Evaluation of the Implementation of the Updated Midwifery Syllabi for Pre-Service Training in Kenya: A Randomized Control Study

Investigators

Duncan Shikuku	Liverpool School of Tropical Medicine (LSTM – Kenya)
Dr. Paul Nyongesa	Moi University (School of Medicine)
Prof. Michael Kiptoo	Kenya Medical Training College (KMTC)
Edna Tallam	Nursing Council of Kenya (NCK)
Dr. Bashir Isaak	Ministry of Health (Department of Family Health)
Dr. Helen Allott	Liverpool School of Tropical Medicine (LSTM – UK)
Fiona Dickinson	Liverpool School of Tropical Medicine (LSTM – UK)
Dr. Sarah White	Liverpool School of Tropical Medicine (LSTM – UK)
Terry Kana	Liverpool School of Tropical Medicine (LSTM – UK)
Lucy Nyaga	Liverpool School of Tropical Medicine (LSTM – Kenya)
Dr. Charles Ameh	Liverpool School of Tropical Medicine (LSTM – UK)

ABSTRACT

Background

Kenya is not on track to meeting maternal and newborn SDG targets. Midwives trained to ICM standards can provide 87% of the needed essential care for women and newborns averting 83% of all maternal deaths, stillbirths and neonatal deaths. Pre-service education and training curriculum in low resource settings is deficient and graduates have limited requisite competencies needed to function adequately as skilled health personnel. The period set aside for internship for graduate midwives is not adequate to develop the competencies required for independent practice. Diploma graduates do not have internship period compounding this deficiency.

Aim

To assess whether training, additional mentoring & provision of equipment improves the quality of teaching, knowledge and the confidence of the midwifery lecturers in delivering an updated diploma level curriculum that is integrated with the competency-based emergency obstetrics and newborn care as well as student performance in the final national midwifery license examination in Kenya.

Methods

This will be a mixed methods study with a cluster randomized control design, in 20 midwifery colleges: 12 intervention and 8 control colleges. A sample of 60 lecturers will be selected through consecutive sampling. All midwifery lecturers totalling 250 in all 84 colleges will receive basic training on delivery of the updated curriculum. Full intervention colleges (5) will receive training, 3-monthly mentoring and obstetric/newborn care skills equipment; partial intervention colleges (7) will receive training and

3-monthly mentoring while control colleges (8) will only receive training. An independent team of experienced lecturers and EmONC master trainers trained as mentors from the KMTC headquarters and the Nursing Council of Kenya will conduct the follow up and mentoring visits, while the LSTM research team will collect data.
Knowledge and teaching competency will be assessed for lecturers at baseline and 3-monthly for 12 months using online surveys. Directed observation of teaching skills will be conducted using a standardized observation checklist at baseline and 12 months. Experiences by lecturers in implementing the updated midwifery curriculum will be collected using key informant interviews and group discussions at 6 and 12 months. Change in students' performance (mean score) before (previous class) and post implementation (current class trained with the updated curriculum) of the updated midwifery syllabi in midwifery in the final qualifying/licensure examinations will be assessed.
Standard qualitative data analysis and mixed-effects linear model analysis will be performed.

Expected outcomes

We anticipate an overall improvement in quality of teaching, knowledge and the confidence of the midwifery lecturers in delivering an updated diploma level curriculum that is integrated with the competency-based emergency obstetrics and newborn care in the intervention colleges compared to the control colleges**.** Lessons learned from this implementation will inform relevant policy and training regulations change in the country for healthcare workers.

Background

Recent estimates show that approximately 295,000 maternal deaths, 2.5 million neonatal deaths and 2.6 million stillbirths occur annually worldwide and most of these deaths occur in resource limited settings (1-3). Reducing the substantial burden of preventable maternal and newborn morbidity and mortality is a key priority enshrined in the Sustainable Development Goals (SDGs) (4) and supported by initiatives and strategies such as the Global Strategy for Women's, Children's, and Adolescents' Health (5), Every Newborn Action Plan (6) and Ending Preventable Maternal Mortality (7). The medical and surgical interventions to prevent this loss of life are known, and most maternal and newborn deaths are in principle preventable (6). Improving access to family planning, Emergency Obstetric and Newborn Care (EmONC) and skilled attendance at birth, are key strategies for improving maternal and newborn health.
The World Health Organization (WHO), International Confederation of Midwives (ICM) and International Council of Nurses (ICN), among other international bodies, define skilled health personnel (SHP) as competent maternal and newborn health (MNH) professionals educated, trained and regulated to national and international standards (8). They are competent to provide and promote evidence-based, human-rights-based, quality, socio-culturally sensitive and dignified care to women and newborns. Skilled health personnel also facilitate physiological processes during labour and birth, to ensure respectful care and promote a quality positive childbirth experience; and identify and

manage or refer women and/or newborns with complications. In addition, as part of an integrated team of MNH professionals they perform all the signal functions of emergency maternal and newborn care, to optimize the health and well-being of women and newborns. Within an enabling environment, midwives trained to (ICM) standards can provide 87% of the needed essential care for women and newborns (9). In addition, they are the most cost-effective suppliers of midwifery services, that could avert a total of 83% of all maternal deaths, stillbirths and neonatal deaths (9).

Although skilled health personnel attendance in Kenya has increased from 42 in 2003 to 62 percent in 2014 (10), in 2017, Kenya's maternal mortality ratio was estimated at 342 per 100,000 live births (11). This is five times higher than the expected global sustainable development goal (SDG) target of less than 70 per 100,000 live births (12). Recent findings in the first Kenya Confidential Enquiry into Maternal Deaths (CEMD) report indicated that 9 out of 10 maternal deaths resulted from substandard quality of care, where delay in starting treatment, inadequate clinical skills and inadequate monitoring were the most frequently identified health work force related factors (13). Even though the proportion of births attended by skilled health workers has increased over the last 15 years, studies have shown that health workers lack the knowledge and skills to provide good quality care (14, 15).

Skills-and-drills competency-based training in emergency obstetric and newborn care (EmONC) is an approach that is successful in improving knowledge and skills, clinical practice and maternal and neonatal health outcomes (16, 17). However, insufficient pre-service and in-service training are key barriers to the provision of quality EmONC services (18-20). There is evidence that the pre-service education and training curriculum in low resource settings is deficient and graduates have limited requisite competencies needed to function adequately as skilled birth attendants (21). The period set aside for internship for graduate midwives is not adequate to develop the competencies required for independent practice. Besides, diploma graduates do not have internship period compounding this deficiency. Murila et al. (2012) study in Kenya showed that the average duration of neonatal resuscitation training was 3 hours with 50 percent of the healthcare providers (HCPs) having missed out on practical exposure (18). A multi-country (including Kenya) longitudinal cohort study to determine retention of knowledge and skills after standardised "skills and drills" training in EmONC showed significant variation in pre-training scores for various cadres between countries (22). With nurse/midwives accounting for 75 percent of the cadres included in that study, this suggests that the training syllabi and curriculum is not standardized for the main frontline skilled health personnel (SHP) providing maternity care services. Typical pre-service nurse/midwife training is largely didactic, despite them being the main providers of maternity care (16, 18). The passive classroom didactic instruction often results in improved knowledge but not improvement in clinical practice as compared

to the use of interactive techniques such as clinical simulation, case–based learning, hands-on practice with anatomic models, and immediate feedback on performance (23).

Liverpool School of Tropical Medicine (LSTM) through the Kenya's Ministry of Health (MOH) has previously supported 18 midwifery and two medical schools by building the capacity of teaching faculty to improve the quality of 'skills and drills' training in EmONC including training and follow-up of midwifery teachers in EmONC, for improved classroom and skills lab teaching techniques, and for clinical preceptorship. In addition, the program worked on strengthening of skills laboratories with EmONC training equipment and supportive supervision of teaching faculty/clinical instructors. Lessons learned from the previous implementation need to be institutionalized and fully embedded in MoH policies and plans, in order to sustain the gains achieved.

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 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.

Justification

Following the World Health Organization new definition of Skilled Health Personnel in 2018 (8), a revision of the midwifery training syllabi in Kenya was essential to ensure competency in the provision of quality EmONC. Findings from a quasi-experimental study in 12 Kenya Medical Training Colleges (KMTCs) showed that an enhanced midwifery curriculum with EmONC training, results in improved knowledge and skills of midwifery students in Kenya, and thus highlights the need to scale up (24). Short and repetitive 'skills and drills' training over time through mentorship and low-dose high frequency training modalities help to build layers of knowledge and skills in life-saving emergency obstetrics and newborn care (22, 25-27). A detailed review of the syllabi to update its content and curriculum was undertaken by key stakeholders including the Nursing Council of Kenya and the Kenya Medical Training Colleges aimed at shifting from the largely theoretical training to a competency-based skills training, that includes EmONC. This will essentially lead to the training of competent healthcare workers in emergency obstetrics and newborn care, nationally to international standards. This approach will provide a strong foundation and reduce the need for longer duration trainings after

graduation. Short intensive skills drills will need to be a cornerstone of in-service continuous professional development trainings.

Study Objectives

The specific aims of the study are to: -

1. Compare the change in knowledge of pre-service educators after training and every 3 months for 12 months on delivery of the updated syllabi through online surveys between those who receive training only and those who receive additional mentoring and equipment.
2. Evaluate the teaching styles of pre-service educators before training and at 12 months after training on delivery of the updated syllabi through direct observation checks.
3. Describe the experiences of pre-service educators implementing the updated midwifery pre-service syllabi using a qualitative research approach including key informant interviews, case studies and semi quantitative online surveys
4. Compare students' mean grades in final midwifery qualifying/licensure examinations pre and post implementation of the updated pre-service midwifery syllabi between the standard and intervention colleges.

Methods

Intervention

The basic nurse/midwives training programs (diploma level) in Kenya are (1) Kenya Registered Community Health Nursing (KRCHN) (2) Kenya Registered Nursing and Midwifery (KRNM) (3) Kenya Registered Midwifery (KRM) (basic and post-basic). Each of the basic training programs consists of a standardised syllabus and curriculum delivered over three years in 84 schools spread across Kenya. At the end of the programme student nurse/midwives are expected to demonstrate competencies based on the International Confederation of Midwives guidelines, to enable them to work independently (Adegoke et al., 2013). The LSTM's MNH program has supported the review of the KRNM and KRM pre-service training programs for midwives to integrate the competency-based EmONC training. Besides EmONC, the updated syllabi has been updated with relevant content on antenatal, intrapartum, postpartum and newborn care and other critical cross-cutting issues of maternal and newborn health importance (see figure 1).

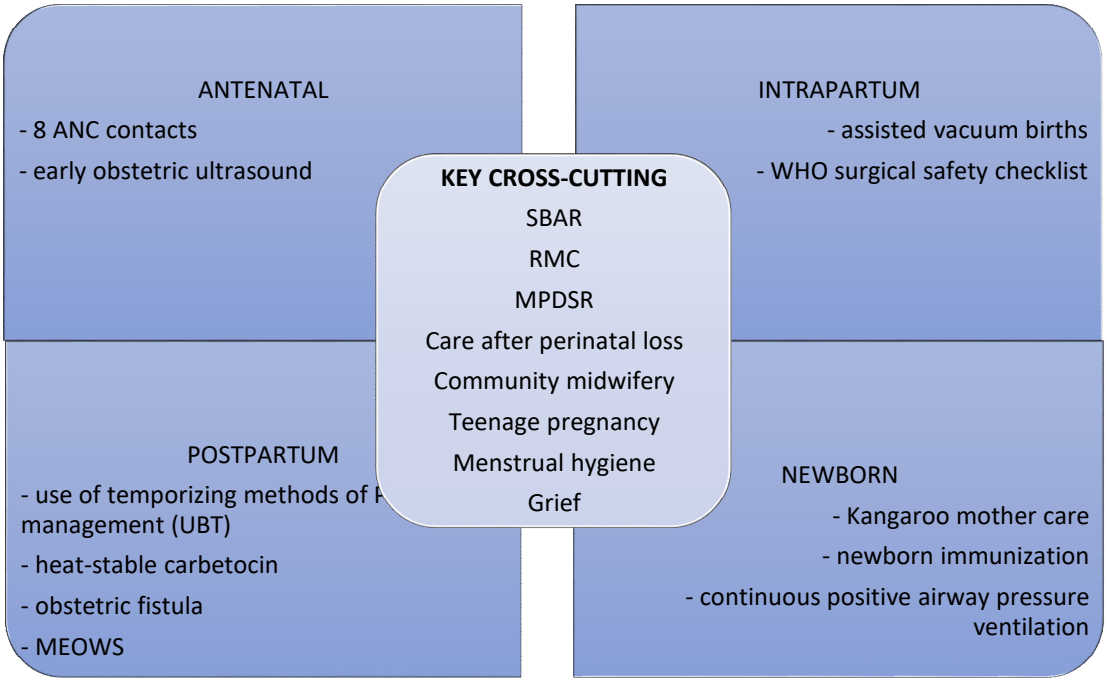

Figure 1: The updated pre-service midwifery training syllabi

All nurse/midwives (KRCHN, KRNM and KRM) are competent to provide and promote evidence-based, human-rights-based, quality, socio-culturally sensitive and dignified care to women and newborns; facilitate physiological processes during labour and delivery to promote a clean and positive childbirth experience; and identify and manage or refer women and/or newborns with complications. As part of an integrated team of MNH professionals, midwives are expected to perform all signal functions of emergency maternal and newborn care to optimize the health and well-being of women and newborns (8). Tutors therefore need to facilitate the learning process for students to apply theory into practice and perform key clinical emergency obstetrics and newborn care skills.

During the intervention, the five training hubs (centres of excellence) identified will be equipped/replenished with the EmONC training equipment. National level midwifery educators will be trained as master trainers (MTs) on the following:

1. Updated training syllabi for midwives, principles of adult learning and teaching
2. Teaching methodologies in clinical settings
3. Staged approach to EmONC skills teaching
4. Principles of assessment in clinical skills
5. Principles of effective feedback
6. Essential elements of an updated institution specific curriculum based on the updated syllabi

The MTs will then cascade the training of midwifery teachers in KMTCs across the country on the delivery of the updated syllabi. These trainings will be conducted in the designated five centres of excellence/hubs (Table 1). A total of 30 lecturers will be trained per phase, in each of the hubs. Tutors will be trained on mixed teaching methodologies integrated with feedback for delivery of the updated competency-based content and key life-saving 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. One student cohort will be trained during the same academic session, in each school across the country, at any one time. 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.

Table 1: Summary of interventions

1. Review of the pre-service midwifery training syllabi and curricula
2. Map out the training hubs/centres of excellence
3. Equip/replenish the hubs' skills laboratories with EmONC training equipment
4. Map out the national level midwifery educators as master trainers (MTs)
5. Train the MTs on the updated syllabi and master training (4.5 days training)
6. Train midwifery teachers in the training colleges across the country on the updated curriculum (3-days training)
7. Mentoring of tutors on teaching methodologies and EmONC skills

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.

The mentoring of tutors 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 role plays/scenarios, videos/films in teaching skills and evaluation of the skills.

Design

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). 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 syllabi 3-monthly. All lecturers (about 250) in all 84 midwifery training institutions will receive basic training on delivery of the updated competency-based syllabi. This robust design in general is thought to yield the highest-quality evidence regarding the effects of specific interventions. This is a prospective study that aims to measure the effectiveness of a new intervention. Although no study is likely on its own to prove causality, randomization reduces bias and provides a rigorous tool to examine cause-effect relationships between an intervention and outcome (28). Additional support (provision of training equipment by LSTM and 3-monthly mentoring) will be given to intervention institutions. Both quantitative (online surveys and observation) and qualitative methods (structured interviews) of data collection will be used (Fig. 2)

