ISRCTN12861565 https://doi.org/10.1186/ISRCTN12861565

Development, implementation, and evaluation of a respectful maternal and newborn care bundle: a mixed-methods study in Malawi and Tanzania

Submission date
27/06/2022

Recruitment status
No longer recruiting

Registration date
28/06/2022

Overall study status
Ongoing

Last Edited
27/06/2022

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

In many settings, women and their babies fail to receive respectful care during pregnancy, labour and the postnatal period. Mistreatment presents as physical, sexual and/or verbal abuse, stigma and discrimination, poor standards of care, poor rapport between women and providers and health system conditions and constraints. Although condemned for decades, few studies have tested interventions to reduce disrespectful care. The aim of this study is to determine whether introducing a group of interventions (bundle) reduces the incidence of disrespectful care in six facilities in Malawi and Tanzania.

Who can participate?

Women aged 18 years and older and health workers in Malawi and Tanzania

What does the study involve?

The study has three related phases: pre-implementation, implementation and sustainability. Evaluation continues throughout all phases.

During the pre-implementation phase the researchers will work with key stakeholders to agree the respectful care bundle components, identify factors likely to impact on successful implementation of the bundle, and develop and test appropriate data collection processes in the local setting.

In the implementation phase the researchers will introduce the bundle to six facilities and document the processes and resources (human and physical e.g. equipment) involved during and following implementation, examine health workers' and womens' experiences of the intervention, and use the knowledge generated to refine the implementation strategy.

In the sustainability phase, the researchers will observe continuation of bundle implementation in routine settings.

The researchers will use mixed methods, including an interrupted time series, community surveys, process audit, consensus meetings, resource utilisation questionnaires, in-depth interviews, and structured observations. Using multiple sources of data collection will enable a

comprehensive understanding of outcomes and processes related to the bundle.
Woman-reported episodes of disrespectful care are collected consistently before and after implementation of the intervention using a touchless smiley survey terminal. Interviews and focus groups will be taped, transcribed and analysed. Observations will be analysed and questionnaire data will be used to generate an estimate of the direct resources required to implement the care bundle.

What are the possible benefits and risks of participating?
There are no direct benefits from participating in the study, although some participants may find it helpful to talk about their experiences.

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?
July 2021 to June 2026

Who is funding the study?
National Institute of Health and Care Research (UK)

Who is the main contact?
Prof. Dame Tina Lavender, Tina.lavender@lstmed.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Prof Tina Lavender

ORCID ID
http://orcid.org/0000-0003-1473-4956

Contact details
2 Pearce Close
Liverpool
United Kingdom
L25 4UN
+44 (0)7874852886
Tina.Lavender@lstmed.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Development, implementation, and evaluation of a respectful maternal and newborn care bundle: a mixed-methods study in Malawi and Tanzania

Study objectives
Implementation of a Respectful Care Bundle decreases the percentage of woman-reported episodes of disrespectful care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 20/05/2022, Catholic University of Health and Allied Sciences/Bugando Research and Ethical Committee (CREC, PO Box 1464, Mwanza, Tanzania; +255 (0)28 298 3384; vc@bugando.ac.tz), ref: CREC/555/2022
2. Approved 15/06/2022, College of Medicine Research and Ethics Committee (COMREC, Kamazu University of Health Sciences, University of Malawi, Private Bag 360, Blantyre, Malawi; +265 (0)1 874 377; comrec@medcol.mw), ref: P.04/22/3610

Study design
Multicenter interventional interrupted time series design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prevention of disrespectful care in women and newborns within maternity services

Interventions

The researchers will use a positive organisational approach (appreciative inquiry) alongside the Behaviour Change Wheel (BCW), a theory-based method for the design of interventions.

