ISRCTN92381311 https://doi.org/10.1186/ISRCTN92381311

Scaling up safer births bundle of care - keeping more mothers and babies safe during and after birth

Submission date
24/09/2025

Recruitment status
No longer recruiting

Registration date
25/09/2025

Overall study status
Completed

Last Edited
31/10/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
The number of stillbirths, newborn deaths, and maternal deaths is unacceptably high in low- and middle-income countries, especially around the time of birth. Despite the existence of evidence-based training programs proven to reduce maternal and neonatal deaths, their full potential is often not realised due to scarce resources and support after implementation. This study aims to optimise the components and implementation of the Safer Births Bundle of Care, aligning closely with routine health system structures and processes, and to generate evidence of healthcare effects, feasibility, acceptability, sustainability, and cost-effectiveness to inform a national scale.

Who can participate?
Women delivering in the hospital and their newborns in 142 health facilities, which provide Comprehensive Emergency Obstetric and Newborn Care in five regions in Tanzania, namely Manyara, Mwanza, Tabora, Shinyanga, and Geita.

What does the study involve?
The SaferBirths Bundle is a well-proven package of innovative clinical tools and training tools coupled with low-dose, high-frequency on-the-job training. The bundle is designed to equip the birth attendants to deliver improved and timely quality care during labor and birth through a cascade of training and feedback loops. In this program, additional components of the essential newborn care, such as Kangaroo Mother care, will be included.

What are the possible benefits and risks of participating?
The intervention aims to improve foetal heart rate monitoring, immediate newborn care, neonatal resuscitation, and birth outcome, as well as essential newborn care. The benefits include quality and timely care of mothers and their newborns. The possible risks include over-treatment.

Where is the study run from?
Haydom Lutheran Hospital is the leading institution. The program will be implemented in 142 hospitals across five regions in Tanzania.

When is the study starting, and how long is it expected to run for?
The first phase (SBBC Phase I) of the study commenced in August 2020 and concluded in December 2023.
This SBBC Phase II program implementation began in April 2024 and will continue through December 2025. However, baseline data were retrospectively collected from January 2023

Who is funding the study?
Global Financing Facility for Women, Children and Adolescents (GFF)

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
01-SBBC/HLH/2024

Study information

Scientific Title
Safer Births Bundle of Care (SBBC Phase II)- A quality improvement implementation project in all health facilities with comprehensive emergency obstetrics and newborn care services in five regions in Tanzania

Acronym
SBBC Phase II

Study objectives
To determine the impact of scaling up the Safer Births bundle of care (therapeutic and training) on improving perinatal and maternal outcomes in the five regions in Tanzania to inform national rollout

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 27/06/2024, National Institute for Medical Research, Tanzania (P.O. BOX 9653, Dar es Salaam, 11101, Tanzania; +255 222121400; ethics@nimr.or.tz), ref: NIMR/HQ/R.8b/Vol. I/1254

2. approved 24/09/2024, Tanzania Commission for Science and Technology (P.O. Box 4302, Dar es Salaam, -, Tanzania; +255 738746509; dg@costech.or.tz), ref: CST00000555-2024

3. approved 23/04/2025, NORWEGIAN Regional Committees for Medical and Health Research Ethics (Kongens gate 14, Oslo, 0153, Norway; +46 55589715; rek-vest@uib.no), ref: 229725

Study design
Interventional pre and post (before and after)

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Intrapartum management of labor and childbirth

Interventions
This is a before-and-after quality improvement project that will be implemented simultaneously across all 142 Comprehensive Emergency Obstetric and Newborn Care health facilities (sites) in the five regions of Tanzania: Manyara, Tabora, Geita, Mwanza, and Shinyanga. Among the facilities, 30 took part in the SBBC phase I (see https://www.isrctn.com/ISRCTN30541755), and 112 facilities are new and were identified in December 2024. The baseline period data were collected from January 2023 to April 2024, followed by the implementation period, which began in May 2024 and will run through December 2025. Baseline data were prospectively collected for 30 sites that took place in SBBC Phase 1 and retrospectively collected for the 112 new sites.