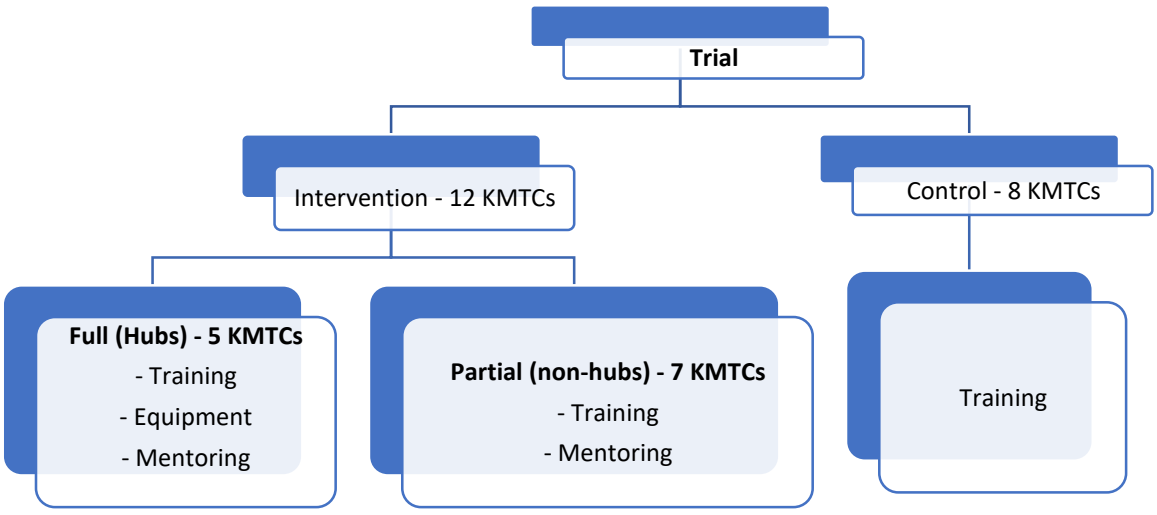

Figure 2 : Summary of study sites and interventions

Change in knowledge and teaching skills over the different periods will be assessed and the difference between and within study arms determined. Pre- and post-training knowledge and teaching methods assessments will be conducted for both intervention and control arms. Knowledge assessments will be conducted through online assessments at quarterly intervals using different sets of questions from

a questions bank developed for this study. Structured direct (non-participant) observation of teaching methodologies will be conducted in the intervention institutions at baseline (before training), 3 months, 9 months and 12 months. Similar observations will be conducted in the control sites at baseline and endline (12 months). Experiences of lecturers in implementing the updated curriculum will be explored. Key elements of good quality teaching and learning that will be observed are: (1) teaching style, (2) use of visual aids, (3) teaching environment and (4) student involvement through a structured, direct observation approach, using a standardised observation form (29). This method is non – intrusive, where participants do what they normally do without being interrupted or disturbed by the observer, and allows the observer see what people do rather than relying on what people say they did (30, 31). This will allow the tutors to be observed in their natural fashion without interfering in their process of teaching the students. Importantly, tutors will first provide a critique of their teaching then feedback will be provided by the observer on the strengths and areas to improve on for the respective tutors observed (32). Support through peer review and reflection will form part of the normal practice for the tutors to strengthen their skills teaching skills.

A qualitative approach will be employed to capture a rich description of the quality of teaching and learning within the training hubs from both educators (33). Key informant interviews and small focussed group discussions (online/face-to-face) will be conducted with the training institutions' management and midwifery tutors respectively to explore experiences and changes in the teaching skills and students' performance in final qualifying and licensure examinations. Case studies with tutors and clinical supervisors on their experiences in implementing the updated midwifery curriculum will be developed by the LSTM research team. Experiences of tutors will be captured and final nursing/midwifery students' performance in final qualifying and mean grades in the midwifery licensure examinations will be analysed and compared for both study arms.

An independent team of experienced lecturers and EmONC master trainers trained as mentors from the KMTC headquarters and the Nursing Council of Kenya will conduct the follow up and mentoring visits. The mentors will visit the intervention colleges every three months and review the teachers' plans, hold one-on-one conversations with the mentee teachers, observe teaching sessions through non-participant observation approach and thereafter provide constructive feedback to promote effective teaching practices with the aim of improving the new teaching practice. During the non-participant observation of teaching, the LSTM research team will collect data. Standardized structured data collection forms will be used and no participant identifying information will be collected (Table 2).

Table 2: Summary of period of assessment and intervention

Parameter/period	Baseline	3 months	6 months	9 months	12 months
Knowledge survey	IC	IC	IC	IC	IC
Teaching observations	IC	I		I	IC
Mentoring		I	I	I	I
Group discussions/interviews			IC		IC

I – intervention sites; C – control sites

Setting

The training of tutors and clinical instructors on the updated pre-service midwifery syllabi will be conducted in the LSTM established five training hubs in the country. The hubs are midwifery training institutions accredited by the Nursing Council of Kenya and are Nairobi KMTC, Kilifi KMTC, Vihiga KMTC, Eldoret KMCT and Pumwani School of Midwifery. To date, the Nursing Council of Kenya has approved 121 nursing/midwifery training institutions to train students at degree, basic and post basic diploma level for various branches of nursing practice (34). A mix of 250 midwifery tutors and clinical instructors from the 84 nursing/midwifery colleges and training hospitals (48 public, 12 private and 24 faith-based institutions) training at diploma level across the country will be trained.

Sample size determination

The design involves randomisation of lecturers in clusters. When randomisation is in clusters the likely correlations between responses of participants in clusters needs to be accounted for in the analysis and hence in consideration of the power of the study. To improve the power of the study baseline measurements will also be used, thereby enabling the changes within participants to be measured. Intra-cluster correlations (ICCs) measure the correlations. For this design there are three which need to be considered: (1) Within period ICC: the correlation between responses of different lecturers within the same college in a given assessment occasion; (2) Cluster autocorrelation (CAC): the correlation between means for a given college on different assessment occasions; (3) Individual autocorrelation (IAC): the correlation between scores for a given lecturer on different assessment occasions.

For sample size calculations the Shiny app (https://clusterrcts.shinyapps.io/rshinyapp/) developed by Karla Hemming for cluster randomised trials has been used (35). Relevant data on which to base selection of the values for use in sample size / power calculations are not available. It has been assumed that ICC will be between 0.1 and 0.2, and that CAC and ICA will be between 0.5 and 0.8. Further it assumed that the score is measured on a continuous scale and the standard deviation is 20%

(thus at baseline if the mean score is 50% then two thirds of responses would be between 30% and 70% and almost all would be between 10% and 90%). The mean (sd) number of lecturers who participate at each college is assumed to be 3 (0.6); this would occur if 18% of facilities have 2 lecturers, 18% have 4 and the rest (64%) have 3 lecturers. It is therefore estimated that 36 and 24 lecturers will participate in the intervention and control arms respectively. Consecutive sampling will be used for selecting the available lecturers until the sample size is achieved. It is assumed that the improvement with training is from 50% to 60% and that with the additional support it would be 78% (26, 36, 37). With CAC and IAC both as high as 0.8 and the within period ICC of 0.2 there would be 90% power to detect a difference of 18% in a total of 20 randomized colleges to participate in the study.

Two levels of randomisation will be required: to study arm and to the sequence in which the assessment tools are used for each participant. 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.

Study Participants

The project will train 50 medical and nursing/midwifery educators and clinical supervisors/instructors as master trainers to deliver the updated nursing & midwifery syllabi focusing on teaching skills and EmONC in a 4.5-day training course. The developed team of master trainers will then train about 250 midwifery and clinical officer tutors/lecturers and clinical instructors selected from across all the midwifery training institutions in the country, on the new syllabi in the five training hubs, through a 3-day training. It is important to note that the Kenya Medical Training College Headquarters and the project team will map out the midwifery educators in the training colleges for selection for training. During training, student midwives go for clinical rotations in the maternity and newborn health clinics and wards under the guidance of the clinical instructors in the clinics/wards. This enables students to practice and apply what was learnt in the classroom environment thereby transforming the theory learnt into clinical practice.

Data collection methods

Recruitment

After randomisation, midwifery institutions will be selected and institutional consent obtained by the Kenya based research team. All tutors from participating training institutions in the training database maintained by LSTM will be informed about the study by the research team and participation will be voluntary where one can take part in the study or withdraw at any time. Tutors whose sessions will be selected will be informed again of the study, a day before data collection.

Knowledge among midwifery tutors

Knowledge will be assessed for all participants at baseline and every 3 months to 12 months from a questions bank developed for this study through an anonymous online survey using Survey Monkey. Five distinct assessment tools (denoted by A, B, C, D and E) are to be used. A randomisation will be prepared for 60 participants; each participant is to be assessed on five occasions, once per tool. In each assessment round each possible tool will be used to assess 12 participants. Prior to training, at baseline each participant will be asked to draw a unique participant ID number at random from a bag. Each number will have been randomly assigned to a sequence in which the five tools are used on the five assessment occasions. Those conducting the trial will not need to know the ID number of each participant. But the participants will need to keep their number safe for use on subsequent assessment occasions. Each time participants are assessed their unique ID number will determine which assessment tool they use.

A questionnaire with multiple choice and case scenario questions on EmONC knowledge and teaching methodologies will be utilized to assess change in knowledge and confidence in using different teaching methodologies among tutors over time. Using online platforms (email and/or WhatsApp application), questions will be deployed by the research lead and will be required to be completed by the tutors within a specified period of time. This is considered a faster mode of communication, reaching a wider audience within a short period of time. Kenya has a high level of smartphones penetration rate, which stands at 41 million (in 2018), with reach at 90.4 per cent of the adult population and the leading globally in share of internet traffic (38).

Teaching skills among midwifery tutors

A pre-designed structured direct observation form for teaching methodologies will be utilized to assess the tutors' skills in providing the teaching on the competency-based EmONC skills. The form is adapted from the previous standardized 'Centre for Maternal and Newborn Health Standardised review form used for observation of lessons' checklist and the 'Teacher Skills Checklist' tools used in other settings (39, 40). There is an underlying assumption when using structured observation techniques that the researchers understand the phenomena to be studied (29). In this study, all structured observations will be conducted by the LSTM research team comprising of experienced EmONC master trainers and nursing/midwifery educators. Since the phenomena to be studied happen over a long time period and it is not possible for the researcher to observe for the whole period, event sampling will be useful to select the 1-2 hour teaching sessions to be observed and keep disruption of the normal school timetable to a minimum in the training institutions (29). The sessions to be observed

will be predetermined by the observers and will be sessions involving an emergency obstetric and newborn care skill/procedure/content (41). Data collectors will be trained in the use of the data collection tool at a pre-observation planning meeting to ensure there is clarity and agreement on how to complete the tool. Data collectors will work in pairs to independently observe each session (one observer for smaller sessions not to impact the class dynamics) using a standardised observation form.

At the end of the observation the researchers will compare and discuss their observations for similarities, differences, and to help maintain consistency. The form used for the observation will then be used to provide the informal feedback to tutors. This feedback will not form any part of the research process. The feedback will be provided to the tutors as a way of completing the event, and as a matter of principle, ensuring sharing of findings with those for whom this is relevant. Participation in the study will not be part of institutional appraisal or promotion process and those eligible for the study who do not consent for the study will not be denied training. Participation will in no way affect the participant's employment and the assessments will not be released to the managers and/or employers. The Nursing Council of Kenya will only observe the teaching and can provide feedback as part of the mentoring exercise.

Experiences of midwifery teachers

A pre-designed, structured training institution evaluation form will collect the training institutions management, tutors and clinical supervisors' experiences in implementing the updated midwifery pre-service curriculum. This will include possible barriers and challenges encountered in the teaching of students quarterly post-training. These will also be conducted by the observer EmONC master trainers and educators (and may also be sent via the online survey for those tutors not observed for teaching skills). Interviews will be recorded and where possible detailed notes will be taken through a less formal interview setting, and to encourage a frank and open interaction minimizing distractions to both the interviewee and interviewer (42). This will be conducted in English as this is the official teaching language for training. Notes taken will be transcribed and expanded immediately following the interview. The audio recordings will be deleted post-transcription.

Students' performance in final licensure exams

Data on final year midwifery students' performance will be requested from the licensing/regulatory body, the Nursing Council of Kenya Examination's Department after students completing the training with the updated curricula. This will be compared with the previous class that trained using the old curricula. Overall college performance of students in the Midwifery paper will be extracted for analysis.

Data management

To mitigate against the 'practice effect' defined as an influence on performance from previous experience – in this case as using similar questions over the course of assessments thereby becoming more familiar and easier (43), different sets of 10 questions selected randomly from a bank of developed questions will be administered to all participants. A single set of questions will be administered at each assessment time. The bank of knowledge multiple choice questions will be developed by the course experts. The questions will be validated by the course experts, standardized and piloted among postgraduate midwife students and experts to ensure content validity, defined as the degree to which tests or questions cover the content of the work to be assessed and measure exactly what one thinks he/she is measuring (44).

Item analysis will be integral in this study and will be conducted for all test items for assessment to provide indicators which test the quality of assessment (i.e. item difficulty, item discrimination & distracter analysis) (45, 46). Questions with item difficulty index (a measure of the proportion of the total examinees who answered an item correctly) of between 50 – 60% as recommended – even though ranges from 30 – 70% are considered good/acceptable (45, 47-49) and questions with a high discrimination index (the ability of a test item to distinguish between candidates of higher and lower abilities) of 0.40 and greater will be retained in the question bank (49, 50).

Data entry and analysis

Data from the online surveys will be extracted and entered in MS Excel 2016 and exported to STATA version 14.2 for statistical analysis. Descriptive statistics will be computed for change in knowledge and skills over time among tutors. Relationships between the tutors' characteristics and the overall mean scores will be computed using the mixed effects model with fixed effects for tutor characteristics and random effects for cluster. To estimate the impact of the intervention knowledge and skills data collected pre-training (baseline) and at 12 months will be used in a mixed effects linear model, with intervention as a fixed effect, baseline as a covariate and random effects for cluster and participant.

Change in students' performance (mean score) before (previous class) and post implementation (current class trained with the updated curriculum) of the updated midwifery syllabi in midwifery in the final qualifying/licensure examinations will be conducted through a mixed effects logistic regression model using individual outcomes (pass or fail) with random effects for institution and a factor for study arm. P – values ≤0.05 will be considered statistically significant.

Qualitative data collected from interviews will be analyzed through thematic coding. Triangulation between quantitative and qualitative data collected will be done to explain the findings. Qualitative data complements the quantitative data which does not provide a deep understanding of a

phenomena under study. Through the qualitative data, we shall be able to understand the salient peculiarities of the study sites and the contexts.

Study limitations

The Hawthorn's effect is a major drawback in direct observation studies, however, this helps to observe the 'where' and 'when' of the ongoing process/situation/behaviour rather than relying on what people say they did. Any impact of the Hawthorn effect will be minimized by assuring the tutors that the purpose of the study is to improve the process, not pass judgment on tutor performance. Besides, tutors will be encouraged to use peer review so they become used to being observed and a self reflection tool intended to support *them* in celebrating their growth and continuing to strengthen their skills teaching practice. Tutors would be observed over a long period of time, which will normally allow human beings to settle into normal work patterns. In addition, the project team would have developed a rapport with tutors during training and mentoring being observed, so they feel comfortable working at a normal pace (51). The response rate for online surveys is anticipated to drop over time, among the participating tutors. Use of the scheduled reminders at intervals to participants will help to ensure that as many participants as possible complete the surveys.

Study timeframe

Parameter/period	**May-Sept 2020**	**Baseline**	**TRAINING**	**3 months**	**6 months**	**9 months**	**12 months**	**15 months**
Ethics application fees (LSTM UK)	X							
Ethics application fees (Kenya)	X							
Pretesting study tools	X							
Knowledge survey		IC		IC	IC	IC	IC	
Teaching observations		IC		I		I	IC	
Mentoring				I	I	I	I	
Virtual or face-to-face focused group discussions/interviews					IC		IC	
Data analysis & report writing								X
Report dissemination								X

Ethical considerations

Ethics approval

Ethics approval will be sort from Moi University/Moi Teaching and Referral Hospital Institutional Research and Ethics Committee (IREC) and Liverpool School of Tropical Medicine's Research and Ethics Committee.

Informed consent

All study participants will be informed about the study by the research team and participation will be voluntary with an explicit option of withdraw at any time with no consequences. A detailed study information booklet will be provided to the participants, containing all information about the study and contact details of the PI and sponsoring institution (Chair LSTM REC). The study information sheet will be sent to participants one week before the training, at the start of the training 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, 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.

Confidentiality

Data collection forms will bear anonymous serial codes to protect the identity of the participants. Tutors whose sessions will be selected for observation will be informed again of the study, a day before data collection. The study carries minimal risk to the participants as their identity will not be revealed at any time and the findings from the study would not form part of their job appraisal or performance management. There will be strict observation of confidentiality at all levels of the implementation.

Risks and benefits

The study has direct benefits to the tutors as it will improve their competency-based teaching skills and their information/experiences will be valuable in improving the teaching methodology required for the delivery of the revised competency-based training syllabi. Personal interaction with the experienced trainers, through the observation and feedback sessions, will potentially improve tutors' teaching skills during delivery of the updated skills-based trainings.

Study questions have been developed in such a way that they do not embarrass or force the participant to divulge information which could result in anxiety or fear. However, should taking part in the study cause significant distress to the participant, this should be reported to the research coordinator who will arrange for appropriate counselling/reassurance by telephone or video conference call from LSTM's specialist.

Potential conflicts of interest

One team will deliver the training on the new curriculum (Master trainers) and another team will collect data (LSTM research team). The researchers will train Master trainers, who will be responsible for training of trainers. The trained trainers at five hubs will train 250 midwifery educators located in the 84 midwifery diploma colleges in Kenya. Master trainers will be from the HQ of Kenya Medical training College and Nursing Council Kenya, they will not be directly involved with data collection. The Master trainers will provide mentoring for study participants in the intervention arm of the study. The

LSTM research team will be responsible for providing study information to participants, consenting participants and data collection (during training, and at 3 monthly intervals up to 12 months after the training).

Absence of tutors from school during the short 3-days training period will have minimal or no disruptions to the school calendar (classroom and clinical activities). To prevent disruptions of classes due to participation of midwifery lecturers, the training for the tutors/lecturers will be conducted in a structured back-to-back approach that will ensure that a proportion of the midwifery tutors will be participating in the training at a given period from the same training institution until all the tutors from the institution are trained. The training intervention will be coordinated centrally by the Kenya Medical Training College headquarters with the principals of all the training institutions. Therefore, principals will ensure that there is very minimal disruption to the normal college timetable by planning their sessions with the relevant departments which may involve frontloading some non-clinical lessons to cover the affected lecturers who will participate in the trainings.

Faculty members identified to be weak or nervous in their teaching skills will be supported through mentorship from the experienced faculty during the supportive visits.

COVID-19

The LSTM UK Study Risk Assessment Form has been completed (see separate form) on containment measures for COVID-19 including handwashing, supplemental use of hand sanitizers and personal protective equipment – face masks. In addition, social distancing measures maintaining a 1.5m distance between participants will be maintained during training (with a spacious training room/lecture hall to accommodate not more than 30 participants at a time).

STUDY IMPLICATIONS

Implementation of a competency-based midwifery curriculum incorporating emergency obstetrics and newborn care (EmONC) at the pre-service level aims to shift from the largely theoretical training and integrate the skills-based training into the curriculum. This is expected to ensure that the health personnel graduating from training institutions are competent in emergency obstetrics and newborn care that is compliant with international standards. This approach will provide a strong foundation and reduce the need for longer duration trainings after graduation and strengthen the evidence based approach of regular short intensive skills/drills as a cornerstone of continuous professional development training. Lessons learned from this study will inform relevant policy and training regulation changes in the country for healthcare workers.

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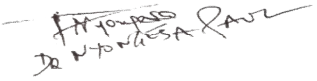
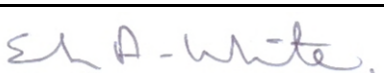
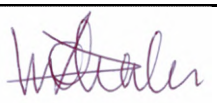
Estimated Budget

Period	Intervention/Activity	No. Training colleges	Total cost (£)
May-20	Ethics application fees (LSTM UK)		750
Jul-20	Ethics application fees (Kenya)		340
	Stationery		80
Baseline	Teaching observations	20	9159
3 months	Teaching observations & Mentoring	12	6748
6 months	Mentoring	12	5097
9 months	Teaching observations & Mentoring	12	6748
12 months	Teaching observations	20	9159
TOTAL			**38081**

Signatures of Investigators/collaborators

	Name	Institution	Signature
1	Duncan Shikuku	Liverpool School of Tropical Medicine (LSTM)	
2	Dr. Paul Nyongesa	Moi University (School of Medicine)	
3	Prof. Michael Kiptoo	Kenya Medical Training College (KMTC)	
4	Edna Tallam	Nursing Council of Kenya (NCK)	
5	Dr. Bashir Isaak	Ministry of Health (Department of Family Health)	
6	Dr. Helen Allott	Liverpool School of Tropical Medicine (LSTM)	H Allott
7	Fiona Dickinson	Liverpool School of Tropical Medicine (LSTM)	
8	Dr. Sarah White	Liverpool School of Tropical Medicine (LSTM)	
9	Terry Kana	Liverpool School of Tropical Medicine (LSTM)	
10	Lucy Nyaga	Liverpool School of Tropical Medicine (LSTM)	
11	Dr. Charles Ameh	Liverpool School of Tropical Medicine (LSTM)	

APPENDICES

Roles of investigators/collaborators in the study

Name	Institution	Role in Study
Duncan Shikuku	LSTM	Principal Investigator (Study design, training of Master Trainers, data collection and analysis)
Dr. Paul Nyongesa	MOI UNIVERSITY	Co - Principal Investigator (Training and mentoring)
Prof. Michael Kiptoo	KMTC	Collaborator (Administrative and dissemination)
Edna Tallam	NCK	Collaborator (Administrative and dissemination)
Dr. Bashir Isaak	MOH	Collaborator (Dissemination)
Dr. Helen Allott	LSTM	Co-Investigator (Training of Master trainers, data analysis)
Fiona Dickinson	LSTM	Co-Investigator (Monitoring & Evaluation)
Dr. Sarah White	LSTM	Co-Investigator/Senior Biostatistician (Study design and analysis)
Terry Kana	LSTM	Co-Investigator (Training of Master Trainers)
Lucy Nyaga	LSTM	Research Administrator
Dr. Charles Ameh	LSTM	Co - Principal Investigator (Study design, training of master trainers, data collection and analysis)

Knowledge Assessment Questionnaire

PARTICIPANT'S CODE…….

NAME OF TRAINING INSTITUTION……

Ownership of training institution (*select the applicable option):* (A) Public (B) Private (C) Faith-based

Midwifery training program offered: (A) KRCHN___ (B) KRNM___ (C) KRM-basic___ (D) KRM-post-basic___ *(tick all the applicable programs)*

Demographics (*select the appropriate option*)

1. Your cadre:

   (A) Nurse/Midwife (B) Clinical Officer (C) Medical Doctor

2. Your qualifications:

   (A) Diploma (B) Degree (C) Masters (D) PhD

3. When did you last teach a class?

   (A) less than 1 month ago (B) between 1 and less than 3 months ago (C) between 3 and 6 months ago (D) over 6 months ago

4. Last class level taught:

   (A) 1st year (B) 2nd year (C) 3rd year (D) 4th year

5. Have you undergone a 'hands on' EmONC training session where you practiced on obstetric mannequins before?
   A. Yes
   B. No

6. If yes in '1' above, how long ago was the training?
   A. Less than 3 months
   B. Between 4 and 6 months
   C. Between 7 and 9 months
   D. Between 10 to 12 months
   E. More than 12 months

SECTION A: MULTIPLE CHOICE QUESTIONS

Instructions: Select the correct response for each of the questions below.

