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SaferBirths Bundle - keeping mothers and babies safe during and after birth

Submission date
11/09/2020

Recruitment status
No longer recruiting

Registration date
12/10/2020

Overall study status
Completed

Last Edited
15/07/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The number of stillbirths and newborn 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. The aim of this study is to determine the impact of scaling up the SaferBirths bundle of care (therapeutic and training) on improving the quality of intrapartum care and maternal and newborn survival.

Who can participate?
Women delivering in the hospital and their newborns in 30 hospitals in five regions in Tanzania

What does the study involve?
The SaferBirths Bundle is a well-proven package of innovative clinical tools (Moyo, upright bag and Neobeat) and training tools (MamaNatalie and Neonatalie live) coupled with low-dose high-frequency on-job training. The bundle is intended to better equip and train birth attendants to provide improved and timely quality care during labour and birth through a cascade of training and feedback loops.

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. 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 (Tanzania)

When is the study starting and how long is it expected to run for?
August 2020 to December 2023

Who is funding the study?
The Global Financing Facility for Women, Children and Adolescents (GFF) through the UNICEF Tanzania country office

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
01-SBB/HLH/2020

Study information

Scientific Title
SaferBirths Bundle - keeping mothers and babies safe during and after birth: a stepped wedge cluster implementation project in selected public hospitals in Tanzania

Acronym
SaferBirths

Study objectives
Implementation of SaferBirths bundle of care will improve perinatal and maternal outcomes in public hospitals in Tanzania.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/05/2020, National Institute for Medical Research (3 Barack Obama Drive, PO Box 9653, 11101 Dar es Salaam, Tanzania; +255 (0)22 2121400; hq@nimr.or.tz, info@nimr.or.tz), ref: NIMR/HQ/R.8a/Vol. IX/3458

Study design
Stratified stepped-wedge cluster randomized quality improvement project

Primary study design
Interventional

Secondary study design
Stepped-wedge cluster randomized

Study setting(s)
Hospital, Training facility/simulation

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Interventions
The SaferBirths bundle of care is a combination of innovative clinical (therapeutic) and training tools tackling the main causes of perinatal death.

Moyo: an effective, user-friendly Fetal Heart Rate Monitor, suitable for low-resource settings. It can be used intermittently or continuously and provides audiovisual alarm, which enables HCW to detect abnormal fetal heart rate patterns earlier and more often compared to fetoscope and hand-held Doppler devices. Moyo facilitates more timely decision-making while reducing midwives' workload, as well as lessens maternal anxiety during labor as she can hear the heartbeat of her unborn baby.

NeoBeat Newborn Heart Rate Meter: a fast, easy and reusable device that provides an accurate and continuous display of a newborn's heart rate during the first seconds of life to remove misclassification and help guide resuscitation activities. Well-trained HCWs using NeoBeat can initiate ventilation of non-breathing newborns within the first minute of life.

Upright with PEEP Newborn Bag Mask: Compared to the horizontal bag-masks, the ergonomic orientation of the Upright bag-mask, and the new and improved Newborn Mask, are designed to make it easier to obtain mask seal and provide effective ventilation. Newborns with low-compliant (stiff) lungs are adequately ventilated with good outcomes using Upright with PEEP

NeoNatalie Live Newborn Resuscitation Trainer: NeoNatalie Live is a ‘smart’ simulator that provides feedback on key elements that providers often have difficulties with during newborn resuscitation. Each training session lasts less than 5 minutes and provides objective feedback on ventilation performance. This ensures greater flexibility to health care providers to train whenever their busy schedules allow them to. NeoNatalie Live also track of individual and team training progress over time. This enables providers as well as management to have a better overview of the number of providers trained, training progress, and areas of improvement. The SaferBirths innovations are not stand-alone products, but rather integrate with and support the existing evidence-based HBB training program. Experiences from implementation of HBB in Tanzania show that low-dose high-frequency training (LDHF) and a culture of continuous quality improvement (CQI) within the facility is essential for retaining and translating skills from training into clinical practice and for helping save lives The data-capturing components of the SaferBirths Bundle enable a system where HCW can receive objective feedback on their training as well as clinical quality of care. This not only helps guide their efforts, but also brings motivation to find ways to continually improve.

