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# Implementing knowledge into practice for improved neonatal survival: a community-based trial in Quang Ninh province, Vietnam

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 07/05/2008 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 07/07/2008 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 18/12/2019 | Neonatal Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Uwe Ewald

**Contact details**
Department of Women's and Children's Health
University Hospital
Uppsala
Sweden
75185

## Additional identifiers

## Study information

**Scientific Title**
Implementing knowledge into practice for improved neonatal survival: a cluster-randomised, community-based trial in Quang Ninh province, Vietnam

**Acronym**
NeoKIP

## Study objectives
The overall objective of this project is to evaluate if facilitation on the community level results in effective improvement of perinatal health and survival. Specifically, we hypothesise:
1. That a cluster-randomised intervention using a facilitation approach targeting primary health care staff and key community members reduces the risk for neonatal death, and
2. That the facilitation intervention will result in increased knowledge and use of evidence-based practice related to maternal and perinatal health among health care staff in intervention as compared to the control clusters

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. The Ministry of Health (Vietnam), 12/10/2007, ref: 3934/QD-BYT
2. The Provincial Health Bureau in Quang Ninh (Vietnam)
3. The Research Ethics Committee at Uppsala University (Sweden), 25/01/2006, ref: 2005:319

## Primary study design
Interventional

## Study design
Single-centre cluster-randomised population-based community intervention trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Neonatal health and survival

## Interventions
The facilitation intervention targets CHC staff and key persons at the community level. Each CHC is accountable for the health care in the community, including all villages. For each village the CHC has one Village Health Worker (VHW) who is responsible for the basic health care. At each CHC, there are 3 - 6 staff working, of whom a midwife or a medical doctor provides perinatal care. Key persons in the community are the vice chairman and the Women Union leader, who both are in decision-making positions. The basic feature of the study intervention is that individuals from the Women Union are acting as facilitators in supporting CHC staff and key persons in their efforts to improve health care practice. Individuals from local Women Union organisations have been recruited and trained for one week to be able to act as facilitators. A locally recruited person act as supervisor of the facilitators; i.e., supporting the facilitators, assisting and coordinating in the facilitation process, and report back to the research team.

A facilitation manual was developed to guide the work of the facilitators. Each facilitator operates within the same communities for the whole intervention period and meet with each community group monthly. Such a group, called the Maternal-Newborn-Health-Group (MNHG), normally consists of three CHC staff, a village health worker, the vice chairman in the community and two women union representatives (community and village level). The facilitator uses a problem solving, participatory and enabling approach (instead of prescribing and directing a set of actions). Basing the discussions on individual and common experiences, the facilitator support critical reflection, problem identification, finding solutions, setting up and accomplish change strategies, using the PLAN-DO-STUDY-ACT cycle. This intervention implies a strong local

ownership and 'bottom-up' approach in empowering health care staff to improve practice. As an ingredient in the facilitation strategy, the recommendations in the National Guidelines are highlighted. Practically the work process entails the development of an action plan at one meeting to be fully or partial implemented until next meeting, where the process proceeds.

The unit of intervention (and thus randomisation) is the community with its Community Health Centre, and will be proportional to the number of deliveries in the communities. Approximately 44 communities will be allocated to the intervention arm of the study.

Controls are communities without intervention.

The total duration of the intervention will be two years. Follow-up will be done three years after the end of intervention.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome(s)
Neonatal mortality, measured one year after intervention start and at the end of intervention (two years)

### Key secondary outcome(s)
1. Effects on home visits by midwifes
2. Exclusive breast-feeding
3. Temperature control
4. Knowledge among health staff
5. Care-seeking behaviour
6. Other indicators for neonatal health

Outcomes will be measured one year after intervention start and at the end of intervention (two years).

### Completion date
31/12/2010

## Eligibility

### Key inclusion criteria
Districts in Quang Ninh province in Northern Vietnam with a neonatal mortality rate (NMR) higher than 15/1000 have been selected for the intervention, resulting in a study involving eight districts composed by 87 communities with a corresponding community health centre (CHC). In 2005 there were 6227 births and 150 neonatal deaths in these districts resulting in a NMR of 24 /1000.

### Participant type(s)
Patient

### Healthy volunteers allowed

No

**Age group**
Neonate

**Sex**
All

**Key exclusion criteria**
Districts in Quang Ninh province with a NMR less than 15/1000 were excluded.

**Date of first enrolment**
02/06/2008

**Date of final enrolment**
31/12/2010

# Locations

**Countries of recruitment**
Sweden

Viet Nam

**Study participating centre**
**University Hospital**
Uppsala
Sweden
75185

# Sponsor information

**Organisation**
Swedish Agency for International Development Cooperation (Sida)/Department for Research Cooperation (SAREC) (Sweden)

**ROR**
https://ror.org/01fn7me06

# Funder(s)

**Funder type**
Government

**Funder Name**
Swedish Agency for International Development Cooperation (Sida)/Department for Research Cooperation (SAREC) (Sweden)

**Funder Name**
Uppsala Universitet

**Alternative Name(s)**
uppsalauni, Uppsala Universitet, Sweden, Uppsala University, UU

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
Sweden

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 28/03/2008 | | Yes | No |
| Results article | results | 01/03/2011 | | Yes | No |
| Results article | results | 01/04/2012 | | Yes | No |
| Results article | results | 01/12/2012 | | Yes | No |
| Results article | results | 01/12/2013 | | Yes | No |
| Results article | results | 29/12/2015 | | Yes | No |
| Results article | results | 13/01/2016 | | Yes | No |
| Results article | results | 01/09/2018 | 18/12/2019 | Yes | No |
| Other publications | study design | 27/09/2011 | | Yes | No |