

## Study protocol

Scaling Up Safer Birth Bundle Through Quality Improvement in Nepal (SUSTAIN)-Stepped Wedged Cluster Randomized Controlled trial in public hospitals

### Abstract

**Background-**Each year, 2.2 million intrapartum related death takes (intrapartum stillbirth and first day neonatal death) place around the globe and 99% of these death takes place in low- and middle-income settings. Despite the accelerated increase in the health facility deliveries in these settings, 2/3<sup>rd</sup> of these deaths are due to lack of access to high quality care. Improving quality of care during the intrapartum period, will require investment in evidence-based quality improvement interventions for intrapartum care. We aimed to evaluate a package of scaled up quality improvement interventions on intrapartum care and survival in hospitals of Nepal.

**Methods-** We will conduct a stepped wedged cluster randomized controlled trial in 8 public hospitals with more than 3000 deliveries a year with intrapartum related mortality of 24 per 1000 birth in 2017. The study will have 8 clusters with the intervention wash out period of 6 weeks in each cluster. With the level of significance of 95% and statistical power of 90% with intra-cluster correlation of 0.0003, a study period of 19 months will be able to detect at least 15% change in intrapartum related mortality. In each hospital, through an approach of bottleneck analysis of problem identification, quality improvement interventions-training, mentoring, audit feedback and continuous improvement cycle for intrapartum care will be instituted. Training on standard basic neonatal resuscitation and essential newborn care will be provided to all health workers. To improve the technology for identifying high risk mothers and newborn, fetal heart monitor and neonatal heart rate monitor will be provided. Mentoring and facilitation will be done in each hospital for improving intrapartum care. In each hospital, an independent research team will be established to collect data on intervention input, process and outcome through record review, observation, interviews. Process evaluation will be done to evaluate the dose response effect in its contextual environment.

**Discussion-** With the global momentum to improve quality of care to prevent premature mortality and impairments, better understanding of the quality improvement interventions within a health facility context is important. We aim to evaluate sets of quality improvement interventions together with new technologies for intrapartum care. The proposed set of quality improvement intervention is based on the learning from a similar scale up trial in Nepal. The learnings of this trial will provide evidence for further scale up of the interventions in similar LMIC settings.

**Key words-**Quality improvement interventions, basic neonatal resuscitation, fetal heart rate monitoring, stepped wedged cluster randomized control trial, Nepal

Trial registration number-ISCRTN.....

**What is known this subject**

- Quality improvement intervention improves perinatal care in health facility settings
- New technologies for fetal heart rate monitoring and neonatal heart rate monitor has acceptability among the health care provider
- Basic neonatal resuscitation reduced intrapartum related mortality

**What is new in the study**

- Evaluate the adequacy of implementation of quality improvement interventions in the public hospitals
- The health facility's acceptability to package of quality improvement interventions with improved technologies for fetal heart rate monitoring and neonatal resuscitation.
- The effect of SUSTAIN package on health worker's adherence to intrapartum care
- The effect of package on intrapartum survival

## Background

The accelerated reduction in maternal and child mortality during the Millennium Development Goal era has led to the realization that further reduction in death can only be achieved if care during the intrapartum period is improved<sup>1,2</sup>. Every year, almost 1.2 million stillborn and 250 thousand mother's death occur during the intrapartum period and a million-newborn die on the first day of birth<sup>3,4</sup>. The United Nations' strategy for every woman and every child strategy 2016-2030 strives to reduce preventable maternal, neonatal and child death in all settings by the end of the Sustainable Development Era<sup>5</sup>. Since, the announcement of the global strategy, there has been numerous efforts made to identify strategies to reduce preventable deaths. One of the key global momentum was led by Lancet Global Health Commission for High Quality Care with a number of commissioners from different countries and expertise<sup>6</sup>. Through different consultations and systematic reviews, the Quality of Care commission, provided a framework on how to improve quality of care in health care settings<sup>7,8</sup>. The five foundations of the framework were; first, understanding the populations needs for care; second, strengthening of structures and governance for improving quality of care at all levels of health systems; third, redesigning or optimizing the health worker force such that conducive environment exist to provide care; fourth, introducing new tools, quality improvement interventions and technologies for delivering care and finally, the adequacy or capacity of health facility to delivery as per the demand of the population. Improvement in foundation for quality of care or its readiness will improve the process of care and hence the outcomes as per the Donabedian model of health care<sup>9</sup>. This has been a useful framework as two third of premature or preventable death occur not due to lack of access to care but due to poor quality of health care<sup>10</sup>. Global health since the announcement of the MDG in 2001, has made significant investments in improving access and availability of maternal and newborn care thus reducing the first and second delay of care for mothers and newborns, however, the third delay of care i.e quality of care remains a challenge<sup>11,12,13,14</sup>.