The study has three related phases: 1) pre-implementation, 2) implementation and 3) sustainability. Evaluation continues throughout all phases.
1. During the pre-implementation phase the researchers will work with key stakeholders to a) agree the respectful care bundle components, b) identify factors likely to impact on successful implementation of the bundle, and c) develop and test appropriate data collection processes in the local setting.
2. In the implementation phase the researchers will a) introduce the bundle to six facilities and document the processes and resources (human and physical e.g. equipment) involved during and following implementation, b) examine health workers' and womens' experiences of the intervention, c) use knowledge generated to refine an acceptable and robust implementation strategy.
3. In the sustainability phase, the researchers will observe the continuation of bundle implementation in routine settings.

The intervention will be implemented over a 9-month period. Women will be followed-up for 6 weeks post-birth. The follow-up period will be 10.5 months.

Evaluation: The researchers will use mixed methods, including an interrupted time series, community surveys, process audit, consensus meetings, resource utilisation questionnaires, in-depth interviews, and structured observations. Using multiple sources of data collection will enable a comprehensive understanding of outcomes and processes related to the bundle.

Analysis: The primary outcome is woman-reported episodes of disrespectful care. The researchers will use an interrupted time series (ITS) analysis (before and after) to compare disrespectful care rates between time points by collecting data consistently before and after implementation of the intervention, using a touchless smiley survey terminal. Interviews and focus groups will be taped, transcribed verbatim and analysed through the framework approach. Observations will be analysed descriptively, providing information on the occurrence of disrespect in relation to different typologies. Questionnaire data will be used to generate an estimate of the direct resources required to implement the care bundle.

Intervention Type
Mixed

Primary outcome measure
Women-reported incidences of dis/respectful care measured using a specifically designed (and piloted) satisfaction rating scale using a smiley survey terminal at exit from the postnatal ward. Measurements will be taken during a 9-month pre-implementation period, 9-month implementation period and 9-month post-implementation period.

Secondary outcome measures
1. Potential confounding interventions collated fortnightly throughout the study, informed by verbal reports and local documents, and recorded in an electronic site log on REDCap
2. Incidences of disrespectful care measured using WHO's validated structured postnatal community survey tool (CS) pre-implementation (month 7) and post-implementation (month 3)
3. Incidences of disrespectful care measured through 48-hour continuous non-participant structured observations using WHO's Labour Observation Tool (LOT) at five timepoints at baseline, 5, 12, 15 and 22 months

4. Experiences of care assessed using in-depth interviews with women (conducted at 16-18 months), health workers (conducted at 8 months and 23 months) and hospital managers (conducted at 8 months and 23 months)
5. Changes in direct resources associated with the implementation of the care bundle captured via a specifically designed questionnaire completed with managers at month 16

Overall study start date
01/07/2021

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Women who are:
1. Admitted to one of the study hospitals for childbirth
2. Are not being transferred to another hospital immediately or taken straight to theatre for caesarean section
3. Are not admitted for abortion or abortion-related complications
4. Are at least 18 years old
5. Are not related to an employee of the facility
6. Are willing and able to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Approximately 30000

Key exclusion criteria
Women who do not have capacity to understand the information

Date of first enrolment
11/07/2022

Date of final enrolment
10/02/2025

Locations

Countries of recruitment
Malawi

Tanzania

Study participating centre
Kamuzu University of Health Sciences
University of Malawi
Blantyre
Malawi
Blantyre 3

Study participating centre
Catholic University of Health and Allied Sciences
Bugando Medical Centre
Mwanza
Tanzania
P.O. Box 1464

Sponsor information

Organisation
Liverpool School of Tropical Medicine

Sponsor details
Research Governance and Ethics Office
Room 221, 2nd Floor LLSA
Daulby Street
Liverpool
England
United Kingdom
L3 5QA
+44 (0)151 702 9396
Denise.Watson@lstmed.ac.uk

Sponsor type
University/education

Website
http://www.lstmed.ac.uk/

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The researchers plan to publish the findings in a high-impact journal in May 2025

Intention to publish date
01/05/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date