ISRCTN14203188 https://doi.org/10.1186/ISRCTN14203188

Evaluation of updated midwifery pre-service training in Kenya

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

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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

Primary study design
Interventional

Study design
Multi-centre cluster randomized controlled trial

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
Protocol file			09/12/2020	No	No