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

Submission date
17/08/2018

Recruitment status
No longer recruiting

Registration date
30/10/2018

Overall study status
Completed

Last Edited
02/10/2024

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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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
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Study participating centre
Chitowo Health Centre
Dedza district
Dedza
Malawi
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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
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Study participating centre
Monkeybay Community Hospital
Mangochi district
Mangochi
Malawi
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Study participating centre
Makanjira Health Centre
Mangochi district
Mangochi

Malawi
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Study participating centre
Koche Community Hospital
Mangochi district
Mangochi
Malawi
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Study participating centre
Namwera Health cente
Mangochi district
Mangochi
Malawi
00

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
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Study participating centre

Chilipa Health Centre
Mangochi district
Mangochi
Malawi
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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
Blanytre 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
Blanytre
Malawi
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Study participating centre
Chilomoni Health Centre
Blantyre district
Blanytre

Malawi
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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
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Study participating centre
Thekerani Health Centre
Thyolo district
Thyolo
Malawi
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Study participating centre
Mikolongwe Health Centre
Thyolo district
Thyolo
Malawi
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Study participating centre

Chimaliro Health Centre
Thyolo district
Thyolo
Malawi
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Study participating centre
Bvumbwe
Thyolo district
Thyolo
Malawi
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Study participating centre
Chisoka
Thyolo
Thyolo
Malawi
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Study participating centre
Nkhatabay district hospital
Nhkatabay district
Nkhatabay
Malawi
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Study participating centre
Chintheche Community Hospital
Nkhatabay district
Nkhatabay
Malawi
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Study participating centre
Mpamba Health Centre
Nkhatabay district
Nkatabay
Malawi
00

Study participating centre
Liuzi Health Centre
Nkhatabay District
Nkhatabay
Malawi
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Study participating centre
Bula Health Centre
Nkkatabay District
Nkhatabay
Malawi
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Study participating centre
Mzenga Health Centre
Nkhatabay district
Nkhatabay
Malawi
oo

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 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?
Results article		30/09/2024	02/10/2024	Yes	No