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# Evaluation of updated midwifery pre-service training in Kenya

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| **Submission date**<br>23/11/2020 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>09/12/2020 | **Overall study status**<br>Completed | |
| **Last Edited**<br>17/01/2025 | **Condition category**<br>Other | |

## Plain English summary of protocol

Background and study aims
Globally, midwives are the main providers of maternity care, providing 87 percent of essential care for women and newborns. Despite this, pre-service midwifery training is criticised for being largely theoretical. There is evidence that the pre-service education and training curriculum in low resource settings is deficient and graduates lack the requisite competencies needed to function adequately as skilled health personnel. The UK AID funded Maternal and Newborn Health programme has supported the regulatory Nursing Council of Kenya to review and integrate the competency-based emergency obstetrics and newborn care (EmONC) training in the diploma midwifery training syllabi so that it is in line with recent WHO definition and competencies for Skilled Health Personnel. This will be followed by training of the midwifery educators to deliver the new curriculum based on the updated syllabi. The objective of this study is to assess whether training, additional mentoring & provision of equipment improves the quality of teaching, knowledge and the confidence of the midwifery teachers in delivering the updated curriculum and student performance in the final Kenya national midwifery license examination.
Lessons learned from this implementation will inform relevant policy and training regulations change in the country for healthcare workers.

Who can participate?
20 colleges offering diploma midwifery training will be randomized to the intervention (12) and control (8) study sites. A total of 36 and 24 educators will participate in the intervention and control arms respectively.

What does the study involve?
The study will involve training, mentoring and replenishment of training equipment. Knowledge assessments will be conducted through online surveys at baseline and quarterly intervals using different sets of questions from a questions bank developed for this study for both intervention and control colleges. Teaching observations using a structured observation checklist will be monitored at baseline and every 3 months after the training for a period of 12 months. Mentoring of the educators in the intervention colleges will be conducted every 3 months after

the training for 12 months. Experiences of educators implementing the updated curricula will be collected through key informant interviews and focus group discussions at 6 and 12 months following training.

What are the possible benefits and risks of participating?
The information obtained from this study including the barriers and experiences in implementing the updated curricula will be beneficial in understanding what works for the midwifery educators in the country. This will provide a platform on which support to the midwifery training programs in the country will be anchored, for the improvement of the teaching experiences. Personal interaction with the experienced trainers, through the observation and feedback sessions, will potentially improve the educator's teaching skills during delivery of the updated skills-based trainings. There are no anticipated risks for participating in the study. Study questions have been developed in such a way that they will not embarrass or force the participant to divulge information which could result in anxiety or fear.

Where is the study run from?
Kenya Medical Training College Headquarters

When is the study starting and how long is expected to run for?
June 2020 to November 2023

Who is funding the study?
This work is not funded. It is within an existing Foreign, Commonwealth & Development Office (FCDO) funded 'Reducing Maternal and Perinatal Mortality in Kenya programme' of work led by Centre for Maternal and Newborn Health – Liverpool School of Tropical Medicine (CMNH-LSTM).

Who is the main contact?
Charles A. Ameh, charles.ameh@lstmed.ac.uk

# Contact information

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Scientific


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# Additional identifiers

**Clinical Trials Information System (CTIS)**
Nil known

**ClinicalTrials.gov (NCT)**
Nil known

**Protocol serial number**
Nil known

# Study information

**Scientific Title**
Protocol for evaluation of the implementation of the updated midwifery syllabi for pre-service training in Kenya: a randomized controlled study

**Acronym**
PRCT

**Study objectives**
Training, mentoring & provision of equipment (intervention) improves the quality of teaching, knowledge and the confidence of the midwifery lecturers to deliver an updated curriculum integrated with the competency-based emergency obstetrics and newborn care (EmONC)

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**
Approved 03/07/2020, Liverpool School of Tropical Medicine Research Ethics Committee (Pembroke Place, Liverpool, L3 5QA, UK; +44 (0)151 705 3100; lstmrec@lstmed.ac.uk), ref: 20-050

**Study design**
Multi-centre cluster randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Pre-service training for midwives

## Interventions
Randomisation
This will be a mixed methods study that involves a cluster randomized control study design and qualitative research methodology in 20 training institutions. Randomisation would be stratified by region (the eight former provinces will be used). Five pre-identified training hubs will receive the training equipment to support the trainings. Prior to commencing the trial the fifteen non-hub sites will be randomised, to study arm, with eight assigned to the control arm and seven to the intervention.
The proposed intervention is the training, provision of training equipment and regular mentoring on the quality of teaching and knowledge about the content of the new curricula 3-monthly (see below for details).

Training
All midwifery educators (about 250) from all the 84 diploma training colleges will receive a 3-day training on mixed teaching methodologies integrated with feedback for delivery of the updated competency-based curricula and key life-saving emergency obstetrics and newborn care (EmONC) skills.This will involve return demonstrations, group discussions, role plays/scenarios in addition to the commonly utilized lectures. Key EmONC skills to be upskilled will include and not limited to breech birth, shoulder dystocia, vacuum extraction, episiotomy repair, manual removal of placenta, management of maternal shock, maternal/newborn resuscitation, use of the situation, background, assessment and recommendation (SBAR) communication tool in clinical practice, respectful maternity care and the WHO checklist. At the end of the training, each training institution will develop an action plan with a specific monitoring of implementation plan of activities that will focus on integrated teaching methodologies to promote learning, assessment tools, feedback mechanisms to promote teaching and learning (student-tutor and tutor-tutor), skills laboratory and teaching environment and update its specific training curricula from the prescribed syllabi by the NCK. These trainings are scheduled to be completed within the first 6 months of the intervention.

Mentoring
The mentoring of midwifery educators will be conducted by select experienced EmONC master trainers and lecturers and will focus on upskilling their teaching skills and reflective practice to promote learning among students especially on performance of critical life-saving EmONC skills. This will involve teaching of actual EmONC skills (including performance of complicated births – breech, shoulder dystocia, vacuum extraction and maternal/newborn resuscitation among others), use of simulations/scenarios, videos/films in teaching skills and evaluation of the skills. This will be conducted every 3 months for a duration of 12 months.

Equipment
The EmONC training equipment (aid in performance of the EmONC signal functions and skills) to be replenished include: obstetric phantom with fetal doll, uterine pelvic model (bony pelvis), Little Anne, kiwi omnicups, airway management trainer, instrumental birthing simulator & fetal

head (Lucy & Mum), MVA syringe and cannula, retained knitted placenta models, resusci baby, episiotomy repair trainer, assorted forceps, ambubag and mask (adult and pediatric) and local consumables among others.

### Intervention Type
Behavioural

### Primary outcome(s)
Measured at baseline, 3, 6, 9 and 12 months:
1. Knowledge of midwifery educators delivering the updated curricula measured using an online survey
2. Confidence of midwifery educators delivering the updated curricula measured using an online survey

### Key secondary outcome(s))
1. Teaching style measured using direct observational checklists at baseline, 3 months and at 12 months
2. Experiences of midwifery educators implementing the updated curricula measured using qualitative key informant interviews and focused group discussions at 6 and 12 months
3. Final year midwifery students' performance measured at the end of the 3-year training using qualifying/licensure examination results

### Completion date
01/11/2023

## Eligibility

### Key inclusion criteria
Midwifery training educators and clinical instructors offering the diploma midwifery training program

### Participant type(s)
Health professional

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Total final enrolment
74

### Key exclusion criteria
Does not meet inclusion criteria

### Date of first enrolment

08/03/2021

**Date of final enrolment**
30/06/2022

# Locations

**Countries of recruitment**
Kenya

**Study participating centre**
**Kenya Medical Training College Headquarters**
Off Ngong Road
P.O. BOX 30195
Nairobi
Kenya
00100

# Sponsor information

**Organisation**
Liverpool School of Tropical Medicine

**ROR**
https://ror.org/03svjbs84

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study will be available upon request from (Dr Charles Ameh, Charles.Ameh@lstmed.ac.uk) for deidentified quantitative and qualitative data. Data will become available after analysis is complete and published late 2022.

In line with LSTM policy data will be available for 5 years type of data and will be shared for research purposes. All data is deidentified and participants will be consented for additional analysis using anonymised data.

Added 22/03/2021:
The study information sheet and consent will be sent to participants 2 weeks before the start of data collection. At the start of data collection any clarifications about the study required by the participants will be addressed by the research team. Participants will then be invited to provide a written consent (for those who did not manage to provide the online consent), and only those who agree to participate will proceed with the study. Those who do not want to participate in the study, will not be denied training.
De-identified personal information may be shared with other researchers on request for research purposes. The research data may be sent to the UK for analysis (by the LSTM UK research team). The study team may share the results of the survey and interviews. They may also share part of the results with the groups named below:
1. The National Bioethics Committee,
2. The Institutional Review and Ethics Committee,
3. Ministry of Health – Kenya, related government departments/organisations and representatives of Liverpool School of Tropical Medicine.
The results of this research may be published as blogs and in peer-review scientific journals but participants will not be identified in any report or publication. After the study has been published (approximately 12 months after data collection is completed), we will make our dataset available on request electronically. The study results will be retained in the research record for at least 6 years after the study is completed. Full anonymised research information entered into the record will be kept indefinitely.
The research team will handle participants' information in strict confidence and shall comply with any and all applicable laws regarding the confidentiality of such information. Data collected will be anonymised for this study and handled in accordance with Kenya Data Protection Act 2019 and UK Data Protection Act 2018.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 31/12/2024 | 17/01/2025 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | | | 09/12/2020 | No | No |