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Does training non-physician clinicians, in Malawi, have an impact on new-born baby and maternal survival?

Submission date
03/05/2012

Recruitment status
No longer recruiting

Registration date
08/06/2012

Overall study status
Completed

Last Edited
08/06/2017

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Death rates are high among mothers and newborns in Malawi. One way of dealing with this is to provide Emergency Obstetric and New born Care (EmONC). Malawi has a shortage of medical doctors who can offer EmONC. To compensate for this shortage, the Government introduced formal training of Non-Physician Clinicians (NPCs), known as Clinical Officers in Malawi, in 1976 to offer such services. However, they lack a clear professional support and supervision policy. Strengthening the position of NPCs has the potential to expand cost-effective, quality health services and improve access to health care, which will in turn reduce the number of mother and baby deaths. The aim of this study is to evaluate the impact of an intervention whereby Clinical Officers/Non-Physician Clinicians are trained as advance leaders in advanced obstetrics and paediatrics.

Who can participate?
Non-physician clinicians in Malawi.

What does the study involve?
Fifteen districts in the Central and Northern Regions of Malawi are randomly allocated to either receive the intervention or to not receive the intervention (control districts). Within the intervention districts about 50 NPCs are provided with the advanced leadership and skills training intervention. The research assistants then invite the trained NPCs to be interviewed about how the intervention has worked/fitted in to the hospital routine. As part of the intervention the trained NPCs are expected to cascade the training they have received to others within their districts (e.g., other NPCs or midwives). The research assistants identify a number of these people from the NPC's records and they are approached and interviewed about the training they received and how they have been able or indeed unable to use what they have been taught.

What are the possible benefits and risks of participating?
This is a low-risk study, no patient identifiable data is used and no patients are approached. All interviewees provide written informed consent and can withdraw at any time. No participant is identified in any reports or write-up.

Where is the study run from?
Warwick Medical School (UK)

When does the study take place?
November 2011 to February 2014

Who is funding the study?
European Commission

Who is the main contact?
Dr Paul O'Hare

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The impact of training non-physician clinicians in Malawi on perinatal / neonate mortality: a cluster randomised controlled evaluation of the Enhancing Training and Appropriate Technologies for Mothers and Babies in Africa (ETATMBA) project

Study objectives
Evaluate the impact on healthcare outcomes of an intervention whereby clinical officers/non-physician clinicians (NPCs) are trained as advance leaders in advanced obstetrics and paediatrics.

Explore changes in hospital outcomes including maternal and perinatal mortality comparing intervention districts with controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Warwick Biomedical Research Ethics Committee, ref 143/09/2011

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Fifteen districts (clusters) of the Central and Northern Regions of Malawi will be randomly assigned to either receive the intervention or to be a control district.

The intervention is the training of NPCs in specific skills. Module 1 will consist of in depth theoretical review and demonstration of prevention and management of the five major killers of mothers and the three most common causes of neonatal death e.g. resuscitation of the newborn, treatment of maternal and neonatal sepsis etc. with facilitated referral in delivery. Module 2 will deal with leadership and module 3 will be on the job training in surgical skills for the management of emergency obstetric complications. The control Districts/Hospitals will continue with their usual EmONC services.

Briefly, the training package is an 18-24 month programme of skills training and practice. The programme will involve three week long intensive training sessions (over a year) in advanced obstetrics and neonatal care, combined with in-service training of two six-month periods to apply enhanced teaching, training and audit. Assessment of knowledge, competence and performance will be examined at the start of the programme and satisfaction, assessment of knowledge, competence and performance will be examined at the end. Trainees will have to successfully complete and pass a number of tasks (e.g. audits, training others, reflective practice) and will be asked to complete a short feedback questionnaire at the end of each days training noting what they feel they have learned and how valuable the training was to them.

The training programme will comprise the major causes of maternal and neonatal mortality, how to teach, and research and leadership skills.

Practical and operative skills in the intervention districts will be supported by a specialist registrar in obstetrics working for a period of four weeks with NPCs to reinforce training, and rotating over the first year to all intervention hospitals. This on the job supervision and support will be supplemented by cell phone and electronic communication between trainees and specialist consultants.

Intervention Type

Other

Phase
Not Applicable

Primary outcome(s)
Perinatal mortality (defined as fresh stillbirths and neonatal deaths before discharge from the health care facility):

Data will be extracted from the maternity log (Malawi Ministry of Health Maternity Register, Ver. 2 (July 2008)) at the district hospital and rural hospitals in each district by the two research assistants monitored by the local and UK team. Other facilities within the district (e.g. health Centres) also complete the same maternity log book from which summary data is returned to the district hospital on a monthly basis. This data will also be gathered by the researchers and the combined data will make up a complete picture of the districts. Data will be collected at three points in time retrospectively (i.e. the year leading up to date). Baseline data will be collected on cases (from the maternity logs and summary logs) for the 12 months prior to the date the training was delivered with two follow-ups at 12 monthly intervals. A paper Case Report Form (CRF) will be produced to facilitate data collection. Data will then be transferred to an MS Excel spread sheet for transfer to the study database.

Key secondary outcome(s))
1. Maternal death rates (case specific)
2. Recorded data (e.g. still births, Post-Partum Haemorrhage, C Section, Eclampsia, Sepsis, Neonatal resuscitation)
3. Availability of resources (e.g. are drugs/blood available)
4. Use of available resources (e.g. are drugs being used)

Alongside this we plan to carry out a process evaluation of the implementation of the intervention to inform future implementation of interventions like these or to develop it further for the future. The process evaluation will include outcomes which will explore how or why the intervention was either effective or indeed not effective. Including:

1. Challenges faced
2. Acceptability
3. Sustainability

Process evaluations particularly help researchers understand the causal pathways by which complex interventions might work and sometimes to interpret equivocal results. The shift towards greater evidence-based-practice means there is a greater need to know why an intervention works and, if it does not, why not. Process evaluation can facilitate this understanding and should be incorporated into the evaluation of health promoting interventions /programmes.

Within the intervention districts at the three time points (baseline, 12 and 24 months) the research assistants will approach the consenting NPCs (primarily to interview them, described below) but also to gather information about project related activities (e.g. who they have trained, when they did this, how many training session done, etc.).

For process evaluation purposes training registers, adherence to training procedures (during the project period), knowledge scores and training feedback will also be collected and collated from

the intervention team. No identifiable data will be recorded (e.g. just numbers of attendances, pre and post scores).

Qualitative Data Collection:
In the intervention districts interviews will be carried out at each of the three time points with consenting NPCs (who have received the intervention training). These will be semi-structured interviews about their experiences relating to the project and its impact on practice. District medical and nursing officers in the intervention districts will be invited to be interviewed about the districts involvement in the intervention and at follow-ups how the intervention has worked /fitted in to the hospital routine. As part of the intervention the trained NPCs are expected to cascade the training they have received to others within their districts (e.g. other NPCs or midwives). The research assistants will identify a number of these people from the NPCs records and they will be approached and interviewed about the training they received and how they have been able or indeed unable to implement what they have been taught.

Completion date
28/02/2014

Eligibility

Key inclusion criteria
A non-physician clinician in Malawi who is receiving ETATMBA training

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/11/2011

Date of final enrolment
28/02/2014

Locations

Countries of recruitment
United Kingdom

England

Malawi

Study participating centre
Warwick Medical School
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (UK)

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme ref: 266290

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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	07/07/2016		Yes	No
Protocol article	protocol	25/10/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes