

# Improving the quality of maternal and newborn health services in high priority districts in Malawi

<b>Submission date</b> 17/08/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/10/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/10/2024	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Every year 303,000 women die due to pregnancy-related complications, 2.6 million babies are stillborn and a further 2.7 million die in the first month of life. Many of these deaths occur in low and middle-income countries and can be prevented if effective and good quality of care is available. Malawi is one of the countries in sub-Saharan Africa with high maternal and newborn deaths. The maternal mortality ratio is 634 deaths per 100,000 live births, representing about 15% of all deaths of women in the reproductive age group (15-49 years). The Malawi demographic survey for 2015-2016 reported a newborn mortality rate of 27 deaths per 1,000 live births, infant mortality of 42 deaths per 1,000 live births, and perinatal mortality at 35 deaths per 1,000 pregnancies. About 43% of all deaths occur during the first month of life. Poor quality of care is one of the major contributors to the unacceptably high death rates for mothers and newborns in Malawi. With the transition from Millennium Development Goals to the new global Sustainable Development Goals, absolute targets have been set to reduce maternal deaths, stillbirth and newborn mortality and there is still more to be done. Improving quality of care for mothers and babies is of the utmost urgency. The aim of this study is to assess the impact of using a standards-based audit on compliance with defined standards for emergency obstetric and newborn care to improve quality of maternal and newborn health care in Malawi.

### Who can participate?

Women and their newborns who attend 43 healthcare facilities providing emergency obstetric and newborn care within five districts in Malawi

### What does the study involve?

The intervention is the adoption by a healthcare facility of standards-based audits for standards of emergency obstetric and newborn care. The aim of the study is to estimate the improvement in compliance with the standard of care when adopting standards-based audits. Training in the conduct of standards-based audit for maternal and newborn health is provided before starting any audit cycle at each facility. For each defined standard the intervention is the action taken in the second month of an audit cycle (the 'action month') within the facility to address any deficiencies in care identified during the first month of the audit cycle. Within each facility there

are two consecutive audit cycle periods, i.e. the study period is six months in total. For the participating facilities the study period starts in one of three consecutive months, which have been randomly allocated, thus the study period for the entire study is eight calendar months.

What are the possible benefits and risks of participating?

There are no direct benefits for a participant in the study. Staff may benefit from training which increases their ability to deliver quality care to mothers and babies. Compliance to standard is expected to improve service delivery and subsequently improve women and newborn outcomes (reduce morbidities and mortalities) and contribute to client satisfaction with care. There are no risks of taking part in the study.

Where is the study run from?

Liverpool School of Tropical Medicine (UK)

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

March 2018 to February 2019

Who is funding the study?

UNICEF

Who is the main contact?

1. Prof. Florence Mgawadere
2. Prof. Nynke van den Broek

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Florence Mgawadere

**ORCID ID**

<http://orcid.org/0000-0003-3341-9118>

**Contact details**

Centre for Maternal and Newborn Health  
Liverpool School of Tropical Medicine  
Pembroke Place  
Liverpool  
United Kingdom  
L3 5QA

**Type(s)**

Scientific

**Contact name**

Prof Nynke van den Broek

**ORCID ID**

<http://orcid.org/0000-0001-8523-2684>

## Contact details

Centre for Maternal and Newborn Health  
Liverpool School of Tropical Medicine  
Pembroke Place  
Liverpool  
United Kingdom  
L3 5QA

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

LRPS-2017-9136548

## Study information

### Scientific Title

Using standard based audit to improve the quality of maternal and newborn health in a low resource setting

### Study objectives

Introducing the practice of conducting standards-based audits within facilities providing emergency obstetric and newborn care in Malawi will improve compliance to standards of care.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

1. Ethics committee of Liverpool School of Tropical Medicine e\_Research Protocol, 21/06/2018, ref: 18-028
2. Study granted ethics review exemption by the Malawi Ministry of Health, 20/06/2018, ref: QMD/10

### Study design

Cluster randomized incomplete stepped wedge trial

### Primary study design

Interventional

### Secondary study design

Cluster randomised trial

### Study setting(s)

Hospital

## **Study type(s)**

Other

## **Participant information sheet**

No participant information sheet available

## **Health condition(s) or problem(s) studied**

Recipient of obstetric or newborn care

## **Interventions**

The intervention is the adoption by a healthcare facility of standards-based audits for standards of emergency obstetric and newborn care. Using the stepped wedge design each participating health care facility (cluster) acts as their own control, providing data for standards audited within the facility both prior to and subsequent to the action phase of the audit cycle.

