

# 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

<b>Submission date</b> 17/07/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/07/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/03/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?

1. Dr Charles Ameh  
charles.ameh@lstmed.ac.uk
2. Dr Marion Ravit  
marion.ravit@lstmed.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Charles Ameh

### ORCID ID

<https://orcid.org/0000-0002-2341-7605>

### Contact details

Liverpool School of Tropical Medicine  
Pembroke Place  
Liverpool  
United Kingdom  
L3 5QA  
+44 (0)7714 75 3844  
charles.ameh@lstmed.ac.uk

### Type(s)

Scientific

**Contact name**

Dr Marion Ravit

**ORCID ID**

<https://orcid.org/0000-0003-4440-0260>

**Contact details**

Liverpool School of Tropical Medicine

Pembroke Place

Liverpool

United Kingdom

L3 5QA

+44 (0)151 832 1687

marion.ravit@lstmed.ac.uk

## **Additional identifiers**

## **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

**Study type(s)**

Other

## **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(s)**

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

## **Key secondary outcome(s)**

There are no secondary outcome measures

## **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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

Female

**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

**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, The Global Fund, The Global Fund to Fight AIDS, Tuberculosis and Malaria, Fonds mondial de lutte contre le sida, la tuberculose et le paludisme, Fonds mondial, Le Fonds mondial, Globalen Fonds, Der Globalen Fonds, GFATM

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

International organizations

**Location**

Switzerland

## Results and Publications

**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