The study duration is 3 years.

Intervention Type
Behavioural

Primary outcome measure
Perinatal mortality defined as intrapartum stillbirth (i.e. stillborn baby with no signs of life at delivery and >28 weeks of gestation with intact skin and no signs of disintegration in utero) and neonatal death within the first 24 h of life, secondary to birth asphyxia, obtained from hospital records at the end of the study (3 years)

Secondary outcome measures
Obtained from hospital records at the end of the study (3 years):
1. Proportion of deliveries with fetal heart rate monitoring as per standard protocol, measured by fetal heart rate monitor (in beats per minute) during the study period
2. Proportion of deliveries in which neonates with an abnormal fetal heart rate during labor is followed by neonatal resuscitation using upright/standard bag during the study period
3. Proportion of deliveries resulting in emergency cesarean sections and instrumental deliveries by different causes during the study period
4. Proportion of non-breathing babies who receive bag and mask ventilation within 1 min of birth using upright/standard bag during the study period
5. Proportion of early neonatal morbidities, i.e. resuscitation, encephalopathy, low Apgar score, and admission to neonatal units during the study period
6. Proportion of mothers with postpartum haemorrhage managed successfully during the study period

Overall study start date
01/08/2020

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Pregnant women in labor at gestation age of 28 weeks and above with a live foetus at recruitment

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
100,000 mother-newborn pairs

Total final enrolment
297755

Key exclusion criteria

1. Macerated stillbirths
2. Births below 28 weeks

Date of first enrolment
01/03/2021

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Tanzania

Study participating centre
Haydom Lutheran Hospital
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
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ROR

https://ror.org/02tzc1925

Funder(s)

Funder type
Other

Funder Name
Global Financing Facility for Women, Children and Adolescents (GFF) through the UNICEF Tanzania country office (PCA Reference: TZA/PCA202066)

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 11/07/2024:
1. Protocol published
2. Halfway paper published
3. Two additional articles are published on project implementation
4. The endline paper is under review by a peer-reviewed journal

Previous publication and dissemination plan:
The protocol is not yet published but the study group intend to publish it. Once published it will be uploaded/made available to ISRCTN. The findings will be published as multiple papers in peer-reviewed relevant open-access international journals and communicated at global conferences. A summary in popular language will be developed for policymakers outlining the required quality improvement (QI) framework for improving care to advocate for more investments in such interventions. Combined workshops and dissemination seminars with relevant stakeholders will be conducted locally. The aim will be to summarise and discuss the findings from the ongoing data collection and related implications for operational changes in care at birth, as well as in the development and implementation of PDSA cycles as part of CQI.

Intention to publish date
30/10/2024

Individual participant data (IPD) sharing plan
Current IPD sharing plan as of 11/07/2024:
The datasets generated during and/or analysed during the current study are/will be available upon request from:
Name: Benjamin Anathory Kamala
Haydom Lutheran Hospital
PO Box 9000, Haydom, Manyara, Tanzania
Email: kamala8086@gmail.com
Patient-level anonymized data may be shared around October 2024.
Consent to provide the data will be sought from the National Institute for Medical Research Tanzania (NIMR).

Previous IPD sharing plan:
The datasets generated during and/or analysed during the current study are/will be available upon request from Benjamin Anathory Kamala, kamala8086@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		18/10/2021	21/10/2021	Yes	No
Interim results article	Halfway evaluation	30/01/2023	11/04/2023	Yes	No
Other publications	Completeness of documentation	26/01/2024	11/07/2024	Yes	No
Other publications	Healthcare workers' perceptions	29/05/2023	11/07/2024	Yes	No
Results article		26/02/2025	15/07/2025	Yes	No