

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

<b>Submission date</b> 24/09/2025	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/09/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/09/2025	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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?

Dr Benjamin Anathory Kamala, kamala8086@gmail.com

## Contact information

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

## **Secondary study design**

Non randomised study

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

## **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 measure**

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 seven days postpartum

## **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

## **Overall study start date**

01/01/2023

## **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)

Patient, Carer

## Age group

Mixed

## Sex

Both

## Target number of participants

600,000

## 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

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<https://haydom.or.tz/>

**ROR**

<https://ror.org/02tzc1925>

**Funder(s)****Funder type**

Charity

**Funder Name**

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

**Results and Publications****Publication and dissemination plan**

Our findings will be published as multiple papers in peer-reviewed, relevant, Open-Access international journals and presented at global conferences. Permission to publish will be obtained from the local IRB before submission to peer-reviewed journals. A brief will be developed for policymakers outlining the required QI framework for improving care to advocate for more investments in such interventions. Combined workshops and dissemination seminars will be conducted with relevant stakeholders both locally and internationally. The aim will be to summarize and discuss the findings from the ongoing data collection, as well as the related implications for operational changes in care at birth and in the development and implementation of Plan-Do-Study-Act (PDSA) cycles as part of CQI.

**Intention to publish date**

30/09/2026

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from:

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**IPD sharing plan summary**  
Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 5.0	23/09/2025	25/09/2025	No	No