The aim of the study is to estimate the improvement in compliance with the standard of care when adopting standards-based audits. Training in the conduct of standards-based audit for maternal and newborn health will be provided prior to commencing any audit cycle at each facility.

For each defined standard the intervention will be the action taken in the second month of an audit cycle (the 'action month') within the facility to address any deficiencies in care identified during the first month of the audit cycle. Within each facility there will be two consecutive audit cycle periods, i.e. the study period will be six months in total. (For the participating facilities the study period starts in one of three consecutive months, which have been randomly assigned, thus the study period for the entire study will be eight calendar months).

## **Intervention Type**

Other

## **Primary outcome measure**

Compliance with defined standard of care aggregated for all emergency obstetric and newborn care standards audited. This will be defined as the mean across all facilities and standards, with each standard audited by each facility carrying equal weight. (Thus, at facility level the means for CEmOC facilities which audit twice as many standards will carry twice the weight of the BEmOC facilities). Standards will be weighted by the number of facilities which audit the standard). Data collected in the following months for a facility will be used for each facility: months 1 and 6 for all standards; month 3 for the standard(s) audited in the first cycle; and month 4 for the standard (s) audited in the second cycle within the facility. The primary outcome will be derived by appropriate aggregation of estimates for individual standards.

## **Secondary outcome measures**

Compliance with defined standard of care for each of the emergency obstetric and newborn care standards audited in the study. Measurements will be made within months 1 and 3 of each audit cycle. Additionally, in facilities which audit a standard in the first audit cycle there will be a (post-intervention) assessment during month 6 for the facility, i.e. 4 months after the intervention ('action month') and in those which audit the standard in the second audit cycle there will be an additional (pre-intervention) assessment during month 1 for the facility, i.e. 4 months before the 'action month'. A standard-specific tool will be used in each month of data collection at a facility to collect data for 25 clients. The data collected will be used to classify each client as having received/not received care which is compliant with the standard.

**Overall study start date**

01/03/2018

**Completion date**

28/02/2019

## Eligibility

**Key inclusion criteria**

Clusters:

43 healthcare facilities providing emergency obstetric and newborn care within five districts in Malawi

Clients:

Women and their newborns who attend the study facilities for obstetric/newborn care addressed by the standard being assessed that month

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

8,100

**Key exclusion criteria**

1. Women who did not give birth at a healthcare facility
2. Facilities not designated to provide emergency obstetric and newborn care services as basic (BEmOC) or comprehensive (CEmOC) level

**Date of first enrolment**

31/07/2018

**Date of final enrolment**

31/12/2018

## Locations

**Countries of recruitment**

Malawi

**Study participating centre**

**Dedza District Hospital**

Dedza district

Dedza

Malawi

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**Study participating centre**

**Mayani Health Centre**

Dedza district

Dedza

Malawi

00

**Study participating centre**

**Lobi Health Centre**

Dedza district

Dedza

Malawi

00

**Study participating centre**

**Chitowo Health Centre**

Dedza district

Dedza

Malawi

00

**Study participating centre**

**Mtakataka Health Centre**

Dedza district

Dedza

Malawi

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**Study participating centre**

**Mtendere Health Centre**

Dedza district

Dedza

Malawi

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**Study participating centre**  
**Chikuse Health Centre**  
Dedza district  
Dedza  
Malawi  
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**Study participating centre**  
**Golomoti Health Centre**  
Dedza district  
Dedza  
Malawi  
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**Study participating centre**  
**Chimoto Health Centre**  
Dedza district  
Dedza  
Malawi  
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**Study participating centre**  
**Mangochi district hospital**  
Mangochi District  
Mangochi  
Malawi  
00

**Study participating centre**  
**Monkeybay Community Hospital**  
Mangochi district  
Mangochi  
Malawi  
00

**Study participating centre**  
**Makanjira Health Centre**  
Mangochi district  
Mangochi

Malawi  
00

**Study participating centre**  
**Koche Community Hospital**  
Mangochi district  
Mangochi  
Malawi  
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**Study participating centre**  
**Namwera Health centre**  
Mangochi district  
Mangochi  
Malawi  
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**Study participating centre**  
**Ndirande Health Centre**  
Blantyre District  
BlantyreM  
Malawi  
00

