

# Uganda Newborn Survival Study: improving newborn health and survival through a community based intervention linked to health facilities

<b>Submission date</b> 31/10/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/02/2010	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 07/02/2017	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## Study information

Scientific Title

Improving newborn health and survival through a community based intervention linked to health facilities: a randomised controlled cluster trial

## **Acronym**

UNEST

## **Study objectives**

Implementation of an integrated care package of four home visits by a community health worker (CHW) during pregnancy and the neonatal period to deliver one on one health messages and promoting linkage to the health facility improves the following maternal-newborn care practices by at least 20% in two years amongst the target population in rural Uganda.

Further information can be found at:

<http://www.ncbi.nlm.nih.gov/pubmed/18570672>

<http://www.ncbi.nlm.nih.gov/pubmed/19710561>

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Uganda National Council of Science and Technology HS626 approved from the 20/08/2009 to 20/08/2010

## **Study design**

Randomised controlled cluster trial

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Maternal and newborn health

## **Interventions**

Through formative research around evidence-based practices, and dialogue with policy and technical advisors, we will construct a home-based neonatal care package implemented by the responsible Village Health Team member, effectively a Community Health Worker. This CHW will be trained to identify pregnant women and make four home visits: two before and two just after birth. Linkages will be made to facility care and targeted messages for home-care and care-seeking delivered. The project will improve care in health units to provide standardised care for the mother and the newborn in both intervention and comparison areas.

The control area is being given the current standard of care provided by the Government. However, health facility quality improvement initiatives are being provided in both control and intervention areas in order to standardise care but also for ethical reasons. This will enable sick newborns in the control area to access care.

## **Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

## 1. In ANC:

- 1.1. % of pregnant women attending ANC two, four or more times
- 1.2. % of pregnant women who know at least two danger signs of pregnancy
- 1.3. % of pregnant women who prepare for birth

## 2. In the intrapartum period:

- 2.1. % of pregnant women who have a skilled attendant at delivery
- 2.2. % of women who went to the HC in an emergency

## 3. In the post-natal period:

- 3.1. % of babies who are initiated on breastfeeding in the first 6 hours of birth
- 3.2. % of babies who are exclusively breastfed during the neonatal period
- 3.3. % of babies whose first bath was delayed for 6 and 24 hours
- 3.4. % of mothers who put nothing on the cord
- 3.5. % of mothers who know at least 3 neonatal danger signs
- 3.6. % women whose children were managed in skin to skin contact after delivery.
- 3.7. Effectiveness of sepsis management (special studies to determine: maternal and CHW knowledge, compliance and timing of referral, and adequacy of treatment following referral)

**Key secondary outcome(s)**

1. Neonatal mortality
2. Perinatal mortality

**Completion date**

30/12/2011

**Eligibility****Key inclusion criteria**

1. Women of childbearing age
2. Pregnant women
3. Newly delivered women
4. Neonates and infants

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

Refusal to consent

**Date of first enrolment**

01/07/2009

**Date of final enrolment**

30/12/2011

**Locations****Countries of recruitment**

Uganda

**Study participating centre**

**Makerere University**

Kampala

Uganda

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**Sponsor information****Organisation**

Save the Children (USA)

**ROR**

<https://ror.org/036jr6x18>

**Funder(s)****Funder type**

Charity

**Funder Name**

Save the Children (USA) (ref: UG01\_232)

**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?
<a href="#">Results article</a>	results	31/03/2015		Yes	No
<a href="#">Results article</a>	results	31/03/2015		Yes	No
<a href="#">Protocol article</a>	protocol	15/11/2012		Yes	No