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A study on the effect of demand and supply side interventions on maternal and neonatal mortality in three districts in Malawi

Submission date	Recruitment status	[_] Prospectively registered
24/03/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/04/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/09/2013	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
05PC02

Study information

Scientific Title

The effect of community mobilisation through womens groups and health facility quality improvement on maternal and neonatal mortality in three districts of Malawi: a two-by-two factorial cluster randomised controlled trial

Acronym
MaiKhanda

Study objectives
1. Community mobilisation through women's groups will reduce maternal and neonatal mortality rates through changes in care practices and health seeking behaviour
2. Quality improvement of obstetric and newborn care at Health Centres and Hospitals will reduce maternal and neonatal mortality rates through improvements in timely and effective management of antenatal care, labour, delivery and the post-partum period

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Health Sciences Research Council (NHSRC) of Malawi 01/04/2007 (ref: Protocol # 420)

Study design
2 x 2 factorial cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Maternal and neonatal mortality

Interventions
1. Quality Improvement trial: Coaching of Health Facility staff in quality improvement methodology (including Plan-Do-Study-Act, Death Reviews, change ideas, bundles and packages) to improve obstetric and newborn care at Health Centres and Hospitals
2. Women's groups intervention trial: Community-based participatory women's groups to mobilise communities around mother and newborn health
3. The two trials are part of a factorial design, where the same participants are enrolled in the control or intervention arms of each trial, producing four different groupings of intervention combinations: 15 clusters with both interventions (WG+QI), 17 clusters with the quality improvement (QI) intervention only; 16 clusters with women's group (WG) intervention only, and 28 clusters with no interventions (control)
4. Note that the original design had 15 WG+QI, 17 QI only, 24 WG only, and 26 control clusters respectively i.e. a 2 x 2 factorial of QI: 32, no QI: 32; WG: 39, no WG 39 with 4 clusters only in the QI trial and 18 clusters only in the WG trial. This was not followed because some health centres (which the clusters were formed around) were not functioning.

Total duration of interventions: 27 months from 01/10/2008 to 31/12/2010 (A period of 15 months of baseline data collection (01/06/2007 to 30/09/2008) preceded the interventions)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Maternal, neonatal and perinatal mortality, assessed by monthly community surveillance of all pregnant women and their infants until two months after delivery throughout the 27 month intervention period (01/10/08 to 31/12/2010).
2. Any mothers or infants who have died were followed up with a verbal autopsy interview to establish the cause of death

Key secondary outcome(s))
The following were determined through monthly community surveillance, monthly health facility surveillance and collection of process data on the interventions:
1. Percentage of deliveries at a health facility (for both interventions)
2. At facility level (for the quality improvement trial):
2.1. Percentage met need for emergency obstetric care
2.2. Number of deliveries at facility
3. Percentage of maternal deaths subjected to maternal death audit
4. Case fatality rate
5. Caesarean section rate
6. Practice of signal obstetric care functions
7. At the community level (for the womens group trial):
7.1. No. of womens groups mobilized annually
7.2. Percentage of women attending womens groups

Completion date
31/12/2010

Eligibility

Key inclusion criteria
All pregnant women who agree to take part in the programme

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria

Women who have no possibility of conceiving during the study period (women who have had hysterectomy or permanent sterilisation)

Date of first enrolment
01/06/2010

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

England

Malawi

Study participating centre
Centre for International Health and Development
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation (UK) 05PC02

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	01/09/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes