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Nepal perinatal quality improvement project (NePeriQIP)

Submission date 02/05/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [X] Individual participant data
Registration date 11/05/2017	**Overall study status** Completed	
Last Edited 24/06/2024	**Condition category** Neonatal Diseases	

Plain English summary of protocol

Background and study aims
Around the globe, every year 2.6 million babies die within the mother's womb (stillbirth) and half of these deaths take place during labour and delivery. Similarly, 2.9 million babies die in the first 28 days of birth (neonatal death). These deaths can be prevented from simple low cost interventions. However, implementing the proven interventions in routine clinical care has proved to be a challenge, especially in low income settings like Nepal. Understanding these challenges within the health system context and developing quality improvement interventions to overcome the barriers is critical. NePeriQIP is a program which aims to improve the behavior of the hospital leaders and decision maker for better clinical care and to build on the capacity of the health workers to set up a system to plan, implement and review the clinical care for mothers and newborns. The aim of this study is to evaluate the effectiveness of NePeriQIP on stillbirth and neonatal death.

Who can participate?
Women who are at least 22 week pregnant and their newborn babies.

What does the study involve?
This study is taking place in 12 hospitals which have a total annual delivery of more than 60,000. For the evaluation purpose, the hospitals are divided into four groups (clusters). In each cluster NePeriQIP program is carried out three months apart. The program involves evaluating the current care given, providing training to health workers to provide better care and to maintain the delivery of this care. Throughout the duration of the study, neonatal death and stillbirth rates are recorded. In addition, health workers are monitored in order to evaluate they are they are providing.

What are the possible benefits and risks of participating?
Participating newborns benefit from receiving improved quality of care which could increase their chance of survival. Health workers benefit from improving their knowledge, skills and performance in looking after newborns. There are no notable risks involved with participating.

Where is the study run from?
Western Regional Hospital and 11 other hospitals (Nepal)

When is the study starting and how long is it expected to run for?
January 2017 to December 2019

Who is funding the study?
1. Swedish Foundation for International Cooperation in Research and Higher Education (Sweden)
2. Swedish Research Council (Sweden)
3. Einhorn Family Foundation (Sweden)
4. UNICEF Nepal (Nepal)

Who is the main contact?
1. Dr Ashish KC (scientific)
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2. Dr Mats Målqvist (scientific)

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1643

Study information

Scientific Title
Nepal Perinatal Quality Improvement Project (NePeriQIP): A cluster randomized scale-up trial in public hospitals

Acronym
NePeriQIP

Study objectives
Primary objective:
To evaluate impact of the NePeriQIP intervention model on intrapartum mortality (intrapartum stillbirth and first day mortality).

Secondary objectives:
1. To evaluate the effect of the intervention model on overall neonatal mortality and morbidity and health worker's performance on neonatal care
2. To evaluate the process of implementation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Review Board-Nepal Health Research Council, 16/03/2017, ref: 1643

Study design
Stepped-wedge cluster-randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

1. Babies who have respiratory depression at birth
2. Preterm babies
3. Neonatal Infection
4. Babies with neonatal encephalopathy

Interventions

A stepped-wedge cluster-randomized design will be applied and the hospitals will be randomly allocated to four wedges with different time points for initiation of intervention; each wedge will thus include three hospitals. The delay in intervention start will be three months, meaning that the preparatory phase will be completed for each step before starting the next. Randomization was performed proportionate to number of deliveries per year in each hospital starting by allocating one of the four largest hospitals to each wedge and then continued with the middle-range hospitals. Finally the four hospitals with the least deliveries per year were randomly allocated to each wedge. This implies that all hospitals will eventually receive the intervention with a total duration of 12 months (3 months preparatory phase and 9 months implementation phase). In order to achieve a sustained effect of the intervention the hospital managements will be stimulated to continue beyond the intervention period of 12 months.

A package of multi-faceted quality improvement interventions will be administered to all 12 participating hospitals. The QI interventions will utilize a combination of three different implementation strategies (1) Facilitation, (2) Audit and Feedback, and (3) Training, with the aim to strengthen the health care system through improved quality improvement processes and information systems, and thereby improving quality of perinatal care.

NePeriQIP will be rolled out in three phases: preparatory, implementation and sustainability phase.

Preparatory phase - In order to enable the introduction and implementation of NePeriQIP, mentors will be recruited externally by central Ministry of Health. These mentors will be clinicians with experience of working in perinatal health. They will be responsible for revitalising and orienting the already existing Quality Improvement/Maternal and Perinatal Death Review (QI/MPDR) committees in each hospital to implement the NePeriQIP intervention. Each mentor will be responsible for four hospitals. The QI/MPDR committee will then use set selection criteria to identify in-hospital 2-3 QI facilitators to implement the QI interventions in clinical units in each of the 12 hospitals. The QI facilitators and mentors will be trained on facilitation skills and standard perinatal care package by the research team. Following this, the QI facilitators will together with clinical unit staff, supported by the mentors, conduct assessment of the readiness, availability and quality of perinatal care. Based on the findings, a causal /bottleneck analysis on inadequacy of quality of perinatal care will be conducted. Results will be shared with the QI/MPDR committee and a plan will be developed and implemented to improve the quality of perinatal care using a Plan-Do-Study-Act (PDSA) cycle approach. Together with QI /MPDR committee, the QI facilitators will mobilize resources to ensure availability of perinatal care equipment. Routine use of in-patient sick newborn register will be strengthened to improve the monitoring of perinatal care. This phase will take 3 months to complete.

Implementation phase - The mentors and QI facilitators will conduct training to build capacity of health workers on WHO Standards for Improving Quality of Maternal and Newborn Care in health facilities and the National Neonatal Clinical Protocol. This training will be the starting point of clinical evaluation. The training will also include instructions on how to conduct skills evaluation and how to fill the progress board on a daily basis. Standardized tools (checklists, progress boards and manikins) will be provided to each clinical unit. The QI facilitator will supervise and facilitate the use of these tools and will conduct unit meetings with staff using

PDSA cycle and facilitation techniques. After six months of implementation, refresher training will be done to health workers on clinical standards. During the implementation phase the mentors will support and supervise the QI facilitators on a periodical basis and conduct individual in-house training if deemed necessary. The mentors will also encourage and enable interaction between QI facilitators at other hospitals. The implementation phase will be on-going for 9 months.

Sustainability phase - In order to fully implement and sustain the NePeriQIP intervention the QI facilitators will be expected to continue with QI activities as an integral component of daily practice.

Intervention Type
Behavioural

Primary outcome measure
1. Intrapartum mortality measured as intrapartum stillbirth (death within uterus 22 weeks of gestation or birth weight 500 gram) as assessed by review of the patient record at the time of delivery
2. First-day neonatal mortality (deaths within first 24 hours of birth) is assessed by review of the patient record at the time of discharge

Secondary outcome measures
1. Early (0-6 days) and late neonatal (7-27 days) in-hospital mortality is measured by review of the patient record at the time of discharge
2. Admittance to Sick Newborn Care Units (SNCU) and morbidity epidemiology is measured by review of the sick newborn chart and register at the time of discharge
3. Rate and severity of neonatal encephalopathy (NE) is measured by review of the NE scoring sheet at the time of discharge
4. Health workers' performance on:
4.1. Fetal surveillance in clinical settings is measured by observation and review of the record by surveillance officer during the time of labour
4.2. Neonatal resuscitation in simulated settings is measured by observation by trainers at the time of training
4.3. Neonatal resuscitation in clinical settings is measured by clinical observation by surveillance officers at the time of birth
4.4. Essential newborn care (immediate newborn care, cord care practices, breast feeding, KMC, routine assessment of newborn) is measured by clinical observation at the time of birth and during first hour of life
4.5. Infection prevention and management is measured by clinical observation at delivery unit as well as sick newborn care unit
5. Beneficiaries' satisfaction on the received care is measured by interview with the client at the time of discharge
6. Acceptability and adequacy of each implementation strategy component is measured by focus group discussion and interview with health workers and stakeholders at 3, 6 and 9 months of implementation of the intervention
7. Mothers' experiences regarding closeness and separation to their infants in the delivery room and at the neonatal care unit is measured by interview at the time of discharge
8. Postnatal staff perceptions on closeness between parents and newborns and what barriers that they can identify at their hospital is measured by interview at 3, 6 and 9 months of

implementation of the intervention
9. Cost-effectiveness of the intervention is measured by interview with beneficiary and review of the patient record at the time of discharge

Overall study start date
02/01/2017

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Mothers:
1. Pregnant women
2. Gestational age equal to or more than 22 weeks
3. With foetal heart sound at admission
4. Agree to participate in the study

Neonates:
Babies weighing 500 gram.

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
There will be 4 wedges with 3 hospital in each wedge. Estimated number of deliveries before intervention-37,000. Estimated number of deliveries after intervention-46,800

Total final enrolment
89014

Key exclusion criteria
1. Women who have antepartum stillbirth, i.e. women admitted to labour room with no fetal heart sound

Date of first enrolment
01/06/2017

Date of final enrolment
31/05/2019

Locations

Countries of recruitment
Nepal

Study participating centre
Western Regional Hospital
Pokhara, Kaski
Pokhara
Nepal
44600

Study participating centre
Mid-Western Regional Hospital
Surkhet
Surkhet
Nepal
21700

Study participating centre
Bardiya district hospital
Guleriya, Bardiya
Gulyeria, Bardiya
Nepal
21800

Study participating centre
Bharatpur Hospital
Chitwan, Bharatpur
Chitwan
Nepal
44200

Study participating centre
Seti Zonal Hospital
Dhangadi, Kailali
Dhangadi
Nepal
10900

Study participating centre

Nuwakot district hospital
Bidhur, Nuwakot
Nuwakot
Nepal
44909

Study participating centre
Koshi Zonal Hospital
Biratnagar, Morang
Biratnagar, Morang
Nepal
56600

Study participating centre
Rapti Sub Regional Hospital
Dang
Ghorahi
Nepal
22400

Study participating centre
Nawalparasi district hospital
Nawalparasi
Sunwal
Nepal
33000

Study participating centre
Lumbini Zonal Hospital
Butwal, Rupendehi
Butwal
Nepal
32907

Study participating centre
Bheri Zonal Hospital
Nepalgunj, Bheri
Nepalgunj
Nepal
21900

Study participating centre
Pyuthan district hospital
Pyuthan
Khalanga
Nepal
22300

Sponsor information

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Sponsor type
Charity

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Funder(s)

Funder type
Government

Funder Name
Swedish Foundation for International Cooperation in Research and Higher Education (STINT)

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
Einhorn Family Foundation

Funder Name
UNICEF

Alternative Name(s)
United Nations Children's Fund, United Nations Children's Emergency Fund, Fonds des Nations Unies pour l'enfance, Fondo de las Naciones Unidas para la Infancia, ,

Funding Body Type
Government organisation

Funding Body Subtype
International organizations

Location
United States of America

Results and Publications

Publication and dissemination plan
The study protocol is planned for publication by end of September 2017. The dissemination of the outcome of the trials will be done after the completion of the project in early 2020.

Intention to publish date
31/03/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Ashish KC (aaashis7@yahoo.com) after the publication of the full report.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/09/2017		Yes	No
Results article	results	09/09/2019	25/02/2020	Yes	No
Results article	results	17/07/2020	24/07/2020	Yes	No
Results article	results	10/09/2020	15/09/2020	Yes	No

Results article	results	08/02/2021	10/02/2021	Yes	No
Results article	Effect of a scaled-up quality improvement intervention on health workers' competence on neonatal resuscitation in simulated settings in public hospitals: A pre-post study in Nepal	29/04/2021	30/04/2021	Yes	No
Results article	secondary outcome analysis	06/06/2022	07/06/2022	Yes	No
Dataset	Effect of a scaled-up quality improvement intervention on health workers' competence on neonatal resuscitation in simulated settings in public hospitals: A pre-post study in Nepal		24/06/2024	No	No
Dataset	Factors associated with poor adherence to intrapartum fetal heart monitoring in relationship to intrapartum related death: A prospective cohort study		24/06/2024	No	No
Results article	Factors associated with poor adherence to intrapartum fetal heart monitoring in relationship to intrapartum related death: A prospective cohort study	23/05/2022	24/06/2024	Yes	No
Results article	Not Crying After Birth as a Predictor of Not Breathing	01/06/2020	24/06/2024	Yes	No
Results article	Performance of health workers on neonatal resuscitation care following scaled-up quality improvement interventions in public hospitals of Nepal - a prospective observational study	19/04/2021	24/06/2024	Yes	No
Results article	Respectful maternal and newborn care: measurement in one EN-BIRTH study hospital in Nepal	26/03/2021	24/06/2024	Yes	No
Results article	The burden of misclassification of antepartum stillbirth in Nepal	11/12/2019	24/06/2024	Yes	No