**Study participating centre**  
**Phirilongwe Health Centre**  
Mangochi district  
Mangochi  
Malawi  
00

**Study participating centre**  
**Lungwena Health Centre**  
Mangochi district  
Mangochi  
Malawi  
00

**Study participating centre**



**Chilipa Health Centre**

Mangochi district

Mangochi

Malawi

00

**Study participating centre**

**Chilonga Health Centre**

Mangochi district

Mangochi

Malawi

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**Study participating centre**

**Nankumba Health Centre**

Mangochi district

Mangochi

Malawi

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**Study participating centre**

**Mkumba Health Centre**

Mangochi district

Mangochi

Malawi

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**Study participating centre**

**Limbe Health Centre**

Blantyre district

Blantyre

Malawi

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**Study participating centre**

**South Lunzu Health Centre**

Blantyre district

Blantyre

Malawi

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**Study participating centre**  
**Mlambe Hospital**  
Blantyre district  
Blantyre  
Malawi  
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**Study participating centre**  
**Mdeka Health Centre**  
Blantyre district  
Blantyre  
Malawi  
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**Study participating centre**  
**Bangwe Health Centre**  
Blantyre district  
Blantyre  
Malawi  
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**Study participating centre**  
**Lundu Health Centre**  
Blantyre district  
Blantyre  
Malawi  
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**Study participating centre**  
**Zingwangwa Health Centre**  
Blantyre district  
Blantyre  
Malawi  
00

**Study participating centre**  
**Chilomoni Health Centre**  
Blantyre district  
Blantyre

Malawi  
00

**Study participating centre**  
**Thyolo District Hospital**  
Thyolo district  
Thyolo  
Malawi  
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**Study participating centre**  
**Malamulo Hospital**  
Thyolo district  
Thyolo  
Malawi  
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**Study participating centre**  
**Khonjeni**  
Thyolo district  
Thyolo  
Malawi  
00

**Study participating centre**  
**Thekerani Health Centre**  
Thyolo district  
Thyolo  
Malawi  
00

**Study participating centre**  
**Mikolongwe Health Centre**  
Thyolo district  
Thyolo  
Malawi  
00

**Study participating centre**

**Chimaliro Health Centre**

Thyolo district

Thyolo

Malawi

00

**Study participating centre**

**Bvumbwe**

Thyolo district

Thyolo

Malawi

00

**Study participating centre**

**Chisoka**

Thyolo

Thyolo

Malawi

00

**Study participating centre**

**Nkhatabay district hospital**

Nkhatabay district

Nkhatabay

Malawi

00

**Study participating centre**

**Chintheche Community Hospital**

Nkhatabay district

Nkhatabay

Malawi

00

**Study participating centre**

**Mpamba Health Centre**

Nkhatabay district

Nkatabay

Malawi

00

**Study participating centre**

**Liuzi Health Centre**

Nkhatabay District

Nkhatabay

Malawi

00

**Study participating centre**

**Bula Health Centre**

Nkkatabay District

Nkhatabay

Malawi

00

**Study participating centre**

**Mzenga Health Centre**

Nkhatabay district

Nkhatabay

Malawi

00

**Study participating centre**

**Liverpool School of Tropical Medicine, Malawi office**

Private Bag B425

Lilongwe

Malawi

00

**Study participating centre**

**Mua Hospital**

Dedza district

Dedza

Malawi

00

## **Sponsor information**

### **Organisation**

Liverpool School of Tropical Medicine

**Sponsor details**

Pembroke Place  
Liverpool  
England  
United Kingdom  
L3 5QA

**Sponsor type**

University/education

**Website**

<https://www.lstmed.ac.uk/>

**ROR**

<https://ror.org/03svjbs84>

## Funder(s)

**Funder type**

Other

**Funder Name**

UNICEF

**Alternative Name(s)**

United Nations Children's Fund, United Nations Children's Emergency Fund, Fonds des Nations Unies pour l'enfance, Fondo de las Naciones Unidas para la Infancia, ,

**Funding Body Type**

Government organisation

**Funding Body Subtype**

International organizations

**Location**

United States of America

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal by mid-2019. Additional documents such as study protocol, statistical analysis plan, other will be available upon request. The protocol is not yet published.

## Intention to publish date

30/06/2019

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Florence Mgawadere and Prof. Nynke van den Broek. The protocol and the dataset for the standards to be audited will be available from September. The current institutional policy requires that data is kept for 5 years after publication. The anonymised data can be shared for any analysis required upon request through the following institutional email address: CMNH@lstmed.ac.uk. All data will be anonymised and consent will be obtained for all the data to be collected and there are no ethical nor legal restrictions at present.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		30/09/2024	02/10/2024	Yes	No