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Scaling up quality improvement for safer birth in public facilities of Nepal

Submission date
21/02/2019

Recruitment status
No longer recruiting

Registration date
02/03/2019

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Mothers and newborns are at the time of high risk of death during labour and first day of life. Reducing the risk of death will require improving care at the time of birth. We aim to conduct a study to evaluate a package of interventions that aims to improve the care at the time of birth.

Who can participate?
Women delivering in the hospital can participate in the study.

What does the study involve?
The study consists of implementation of package of quality improvement interventions. The quality improvement interventions consist of training, mentoring, weekly meeting and provision of equipment.

What are the possible benefits and risks of participating?
The intervention aims to improve the fetal heart rate monitoring, immediate newborn care, neonatal resuscitation and birth outcome. The risk of participating for women and children might be exposure to over-treatment.

Where is the study run from?
The study will be implemented in 8 public hospitals with delivery more than 3000 per year.

When is the study starting and how long is it expected to run for?
The study will start on 1 April 2019 and expected to end 15 December 2020.

Who is funding the study?
The study is funded by Government of Canada, Grand Challenges Canada.

Who is the main contact?
Rejina Gurung

Study website

N/A

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
N/A

IRAS number

ClinicalTrials.gov number
N/A

Secondary identifying numbers
N/A

Study information

Scientific Title
Scaling up safer birth bundle through quality improvement in Nepal: a stepped wedged cluster randomized controlled trial in public hospitals

Acronym
SUSTAIN

Study objectives
Can a set of quality improvement interventions bundled with technology improve the quality of intrapartum care in public facilities of Nepal?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/02/2019, Ethical Review Board of Nepal Health Research Council (Nepal Health Research Council, Ramshah Path, Kathmandu, Nepal, P.O.Box 7626; address-approval@nhrc.org.np; +977-4255987), ref: 110-2019.

Study design
Stepped Wedged Cluster Randomized Controlled Trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Childbirth

Interventions
The SUSTAIN Package is a bundled kit of interventions which empower health care workers to efficiently monitor, provide care, and review care provided during the intrapartum and immediate postpartum period. The tools in this bundle (referred to as the Safer Births Bundle) are evidence-based and align with global guidelines. The interventions in the SUSTAIN package include training (Helping Babies Breathe Educational Program, NeoNatalie Advanced Newborn Ventilation Training Manikin), intrapartum monitoring (Moyo Fetal Heart Rate Monitor),

postpartum care (Upright Newborn Bag Mask, NeoBeat Newborn Heart Rate Monitor), and a supporting system of review.

Interventions include:
1. Perform a bottleneck analysis on the care of deliveries and set up a mechanism of continuous review and planning of care in the hospital to improve leadership accountability.
2. Introduce the Safer Births Bundle – a set of proven, cost-effective tools for training and therapy to improve labour monitoring (Moyo FHR Monitor) and neonatal resuscitation (Upright Bag-Mask, NeoBeat Newborn HR Meter, NeoNatalie LiveTraining Manikin)24.
3. Implement QI interventions in the delivery room including daily skill check for neonatal resuscitation, use of a checklist for the preparation for birth and resuscitation, use of self-review /evaluation checklist after conducting neonatal resuscitation, and weekly review meetings to track the progress made from the implementation of new tools and standards.
4. Set up a system of continuous measure & improve to assess the change in the quality of intrapartum care in the hospital by utilizing a Plan-Do-Study-Act (PDSA) approach. This approach harnesses local ownership of challenges and provides an actionable framework to monitor and evaluate progress to improve and sustain QI changes.

This is a stepped wedge design. Where in the hospitals are clustered into different groups randomly. The interventions will be implemented in a stepped wedge manner, ie with a time lag of 2 months. The control area will be the total baseline period in the total hospital and the intervention area will be the total intervention period. Please see the figure. The 8 hospitals will be randomly allocated using a lottery technique.