In Nepal, several studies have shown that quality of care has been a significant barrier for further reduction in maternal and neonatal care, especially during the intrapartum period<sup>15,16,17</sup>. Through several implementation research on quality improvement interventions low income settings, we have gathered few key learnings<sup>18,19,20</sup>. First, strengthening the leadership and governance in health care context for change is the first lever for bringing organizational change<sup>21</sup>; second, setting up both external and internal drivers such as mentoring and continuous quality improvement process is the second lever for bringing change in the clinical units; third, introducing new standards and tools for improving efficiency is the third lever to implementing the standards and finally, setting up a data platform for instigating accountability of care is the instrumental. The dose response of the mentioned four interventions in a particular system depends upon the adequacy and the context of implementation<sup>20</sup>.

In this safer birth bundle we aim to improve intrapartum care through introduction of set of quality improvement interventions as well as technologies (figure 1). The set of interventions is based on the learning from our previous implementation research on quality improvement for intrapartum care<sup>22</sup>. The objective of this imbedded implementation research in this quality improvement project-SUSTAIN are

- to evaluate the impact of the SUSTAIN package on intrapartum related survival,
- to evaluate the impact of the package on health workers performance on fetal heart rate monitoring, essential newborn care and neonatal resuscitation,

- to evaluate the adequacy of implementation of the quality improvement interventions in hospitals and
- to evaluate the acceptability of the SUSTAIN package implementation in the hospitals

## Methods

**Trial design**-This is a stepped wedged cluster randomized controlled trial with 8 cluster and same wedge in 8 public hospitals of Nepal. Each cluster is a hospital. The total implementation period in each hospital is 2 months (Figure 2).

**Hospital setting**-These hospitals have delivery of more than 3000 per year with the intrapartum related mortality ranging from 11 to 36.5 per 1000 birth.

All the hospital had two units for delivery-labour unit and operation theatre. The normal and complication vaginal delivery takes place in labour unit and cesarean section takes place in operation theatre. There is a postnatal unit and sick newborn care unit in each hospital. These hospitals provide level II sick newborn care services (management of hypoxic ischemic encephalopathy, infection, hyperbilirubinemia, respiratory distress syndrome). The obstetric service is led by obstetrician and the sick newborn care is led by pediatrician.

## **Participants**

**Eligible criteria for the participants**-Delivering women in labour admitted to the labour and delivery unit with fetal heart sound at admission, who consented to be enrolled in the study.

**Exclusion criteria**-Delivering women who were referred from the labour room to operation theatre for delivery or women who are referred to other facilities and donot have fetal heart sound at admission.

**Inclusion criteria**-Women with gestational age 22 weeks or more and who is in labour period.

## **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 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 labor monitoring (Moyo FHR Monitor)<sup>23</sup> 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 checklist for 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 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.

Quality improvement interventions include (Table 3).

**Training-** In SUSTAIN project, training to facilitators will be provided for a period of 7 days, with training to all health workers for 3 days. The training package will contain Helping Babies Survive and quality improvement intervention.

**Continuous quality improvement (CQI)** In SUSTAIN project, a bottleneck analysis will be conducted with the hospital leadership, based on which planning will be done. A weekly review meeting process (Plan-Do-Study-Act) will be introduced such that plan implementation will be assessed and a new planning will be done.

**Mentoring-** In SUSTAIN project, external mentor, who are expert clinicians and facilitator, will support the hospitals in the implementation of PDSA process, and audit and feedback.

