

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

<b>Submission date</b> 21/02/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 02/03/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/12/2020	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

## Contact information

**Type(s)**

Public

**Contact name**

Dr Ashish KC

**ORCID ID**

<https://orcid.org/0000-0002-0541-4486>

**Contact details**

Uppsala University, Uppsala, Sweden

Uppsala

Sweden

751 05

9841453806

ashish.k.c@kbh.uu.se

**Type(s)**

Public

**Contact name**

Mrs Rejina Gurung

**ORCID ID**

<https://orcid.org/0000-0002-4262-3543>

**Contact details**

Golden Community

Lalitpur

Nepal

977

+9779849979661

rejugrg@hotmail.com

## Additional identifiers

**Clinical Trials Information System (CTIS)**

N/A

**ClinicalTrials.gov (NCT)**

N/A

**Protocol serial number**

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

## Study type(s)

Treatment

## 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)<sup>24</sup>.
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(s)**

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

### **Key secondary outcome(s)**

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.

### **Completion date**

15/07/2021

## **Eligibility**

### **Key inclusion criteria**

1. Women with gestational age  $\geq 22$  weeks
2. In labour

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Sex**

All

**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  
Nepal  
977

# Sponsor information

## Organisation

Grand Challenges Canada

## ROR

<https://ror.org/02snbhr24>

## Organisation

Laerdal Foundation for Acute Medicine

# Funder(s)

## Funder type

Government

## Funder Name

Grand Challenges Canada

## Alternative Name(s)

Grands Défis Canada, gchallenges, Grand Challenges Canada / Grands Défis Canada, grandchallengescanada, GCC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

Canada

## Funder Name

Laerdal Foundation for Acute Medicine

# Results and Publications

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?
<a href="#">Protocol article</a>	protocol	19/06/2019	27/08/2019	Yes	No
<a href="#">Other publications</a>	Nested prospective observational study	01/10/2020	31/10/2022	Yes	No
<a href="#">Protocol file</a>		21/02/2019	04/03/2019	No	No