Intervention Type
Behavioural

Primary outcome measure
To be measured using patient record review:
1. Intrapartum stillbirth-In-utero fetal death during labour after 22 weeks of gestational age with no signs of life (no breathing or no heart rate until 10 minutes of life).
2. First-day neonatal mortality rate
3. Pre-discharge neonatal mortality-death of baby before discharge

Secondary outcome measures
1. Improvement in the proportion of delivery with fetal heart rate monitoring practice (every half an hour) will be determined using observation.
2. Improvement in the proportion of women to whom Moyo's FHMR is used to monitor fetal heart rate will be determined using observation.
3. Improvement in the proportion of babies heart rate monitored using neo-beat after birth will be determined using observation.
4. Whether maternity care was dignified will be determined by an interview with participating women.
5. Improvement in the proportion of non-breathing babies with bag and mask ventilation at 1 minute will be determined using observation.
6. Whether health workers are competent in neonatal resuscitation immediately after training will be determined using observation.
7. Whether health workers maintain neonatal resuscitation competency 6 months after training will be determined using observation during drills.
8. Whether health workers are competent in immediate newborn care will be determined using observation.

9. The proportion of health workers practicing skill drills in neonatalie at least 8 times in 3-month interval will be determined using observation.
10. The proportion of hospitals conducting bottleneck analysis and quality improvement plan development will be determined using observation.

Overall study start date
15/01/2019

Completion date
15/07/2021

Eligibility

Key inclusion criteria
1. Women with gestational age ≥22 weeks
2. In labour

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
89000 women

Key exclusion criteria
1. Referred from the labour room to operation theatre for delivery
2. Referred to other facilities
3. Do not have fetal heart sound at admission.

Date of first enrolment
01/04/2019

Date of final enrolment
01/07/2021

Locations

Countries of recruitment
Nepal

Study participating centre
Koshi Zonal hospital
Biratnagar

Province 1, Morang, Biratnagar
Nepal
977

Study participating centre
Janakpur Zonal hospital
Janakpur
Province 2, Janakpur
Nepal
977

Study participating centre
Bharatpur Hospital
Chitwan
Province 3, Bharapur
Nepal
977

Study participating centre
Lumbini Zonal Hospital
Province 5, Lumbini
Lumbini
Nepal
977

Study participating centre
Bheri Zonal hospital
Nepalgunj
Province 5, Bheri
Nepal
977

Study participating centre
Mid-Western Regional Hospital
Surkhet
Surkhet road, Surkhet
Nepal
977

Study participating centre
Seti Zonal hospital
Kailali
Dhangadi, Nepal
Nepal
977

Study participating centre
Dadeldhura Sub-Regional Hospital
Dadeldhura
Province 7
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977

Sponsor information

Organisation
Grand Challenges Canada

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Sponsor type
Government

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https://www.grandchallenges.ca/contact-us/

ROR
https://ror.org/02snbhr24

Organisation
Laerdal Foundation for Acute Medicine

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Sponsor type
Charity

Website
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Funder(s)

Funder type
Government

Funder Name
Grand Challenges Canada

Alternative Name(s)
Grands Défis Canada, GCC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Laerdal Foundation for Acute Medicine

Results and Publications

Publication and dissemination plan
We aim to publish a process and impact evaluation in a peer-reviewed journal.

Intention to publish date
30/12/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a secured repository of the Golden Community server and will be made public upon request. The participants location and identity will be anonymized.
The datasets generated during and/or analysed during the current study will be stored in a secured repository of the Golden Community server. The access of the data will be with the data management officer-Omkar Basnet- basnetom21@gmail.com , interim analysis of the background characteristics and outcome will be done during study. The data will be not be made available until 15 July 2021.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		21/02/2019	04/03/2019	No	No
Protocol article	protocol	19/06/2019	27/08/2019	Yes	No
Other publications	Nested prospective observational study	01/10/2020	31/10/2022	Yes	No