SBBC's training innovations are designed to integrate with simulation scenarios, focusing on key maternal and newborn lifesaving skills. This bridges the gap between clinical theory and care. The local facility champions facilitate regular simulation training on labor management, postpartum bleeding, newborn resuscitation, and essential newborn care. The training sessions are guided by the Helping Mothers and Babies Survive programs. The local facility champions receive weekly feedback on their own facility's clinical data (key performance indicators and perinatal outcomes) and adjust ongoing training to address identified gaps. The clinical innovations are designed to ease the job of the health workers in fetal heart rate monitoring and newborn resuscitation.

Continuous Quality Improvement (CQI) is integrated through regular on-the-job, low-dose, high-frequency simulation-based training. Targeted training is done by utilizing local data and feedback loops to visualize gaps in clinical care and guide areas for improvement. Adequate training of local facility champions who can facilitate CQI simulation training is considered essential for these processes to occur, thereby stimulating a gradual and sustainable culture change. To implement SBBC sustainably, it is also crucial that the program is integrated into national systems.

The first phase lasted three years, from January 2020 through December 2023, and the results were published (see DOI: 10.1056/NEJMoa2406295)

The second phase (under this Protocol), from January 2023 through December 2025, will be divided into two periods: January 2023 to April 2024 will serve as the baseline period, and May 2024 through December 2025 will be the implementation period.

Additional components in the second phase:
• Scale up from 30 to 142 sites in the same five regions
• Management of preeclampsia, difficult deliveries, and prolonged labour, kangaroo mother care, and other essential newborn care components

• CQI is facilitated by a new Data Management Platform, a Learning Improvement and Facilitation Tool (LIFT)
• Collaborate with the Ministry of Health to configure DHIS-2 to be able to create an automatic facility periodic dashboard for feedback to the healthcare workers, strengthening CQIs
. Link SBBC II training and CQI activities with the Continuous Professional Development (CPD) accreditation system
. Integrate data collection and use within routine systems through health management of information systems registers, DHIS-2, and electronic medical records in all SBBC II regions

Intervention Type
Behavioural

Primary outcome(s)
Measured using patient records:
1. Perinatal deaths, defined as intrapartum stillbirth (ISB) or newborn death within the first 24 hours of life
2. Maternal deaths within 7 days postpartum

Key secondary outcome(s))
Current secondary outcome measures as of 31/10/2025:
Measured using patient records:
Secondary outcomes:
1. 24-hour newborn deaths.
2. Intrapartum stillbirths (ISB)
3. 7-days perinatal deaths (including ISB)

Other process and output indicators:
1. Antepartum stillbirths (ASB)
2. 2-7 days newborn deaths
3. Proportion of deliveries followed by neonatal resuscitation (stimulation, suction, and bag-mask ventilation)
4. The attitudes, perceptions, and acceptability of SBBC among HCWs and health managers, as well as patient satisfaction, will be assessed
5. Frequency of skills- and team-scenario trainings conducted in each facility, per number of relevant HCWs
6. Frequency of mentorship/supportive supervision at each facility

Previous secondary outcome measures:
Measured using patient records:
1. 24-hour newborn deaths
2. 7-day perinatal deaths
3. 2-7-day newborn deaths
4. Intrapartum stillbirths
5. Antepartum stillbirths
6. Proportion of deliveries followed by neonatal resuscitation (stimulation, suction, and Bag Mask Ventilation)
7. Proportion of deliveries resulting in emergency cesarean sections and vacuum delivery
8. The attitudes, perceptions, and acceptability of the Safer Births Bundle among Health Care Workers and health managers, as well as patient satisfaction, will be assessed

9. Frequency of skills- and team scenario trainings conducted in each facility/number of relevant healthcare workers
10. Frequency of mentorship/supportive supervision visits to each facility

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Pregnant women and their fetuses in labor at gestation age of 28 weeks and above

Participant type(s)
Carer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
Births below 28 weeks

Date of first enrolment
01/01/2023

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Tanzania

Study participating centre
Haydom Lutheran Hospital
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Sponsor information

Organisation
Haydom Lutheran Hospital

ROR
https://ror.org/02tzc1925

Funder(s)

Funder type
Charity

Funder Name
Global Financing Facility for Women, Children and Adolescents (GFF)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from:
Name: Benjamin Anathory Kamala
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IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Data management plan		29/10/2025	No	No
Protocol file	version 5.0	01/03/2024	29/10/2025	No	No
Statistical Analysis Plan	version 1.0	28/10/2025	29/10/2025	No	No