**Audit and feedback-** A daily skill drills on neonatalie to the health workers will be introduced in SUSTAIN project.

## Outcomes

### Primary outcome

- *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).
- *First day mortality*-Death of baby on the within 24 hours of birth
- *Intrapartum related death*-The intrapartum stillbirth and first day neonatal mortality
- *Pre-discharge neonatal mortality*-Death of baby before discharge

### Secondary outcome

- Proportion of delivery with fetal heart rate monitoring practice (every half an hour)
- Proportion of women to whom Moyo's FHMR is used to monitor fetal heart rate
- Proportion of babies whose heart rate is monitored using neobeat after birth
- Proportion of non-breathing babies who bag and mask ventilation at 1 minute
- Proportion of health workers maintaining neonatal resuscitation skills 6 months after the training

- Proportion of health workers practice skills drills in neonatalie Live at least 8 times in 3 months interval
- Proportion of hospital conducting bottleneck analysis and quality improvement plan development
- Proportion of labour unit conducting at least 12 bi-weekly meeting for PDSA process
- Proportion of labour unit implementing at least 4 identified plans in the labour unit
- Proportion of hospitals receiving at least 6 mentoring visits

### **Sample size**

With the level of significance (type I error rate, two tailed) of 0.05, statistical power (type II error rate, two tailed) of 90%, intra-cluster correlation of 0.003<sup>25</sup> and cluster size of 4800 and design effect of 34, the effective sample size for control group will be 233 and in the intervention group will be 273 to detect 15% reduction in intrapartum related mortality. The actual required number of births in control group will be 35,000 and in the intervention group will be 40,000. With the estimated loss to follow up of 6-8% based on our previous research experience a total of 37000 will be required in control group and 43000 in intervention group.

### **Randomization**

The principal investigator generated a random sequence among the eight hospitals, to determine the sequence of the cluster through simple random technique. The allocation of treatment or intervention in each hospital is done in a stepped wedged pattern, where in the hospital were allocated based on the sequence number generated. The blinding of the hospital and individual participants to the intervention and outcome was not possible.

### **Data collection**

An independent data collection team will be established in each hospital for data collection on implementation, process and outcome.

*Implementation level data-* To collect data on the implementation of the interventions, a set proforma on the number of stakeholders engaged in each intervention will be collected.

- The hospital readiness and service availability assessment tool will be used to conduct the bottleneck analysis of the service readiness for intrapartum care. A planning tool will be used to develop the plan based on the bottleneck analysis.
- Data on change in the health workers knowledge and skills on intrapartum care before and after training will be collected using a multiple-choice questions and skill checklist.
- The data on the continuous quality improvement process will be collected using a Plan-Do-Study-Act dairy tested in our previous study.
- The periodic performance of the health workers will be done using skill checklist

*Process level data-* To collect data on the health workers performance in simulated and clinical setting on intrapartum care, a separate data collection system will be established.

- Use of neonatal live mannikin will be assessed through skill drills in a application based system by the data collection.
- The use of fetal heart rate monitor and neobeat will be assessed by a separate group of data collector using an observation checklist

- The health workers performance on fetal heart rate monitoring, immediate newborn care and neonatal resuscitation will be collected using an observation checklist
- A qualitative evaluation using the indepth interview and focus group discussion will be done to evaluate the adequacy of implementation of the interventions in the SUSTAIN package
- An acceptability study on the health workers acceptability on newer technologies as well as barriers for use of the device

*Outcome level data*-The mortality as well as the clinical events during intrapartum care will be collected from the patient case notes as well as labour and delivery register.

*Socio-economic data*-The socio-demographic information of the women will be collected through semi-structured interview.

#### Data management

A strict adherence to the national standard for data management to ensure the quality of data. A confidentiality will be maintained, where in the location and identity of individual level participants. To ensure the protection of the data from being lost, all the paper-based forms will be kept in a secure vault.

In each hospital a data collection coordinator will assess the quality of data collected and its completeness every day. Every Sunday, the collected paper-based data will be sealed in an envelope and sent via courier to the central research hub in Kathmandu. The paper-based form from each hospital will be indexed and a master ID will be provided to each form for data entry. Before the data entry, the review of the forms for missing variable(s) and coding of the open-ended responses will be done. Data entry will be done in a CS-PRO data base.