1. **In the 4-staged method of skills teaching,**
   A. Stage 1 involves the facilitator allowing the candidate to demonstrate the skill
   B. Stage 2 has the facilitator demonstrating the skill 'real time'
   C. Stage 3 has the facilitator demonstrating the skill with candidate commentary
   D. Stage 4 allows the facilitator to demonstrate the skill with commentary

2. Feedback after a clinical assessment should

A. Focus on overall candidate performance during the semester/term
B. Reinforce negative outcomes and behaviours
C. Have an action plan with points for improvement
D. Be provided 72 hours after the assessment to allay anxiety from the student

3. Regarding validity of an assessment

A. Test items should be based on stated objectives
B. It focuses on student's progress in mastering the required skill and knowledge only
C. If the questions are not valid, they should be asked only in 50% of the assessment
D. Validity and reliability of an assessment are similar

4. In determining and interpreting the difficulty index of a question,

A. A score of less than 30% indicates the item as too easy
B. A score of over 70% indicates the item as too difficult
C. A score of 60% is considered ideal and acceptable
D. At least 70% of the students should pass the test item

5. In clinical skills assessments,

A. Assessors should discuss the strengths and weaknesses with the candidates
B. Difference between the two assessors should be at least 5%
C. Mentoring should be considered for students who passed the assessments to perfect their skills
D. Only one assessor should provide detailed feedback to the candidate

6. In scenario teaching

A. Encourage the use of SBAR both at the beginning of the session and in reporting at the end
B. Not all participants have a chance to contribute
C. Knowing the practice area of the learners is not relevant for their practice
D. Learning experience is not as close to real life as possible

7. Regarding episiotomy

A. Should be routine for short women in labour
B. Should be a routine practice procedure for women in labour
C. Should be a non-routine practice procedure in labour
D. Should be performed in cases of obstructed labour

8. Which one of the following practices is recommended in maternity care?

A. Early cord clamping
B. Delayed cord clamping
C. Avoid food and fluids during labour
D. Restrict movement of labouring women

9. Which of the following is an indication for assisted vaginal delivery?

A. Shorten duration of first stage of labour if prolonged
B. Shorten duration of second stage of labour if prolonged
C. Shorten duration of first stage of labour if labour is obstructed

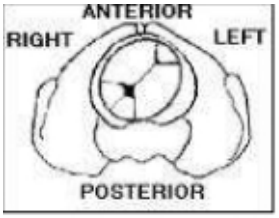
D. Shorten duration of second stage of labour if labour is obstructed

10. In the application of the SBAR tool in handover communication, which of the following is true?

A. Prevents the hit and miss process of 'hinting and hoping'
B. Is a tool for doctor-doctor communication for all maternity cases
C. Encourages staff to communicate then think and prepare for care
D. Makes handover slower and less effective for urgent maternity cases

SECTION B: SCENARIO/OBJECIVE STRUCTURED CLINICAL EXAMINATION

ASSISTED VAGINAL DELIVERY



1. What is the position of the fetal head?
   a. Right Occipito Anterior
   b. Right Occipito Posterior
   c. Left Occipito Anterior
   d. Left Occipito Posterior

2. Which 3 of the following are indications for vacuum extraction?
   a. To expedite delivery of a premature infant
   b. Prolonged second stage
   c. Foetal distress in the second stage
   d. Severe cephalopelvic disproportion in second stage
   e. To expedite delivery at full dilatation

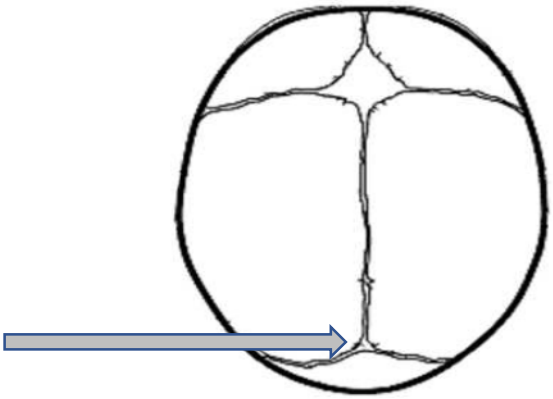
3. When performing vacuum extraction, at what stage would you start pulling?
   a. Pressure at yellow
   b. Pressure at green
   c. Pressure at red

4. Which 3 of the following are potential complications of correctly performed vacuum delivery?
   a. Skull fracture
   b. Localised scalp oedema
   c. Cephalohaematoma
   d. Brain damage
   e. Cervical tears
   f. Neonatal jaundice

5. If vacuum delivery fails, the baby should be delivered by which means?
   a. Normal delivery
   b. Forceps
   c. Caesarean section

6. What is the name of the fontanelle identified by the arrow in the diagram?

   ……



SECTION C: SELF – EFFICACY EVALUATION

7. Have you undergone a 'hands on' EmONC training session where you practiced on obstetric mannequins before? Yes …… No…….

8. On a scale of 1 to 5, how confident do you feel teaching the following EmONC skills? (please cross x)

		Not confident				Very confident
		1	2	3	4	5
1	PPH					
2	Hypovolemic shock					
3	AMTSL					
4	MEOWS					
5	Administering Magnesium Sulphate					
6	Vacuum delivery					
7	Partograph use					
8	Newborn resuscitation					
9	Physiological birth					

9. On a scale of 1 to 5, how confident do you feel teaching using the following skills? (please cross x)

		Not confident				Very confident
		1	2	3	4	5
1	Lecture					
2	Role play/scenario					
3	Small group discussion					
4	Use of peer observation					
5	Give effective feedback					

Training Institution Evaluation Form

A. DEMOGRAPHICS

1. Date: _____
2. Name of training school: _____
3. Ownership of training institution: Public _____ Private_____ Faith-based_____
4. Midwifery training program offered: KRCHN___KRNM___KRM-basic____KRM-post-basic___ (tick applicable program)
5. Curriculum updated with competency based EmONC content: Yes ____ No ____
6. Institution delivering the updated curriculum: Yes _____ No_____
7. When was the current curriculum being implemented revised/updated? (select most appropriate response)

   (A) pre-2010_____ ___

   (B) 2010 – 2015_____

   (C) 2016 – 2020_____

Staffing

8. How many KMTC staff are involved with teaching EmONC modules? _____
9. In the last 5 years, what training/updating in **Emergency Obstetrics Care (EOC)** have these members of staff received? (please give details – who, when, where, what, by whom)

WHO	WHEN	WHERE	WHAT	BY WHOM

B. <u>CLINICAL PLACEMENTS</u>

1. How are students prepared for clinical placements (Orientation, specific mentor or tutor allocated)? (tick all that apply)

   A. Orientation done to the classroom and ward

B. Specific mentor or clinical instructor allocated

C. specific mentor/clinical instructor and tutor/lecturer allocated

D. Specific tutor/lecturer allocated

2. Do members of KMTC staff carry out clinical supervision with students when they are out on clinical placement? Yes _____ No_____

   a. If so, how often?

      A. Every 1 week

      B. Every 2 weeks

      C. Every 4 weeks

      D. After more than 4 weeks

   b. If not, why not? _____

C. TRAINING INSTITUTION SKILLS LAB INFRASTRUCTURE

S/no.	Skills lab infrastructure	Yes	No	NA
1	Skills lab or room for conducting practical training sessions available			
2	Can students access it at other times on their own for skills practice?			
3	Is there a full set of EOC equipment in the skills lab?			
4	Is the set of equipment in good working order			
	Any other comments about use of the skills lab (including maintenance of equipment)			

D. <u>TEACHING CONTENT</u>

1. Are these EOC topics taught as Theory/didactic, Practical (mannequins), Bedside?

S/no	Topic	Mode of teaching (tick as applicable)		
		Theory/didactic	Practical (mannequins)	Bedside
1	Maternal Resuscitation			
2	Newborn Resuscitation			
3	Administering Magnesium Sulphate			

S/no	Topic	Mode of teaching (tick as applicable)		
		Theory/didactic	**Practical (mannequins)**	**Bedside**
4	Shoulder Dystocia			
5	Manual Removal of Placenta			
6	Breech Delivery			
7	Management of APH			
8	Management of PPH			
9	Vacuum Delivery			
10	Managing Complications of Abortion			
11	Completing Partograph			
	Comments			

E. <u>EXPERIENCE IMPLEMENTING UPDATED CURRICULUM</u>

1. What is your experience in implementing the new updated curriculum integrated with EmONC?

2. What are the bottlenecks experienced in implementing the updated curriculum at the institution?

TEACHING OBSERVATION FORM

A. OBSERVATION OF TEACHING

Instructor's serial code:_____

Observer's name: _____

Course title:_____

Topic covered: _____

Type of session: Lecture____ Practical _____ Tutorial_____ (tick the applicable option)

Class Level: ___ 1st year ___ 2nd year ___ 3rd year ___ 4th year ___ Graduate (tick the applicable option)

Number of students: _____ (In the class observed)

Directions: Please respond to each of the following statements by checking the blank (X) which corresponds to your observation
Yes: Observed **No:** Not observed; would have been appropriate **NA**: Not Applicable

A	**Content**	**Yes**	**No**	**NA**
1.	Is there a written teaching plan for the lesson?			
2.	Stated the purpose of the class session (learning outcomes)			
3.	Made explicit the relationship between today's and other aspects of the course			
4.	Arranged and discussed the content in a systematic and organized fashion			
5.	Asked questions periodically to determine whether too much or too little information was being presented			
6.	Used alternate explanations when necessary			
7.	Periodically summarized the most important ideas			
8.	Did not often deviate from the main topic			
	Comments			
B	**Use of questions**			
	Asked questions to assess student knowledge on the lecture topic			
	Addressed questions to individual students as well as to the group at large			
	Paused after questions to allow students time to think of an answer (students challenged to think)			
	Received student questions politely and enthusiastically			
	Encouraged students to answer difficult questions by providing cues or rephrasing			

	Comments			
C	**Resources**			
1.	Were visual aids, models, IT and/or communications technology used?			
2.	Writing on board/ overhead/ slides was legible (font size, contrast, neatness)			
3.	Information presented on board/overhead/ slides was organized and easy to follow			
4.	The resource materials were handled competently (e.g., the instructor did not walk in front of the image for slide projector; the instructor spoke to the class not the screen or board; etc.)			
	Comments			
D	**Use of examples**			
1.	Were examples used to enhance student understanding?			
2.	Were student examples asked for?			
3.	Were links made to previous learning?			
	Comments			
E	**Individual style**			
1.	Voice could be easily heard			
2.	Voice was raised or lowered for variety and emphasis			
3.	Was there room for questions and discussion?			
	Comments			

B. THE POST OBSERVATION DISCUSSION
(To be completed following the feedback discussion)

Strengths (positive observations): In what ways was this a good demonstration of effective teaching/learning practice in your discipline?	

Areas for improvement:	

Was there particularly innovative or excellent practice that might be shared with other colleagues?

C. EXPERIENCE IMPLEMENTING UPDATED CURRICULUM

3. **What is your experience in implementing the new updated curriculum integrated with EmONC?**

4. **What are the bottlenecks experienced in implementing the updated curriculum at the institution?**

MOI UNIVERSITY COLLEGE OF HEALTH SCIENCES / MOI TEACHING AND REFERRAL HOSPITAL INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC) INFORMED CONSENT FORM (ICF)

Study Title: [Evaluation of the Implementation of the Updated Midwifery Syllabi for Pre-Service Training in Kenya: A Randomized Control Study]

Name of Principal Investigator(s): [Duncan Shikuku and Dr. Paul Nyongesa]

Co Investigators: [Edna Tallam, Prof. Michael Kiptoo, Dr. Isaak Bashir, Dr. Helen Allott, Dr. Sarah White, Fiona Dickinson, Lucy Nyaga and Dr. Charles Ameh]

Name of Organization: [Liverpool School of Tropical Medicine]

Name of Sponsor: [This work is funded by DFID/UK Aid (Reducing Maternal and Perinatal Mortality in Kenya), within an existing programme of work led by Centre for Maternal and Newborn Health – Liverpool School of Tropical Medicine (CMNH-LSTM)]

Informed Consent Form for: [Midwifery Educator]

This Informed Consent Form has two parts:

- Information Sheet (to share information about the study with you)
- Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the signed Informed Consent Form

Part I: Information Sheet

Introduction:

You are being asked to take part in a research study. This information is provided to tell you about the study. Please read this form carefully. You will be given a chance to ask questions. If you decide to be in the study, you will be given a copy of this consent form for your records.

Taking part in this research study is voluntary. You may choose not to take part in the study. You could still receive other treatments. Saying no will not affect your rights to health care or services. You are also free to withdraw from this study at any time. If after data collection you choose to quit, you can request that the information provided by you be destroyed under supervision- and thus not used in the research study. You will be notified if new information becomes available about the risks or benefits of this research. Then you can decide if you want to stay in the study

Purpose of the study:
The purpose of the study is to find out whether…..
[We would like to invite you to participate in a study 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.]

Type of Research Project/Intervention:

[This will be a randomized controlled trial where you will either be in the intervention group (you will receive training and additional mentoring at every 3 months for a period of one year on the updated competency-based curriculum integrated with emergency obstetrics and newborn care (EmONC)) or control group (you will receive training on delivery of the updated competency-based curriculum integrated with emergency obstetrics and newborn care (EmONC)). The training will be conducted by highly experienced EmONC faculty and quality assured by Liverpool School of Tropical Medicine. The training will major on the updated EmONC content and how to deliver/teach the updated EmONC skills and provide feedback. Mentorship will be done by the expert team of EmONC mentors to strengthen your teaching and performance of the lifesaving EmONC skills. Your participation will in no way affect your employment and the assessments/findings will not be released to your managers and/or employers. You are free to withdraw from the study at any time and the research team will check that you are happy to proceed with the study at each data collection point.]

Why have I been identified to Participate in this study?
[Your training institution was randomly selected to participate in the study. As a key midwifery educator in the country, you have been recognized for the critical role you play in training competent healthcare workforce in the reproductive, maternal, newborn, child and adolescent health space. Your useful views will be integral to shaping the training of competent skilled health personnel for the country and international market as well.]

How long will the study last?

You will be in this study for….

[If you agree to participate, you will be requested to complete the anonymous online knowledge check survey every 3 months for a period of one year. It is estimated that it will take about 15 - 20 minutes of your time to complete the online survey. In order to gain a deeper understanding of the challenges and enablers in the implementation of the new curriculum, you may be requested to participate in an online small group discussion or as a key informant with the research team (which will not take more than 40 minutes) at 6 months and at 12 months after the training.]

What will happen to me during the study?
A. Provide a brief introduction to the format of the research study.

We are asking you to help us learn more about the updated competency-based curriculum integrated with EmONC training. If you accept, you will be requested to complete the anonymous online knowledge check survey every 3 months for a period of one year. It is estimated that it will take about 15 - 20 minutes of your time to complete the online survey, and if you agree to participate, please complete the survey in your free time.

Your responses will not be identified by your names, email or IP addresses in the electronic survey software. At some stages, the research team (not more than two at any time) will observe your teaching sessions as non-participant observers (meaning that they will not interfere with your delivery of the classroom teaching). Based on teaching timetable you provide; the study team will select sessions to observe and communicate this with you in advance. At the end of the teaching session, you will have a dialogue constructive feedback session with a trained mentor. This feedback will not form any part of the research process. Besides, the observations will not have or form any part of your appraisals hence the feedback will be an informal discussion only.

In order to gain a deeper understanding of the challenges and enablers in the implementation of the new curriculum, you may be requested to participate in an online/face-to-face small group discussion or as a key informant with the research team (which will not take more than 40 minutes) at 6 months and at 12 months after the training.

Your participation will in no way affect your employment and the assessments/findings will not be released to your managers and/or employers. You are free to withdraw from the study at any time and the research team will check that you are happy to proceed with the study at each data collection point.]

B. Explain the type of questions that the participants are likely to be asked in the focus group, the interviews, the survey or other relevant approach. If the research involves questions or discussion which may be sensitive or potentially cause embarrassment, inform the participant of this.

If you agree to participate, the questions have been developed to cover understanding of EmONC and teaching methodologies in the updated curriculum. The questions will basically check on your understanding of EmONC, your confidence to teach the EmONC skills, feedback mechanisms and the enablers and challenges experienced in delivering the updated curriculum. Study questions have been developed in such a way that they do not embarrass or force you to divulge information which could result in anxiety or fear.

What side effects or risks I can expect from being in the study?

This study is less likely to pose any risks to you by participating in the study. Study questions have been developed in such a way that they will not embarrass you or force you to divulge information which could result in anxiety or fear. However, should taking part in the study cause significant distress to you; please notify the research team (See contacts below) and the research team will arrange for appropriate support.

Are there benefits to taking part in the study?

The information obtained from this study including the barriers and experiences in implementing the updated syllabi/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. Your personal interaction with the experienced trainers, through the observation and feedback sessions, will potentially improve your teaching skills during delivery of the updated skills-based trainings.

Reimbursements:

[We very much appreciate the time you take participating in this study. However, we are not able to provide any financial compensation. We hope that the feedback sessions will be useful in strengthening

your teaching practice, to create highly competent and competitive skilled health care personnel for our maternal and newborn health services.]

Who do I call if I have questions about the study?

