audit for one standard will be commenced at two-monthly intervals.

Intervention Type
Other

Primary outcome measure
1. Percentage compliance with standards (aggregate) measured with standard-specific tool at baseline (month 1 and 2), then every alternate month from month 2 to month 15, or month 3 to 16, depending on stratum, plus at endline at month 15 or 16 depending on stratum
2. Proportion of ANC and PNC signal functions available measured using a standardised tool monthly

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
20/05/2019

Completion date
30/11/2020

Eligibility

Key inclusion criteria
Note: This is a clustered trial where healthcare facilities represent one cluster

In consultation with the Ministry of Health districts or regions will be identified and all public or private HCFs that are:
1. Designated to provide ANC and PNC
2. in a state of readiness to provide ANC and PNC (i.e. equipment and consumables in principle in place)
3. Provide ANC to at least 25 women per month
will be eligible for inclusion.

For objective i) measurements will be done from facility registers and will not need inclusion of participants
For objective ii) measurements will be done either from facility registers, either through exit interviews depending on the standard audited. Participants will be women coming for ANC or PNC within the healthcare facility.

Eligible women will be those attending ANC-PNC in the selected facilities

Participant type(s)
Patient

Age group
Mixed

Sex
Female

Target number of participants
There are 18 clusters (healthcare facilities). In total, there will be a maximum of 600 participants per cluster (50 women per cycle for 6 cycle + 150 baseline and 150 for endline). This number could be lower as some standard audited can be measured on cases from facility registers and do not involve participants.

Total final enrolment
7867

Key exclusion criteria
1. Women from non-selected facilities
2. Women that do not consent to be interviewed for audits measurements

Date of first enrolment

05/08/2019

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
Togo

Study participating centre
Centre De Sante Lomé
Lomé
Togo
-

Study participating centre
CHR Lomé
Lomé
Togo
-

Study participating centre
Hospital de District (HD) de Be
Lomé
Togo
-

Study participating centre
Polyclinique Be Kpota / Hopital D2, Lomé Region
Lomé
Togo
-

Study participating centre
CMS UTB Circulaire
Lomé
Togo
-

Study participating centre
CMS Cacaveli
Lomé
Togo
-

Study participating centre
CHP Kpalime
Kpalimé
Togo
-

Study participating centre
CHR Atakpame
Atakpamé
Togo
-

Study participating centre
CMS notre dame de misericorde
Kloto
Togo
-

Study participating centre
USP Akpare
Akparé
Togo
-

Study participating centre
CMS Anna Maria,
Ogou
Togo
-

Study participating centre

USP Homagan
Homagan
Togo
-

Study participating centre
CHP Mango
Mango
Togo
-

Study participating centre
Hopital De L'esperance / Hopital Baptiste De Mango
Mango
Togo
-

Study participating centre
CHR Dapaong
Dapaong
Togo
-

Study participating centre
Polyclinique Dapaong
Dapaong
Togo
-

Study participating centre
CMS Gando
Gando
Togo
-

Study participating centre

CMS Barkoissi
Barkoissi
Togo
-

Sponsor information

Organisation
Liverpool School of Tropical Medicine

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Sponsor type
University/education

Website
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ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Research organisation

Funder Name
Global Fund to Fight AIDS, Tuberculosis and Malaria

Alternative Name(s)
Global Fund, Fonds mondial, The Global Fund to Fight AIDS, Tuberculosis and Malaria, Fonds mondial de lutte contre le sida, la tuberculose et le paludisme, The Global Fund, Le Fonds mondial, GFATM

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Switzerland

Results and Publications

Publication and dissemination plan
The researchers intend to have the protocol published in a journal. Planned publication of the results in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 07/07/2022:
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Marion Ravit (marion.ravit@lstmed.ac.uk) or via the unit's email address (gfpu@lstmed.ac.uk). Data will be accessible once the trial publication is published. The data dictionary with information on data available (variables and characteristics of variables) can be reviewed by interested parties. Use of data would need to be agreed in advance, following legal and ethical guidelines. Data in this trial relate to health facilities, not individual people, but the information on healthcare facilities will be suitably anonymised to protect the individual facilities. LSTM require data to be preserved for a minimum of five years, but there is no cap for how long the data would be stored.

Previous individual participant data (IPD) sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Barbara Madaj (Barbara.Madaj@lstmed.ac.uk) or via the Centre’s email address (cmnh@lstmed.ac.uk). Data will be accessible once the trial publication is published. The data dictionary with information on data available (variables and characteristics of variables) can be reviewed by interested parties. Use of data would need to be agreed in advance, following legal and ethical guidelines. Data in this trial relate to health facilities, not individual people, but the information on healthcare facilities will be suitably anonymised to protect the individual facilities. LSTM require data to be preserved for a minimum of five years, but there is no cap for how long the data would be stored.

IPD sharing plan summary
Available on request