#### Data analysis

Following the completion of the study, the data cleaning will be done and a data analysis strategy will be developed. Evaluation of the implementation and process level data will be done using a Medical Research Council process evaluation process. The outcome level data will be analysed using the CONSORT guideline. Missing variables will be treated as per the standard norm.

#### Ethics

The study protocol has been finalized through a consultative process with professional bodies, academia, global experts and Ministry of Health and Population. Ethical approval has been taken from the ethical review board of Nepal Health Research Council. Written consent will be taken from all the participants who agreed to be part of the study. A strict adherence to the General Data Protect Regulation will be ensured. A clinical trial registration will be done for the study in the ISRCTN registry.

#### Discussion

We aim to provide an evidence-based package of quality improvement interventions and technologies for improving quality of intrapartum care. This implementation research will provide new information on what intensity of quality improvement interventions will be required for improving care in hospitals. Further, we aim also to construct an evidence-based framework for quality improvement and technology-based solution for intrapartum care. Upon the availability of the evidence on process and outcome evaluation, three

different tools will be used for translating evidence into action. First, a plain language summary of the result will be disseminated in local and national media on the importance of the QI package to general audience. Second, a policy brief will be developed for policy makers, on the required QI framework for improving care such that the investment can be accelerated. Third, publication of the results will be done in peer reviewed journal for international academic, researcher and program experts. We hope that in light of the global momentum for improving high quality care in the SDG era, this implementation research aims to provide evidence on the scalable model of quality improvement interventions and technologies for improving intrapartum care.

## **Abbreviation**

## **Declarations**

### **Ethics approval and consent to participate**

Ethics approval has been received from the Ethical Review Board of Nepal Health Research Council (ref 110-2019) on 15 March 2019. Written consent will be taken from participants.

### **Consent for publication**

Not applicable

### **Availability of data and material**

Not applicable

### **Competing interests**

The Laerdal Medicine provided the equipment's for use in the study. The team had no influence in the design of the evaluation

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## **Authors' contributions**

AKC and RG conceptualized the study. AKC made the first draft of the protocol. RG and PP made the ethics application from Nepal Health Research Council. PP, RC..., received approval from the Ministry of Health and Population for roll out of the SUSTAIN package. All the co-authors reviewed the first draft and provide comment in the protocol and study design. All of them approved the final version of the manuscript.

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Figures

Figure 1. Intervention design of SUSTAIN package



Figure 2. Stepped wedged Cluster randomized controlled design

	Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Koshi Zonal Hospital	Cluster hospital 1	2275																		5460
Janakpur Regional Hospital	Cluster hospital 2	7152																		13112
Bharatpur hospital	Cluster hospital 3	6419																		9170
Lumbini Zonal hospital	Cluster hospital 4	5768																		6489
Rapti Zonal Hospital	Cluster hospital 5	2331																		2072
Mid-western regional hospital	Cluster hospital 6	3210																		2247
Bheri Zonal hospital	Cluster hospital 7	3784																		2064
Seti Zonal hospital	Cluster hospital 8	6276																		2615

Table 1. Total birth and mortality rate in the hospital

	Total birth	Intrapartum stillbirth rate (1000 birth)	First day neonatal mortality rate (1000 live birth)	Intrapartum related death rate (1000 birth)
Koshi Zonal Hospital	5464	9.3	4.4	13.7
Janakpur Regional Hospital	14300	11.9	23	34.9
Bharatpur hospital	11006	7.3	3.7	11.0
Lumbini Zonal hospital	8649	11.2	12.3	23.5
Rapti Sub-Regional Hospital	3112	10.3	4.4	14.7
Mid-Western Regional Hospital	3847	5.0	25	30.0
Bheri Zonal Hospital	4132	1.2	35.3	36.5
Seti Zonal Hospital	6277	0.2	27.7	27.9

Table 2. Health workers in each hospital

	Number of nurses	Number of doctors	Other health workers	Total health workers
Koshi Zonal Hospital	25	8	45	78
Janakpur Regional Hospital	60	22	0	82

Bharatpur hospital	86	20	17	123
Lumbini Zonal hospital	81	7	36	124
Rapti Sub-Regional Hospital	42	2	13	57
Mid-Western Regional Hospital	20	3	22	45
Bheri Zonal Hospital	33	4	26	63
Seti Zonal Hospital	32	6	56	94

Table 3. Intensity of each QI intervention in SUSTAIN project

Quality improvement package	Definition	Number
Facilitators training on HBS	Training on continuous quality improvement package. Checklist use HBS package	6 days
Continuous Quality Improvement	An orientation with the hospital leadership in the improvement process for mother and newborn	Two hours
	Orientation to the tools to the facilitator on the bottleneck analysis process	2-4 hours
	Assessment of the maternal and newborn service in the hospital	2 days
	Bottleneck analysis of the maternal and newborn service	Half day
	Development of the problem-solving process using the PDSA approach	2 hours
Training	Training to health workers on HBS package and CQI	3 days
Mentoring	Monthly visit by clinical mentors on the implementation of the standards	1 days each month
Audit and feedback	Use of progress board Daily drills	Daily

Table 4. Logical framework

Indicator		numerator	denominator	Means of verification
Level	Impact			
1.1	Change in intrapartum stillbirth rate	Intrapartum stillbirth ( $\geq 500$ gram or gestational age $\geq 22$ weeks with no signs of life-no heart rate and no breathing)	Total birth	Record review
1.2	Change in first day neonatal mortality rate	First day neonatal death (0 day)	Total live birth	Record review
1.3	Change in pre-discharge neonatal mortality rate	Pre-discharge neonatal death	Total live birth	Record review
Level	Outcome			
2.1	Improvement in proportion of delivery with fetal heart rate monitoring practice (every half an hour)	# of delivery with fetal heart rate monitored at the rate of every 30 minutes	Total delivery	Observation
2.2	Improvement in proportion of women to whom Moyo's FHMR is used to monitor fetal heart rate	# of women with fetal heart rate monitored using Moyo	Total delivery	Observation
2.3	Improvement in proportion of babies heart rate monitored using neo-beat after birth	# of babies whose heart rate is monitored using neobeat after birth	Total birth	Observation

2.5	Improvement in proportion of non-breathing babies with bag and mask ventilation at 1 minute	# of non-breathing babies with bag and mask ventilation started 1 minute	Non-breathing babies	Observation
2.7	Improvement in breast-feeding within half an hour of birth	Breast feeding within half an hour of birth	Total live birth	Observation
Level	Output			
3.1	Health workers competent in neonatal resuscitation immediately after training	Competency of health worker in neonatal resuscitation after the training	Total health workers trained	Observation
3.2	Health workers maintains the neonatal resuscitation competency 6 months after training	Competency of health workers in neonatal resuscitation 6 months after the training	Total health workers in the labour room	Observation during drills
3.3	Health workers competent in immediate newborn care	Competency of health workers in delayed cord clamping and immediate breast feeding after training	Total health workers trained	Observation
3.4	Proportion of health workers practice skill drills in neonatalie at least 8 times in 3-month interval	Health workers practice skill drills in neonatalie at least 8 times in 3-month interval	Total health workers in labour room	Observation
3.5	Proportion of hospital conducting bottleneck analysis and quality improvement plan development	Number of hospitals which conducted bottleneck analysis and developed quality improvement plan	Total hospitals	Observation
3.6	Proportion of labour unit conducting at least 12 bi-weekly meeting for PDSA process	Number of labour unit conducting at least 12 bi-weekly meeting for PDSA process	Total labour unit	Observation
3.7	Proportion of labour unit implementing at least 4 identified plans in the labour unit	Number of labour unit implementing at least 4 identified plans in the labour unit	Total labour unit	PDSA dairy review
3.8	Proportion of hospitals receiving at least 6 mentoring visits	Number of hospitals receiving 6 mentoring visits	Total hospitals	Mentor's report
Level	Input			
4.1	Proportion of health worker trained in SUSTAIN package	Number of health worker trained in SUSTAIN package	Total health workers	Training report
4.2	Proportion of hospital completing SUSTAIN package implementation	Number of hospitals completing SUSTAIN package implementation	Total hospitals	Observation