Questions about the study: PI Contact Info…

Research lead (Kenya): Duncan Shikuku Email: Duncan.Shikuku@lstmed.ac.uk Tel: 0725523716

Questions about your rights as a research subject: You may contact Institutional Review Ethics Committee (IREC) 053 33471 Ext.3008. IREC is a group of people that reviews studies for safety and to protect the rights of study subjects.

Will the information I provide be kept private?

All reasonable efforts will be made to keep your protected information (private and confidential. Protected Information is information that is, or has been, collected or maintained and can be linked back to you. Using or sharing ("disclosure") of such information must follow National privacy guidelines. By signing the consent document for this study, you are giving permission ("authorization") for the uses and disclosures of your personal information. A decision to take part in this research means that you agree to let the research team use and share your Protected Information as described below.

As part of the study, [Duncan Shikuku] and [his] study team may share the results of your [survey and interviews etc]. These may be study or non-study related. They may also share portions of results with the groups named below:

- The National Bioethics. Committee,
- The Institutional Review and Ethics Committee,
- [Ministry of Health and representatives of {Liverpool School of Tropical Medicine].

National privacy regulations may not apply to these groups; however, they have their own policies and guidelines to assure that all reasonable efforts will be made to keep your personal information private and confidential.

[The sponsor may give your personal health information, not containing your name, to others or use it for research purposes other than those listed in this form. In handling your personal information, the sponsor, [Duncan Shikuku] and associated staff will keep your information in strict confidence and shall comply with any and all applicable laws regarding the confidentiality of such information.]

The study results will be retained in your research record for at least six years after the study is completed. Any research information entered into your medical record will be kept indefinitely.

Unless otherwise indicated, this permission to use or share your Personal Information does not have an expiration date. If you decide to withdraw your permission, we ask that you contact [Duncan Shikuku] in writing and let [him] know that you are withdrawing your permission. The mailing address is [duncan.shikuku@lstmed.ac.uk]. At that time, we will stop further collection of any information about you. However, the health information collected before this withdrawal may continue to be used for the purposes of reporting and research quality.

Your participation in the trainings including support to your institution will not be affected if you decide not to take part. You will receive a copy of this form after it is signed.

Part II: Consent of Subject:

I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits (if any) of the study. I freely volunteer to take part in this study.

[This section must be written in the first person. It should include a few brief statements about the research. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the informed consent and not a stand-alone document, the layout or design of the form should reflect this]

_____	_____	_____
Name of Participant (Witness to print if the subject is unable to write	Signature of subject/thumbprint	Date & Time

_____	_____
Name of Representative/Witness	Relationship to Subject

_____	_____	_____
Name of person Obtaining Consent	Signature of person Obtaining Consent	Date

_____	_____	_____
Printed name of Investigator	Signature of Investigator	Date

MEMORANDUM OF UNDERSTANDING

BETWEEN

KENYA MEDICAL TRAINING COLLEGE HEADQUARTERS (KMTC-HQ)

AND

LIVERPOOL SCHOOL OF TROPICAL MEDICINE - KENYA (LSTM- KENYA)

The **LIVERPOOL SCHOOL OF TROPICAL MEDICINE – KENYA (LSTM-KENYA)** wishes to enter into a Memorandum of Understanding (MoU) with the **KENYA MEDICAL TRAINING COLLEGE (KMTC) HEADQUARTERS** to improve the quality of maternal and new-born care delivered by healthcare providers with an overall aim of reducing preventable maternal and neonatal morbidities and mortalities.

This Memorandum of Understanding, herein referred to as **MOU**, is entered on this ..29th..... day of the month of ..May..,.2020..... between on the one hand,

KENYA MEDICAL TRAINING COLLEGE HEADQUARTERS

AND

LIVERPOOL SCHOOL OF TROPICAL MEDICINE – KENYA

1. PURPOSE AND SCOPE OF THE MOU

This MOU outlines the relationship and objectives of implementing the **Reducing Maternal and Newborn Deaths Program** between Liverpool School of Tropical Medicine, Kenya (LSTM – KENYA) and the Kenya Medical Training College (KMTC) Headquarters. It provides the mutual framework of agreement for the engagement in delivering the aforementioned project objectives aimed at reducing preventable maternal and neonatal morbidities and mortalities in Kenya.

2. BACKGROUND

2.1 Liverpool School of Tropical Medicine - Kenya

The Liverpool School of Tropical Medicine, Kenya (LSTM-KENYA), is affiliated to the Liverpool School of Tropical Medicine (LSTM), UK. LSTM UK hosts the Centre for Maternal and Newborn Health (CMNH), an internationally recognised Centre of Excellence in Maternal and Newborn Health. LSTM- CMNH's vision is to end preventable maternal deaths, stillbirths and early neonatal deaths and improve the health of mothers and babies in low-and middle-income countries. LSTM-Kenya, in collaboration with LSTM UK's CMNH, has delivered successful programmes that aim to improve maternal and newborn health in Kenya since 2009. With funding from the UK Department for International Development (DFID), LSTM has delivered scalable competency-based training in Emergency Obstetric and Newborn Care (EmONC). This includes delivering competency based EmONC & NC training in pre-service training institutions by supporting capacity building of teaching faculty, strengthening skills labs and supportive supervision of teaching faculty/clinical instructors; equipping pre-service training institutions with EmONC & NC training equipment in the skills labs; and training midwifery educators, tutors and medical interns. This has contributed to increased and sustainable availability of quality maternal and newborn health (MNH) services promoting and supporting the institutionalisation and effective stewardship of strategies and interventions to reduce maternal and neonatal mortality and morbidity and to reduce stillbirths. LSTM Kenya has a long-standing and effective working relationship with the Ministry of Health (MoH) in Kenya, as well as with key stakeholders active in the health sector including the Department for International, United Nations Population Fund (UNFPA), UNICEF and World Health Organization (WHO).

2.2 The Reducing Maternal and Newborn Deaths Program

A new phase of the reducing Maternal and Newborn Deaths programme in Kenya, began in April 2019. This phase will be implemented until March 2023. In this phase of the programme CMNH-LSTM will focus on developing and sustaining strategies to improve maternal and newborn health and healthcare services. Among other key outcomes, the programme aims to strengthen capacity of pre-service training institutions by training pre-service-tutors to deliver EmONC training and also increase

the number of pre-service institutions delivering competency-based EmONC training within the pre-service curriculum for nurses and clinical officers.

Program Goal: Promote and support the institutionalisation and effective stewardship of strategies and interventions to reduce maternal and neonatal mortality and morbidity and to reduce stillbirths in Kenya at national level, as well as directly at county levels.

Program Impact: To reduce maternal and neonatal mortality in Kenya

Program Outcome: Increased and sustainable availability of quality MNH services

Programme result areas:

i. Support the implementation of methods to improve Quality of Maternal and Newborn Care
ii. Strengthen capacity of the workforce through in-service EmOC&NC training interventions
iii. Strengthen capacity of pre-service training institutions
iv. Support development and implementation of a mentorship and supportive supervision package (M-SS)
v. Disseminate findings and lessons learned

3. RESULT AREAS AND OUTPUT INDICATORS THAT DIRECTLY FORM THE CORE OF THIS MOU

The result area related to strengthening the capacity of pre-service training institutions directly relates to this MoU. This will be measured through three output indicators namely,

- Number of pre-service health workers trained in EmONC Skills
- Number of pre-service-tutors trained to deliver EmONC training
- Number of pre-service institutions delivering competency-based EmONC training within the pre-service curriculum for (i) nurses, (ii) clinical officers.

4. ROLES AND OBLIGATIONS OF LIVERPOOL SCHOOL OF TROPICAL MEDICINE - KENYA

Support strengthening of the capacity of pre-service training institutions by:

1. Mapping of pre-service training institutions to inform identification of 4 KMTCs institutions to function as training hubs
2. Support the National Pre-Service Training Task Force to review and finalise the pre-service nursing and midwifery curricula and syllabi to incorporate EmONC
3. Establishing and replenish/supplementing EmONC training equipment required for four (4) pre-service training hubs/centres of excellence
4. Conduct a 5-days training for 50 Medical and Nursing/Midwifery Educators/Clinical Supervisors to deliver updated Kenya Medical Training pre-service EmONC training (nursing/midwifery and clinical officers) curriculum
5. Train 250 midwifery and clinical officer tutors/lecturers and clinical instructors on the updated curricula and syllabi
6. Monitoring of implementation, facilitation of knowledge sharing and management at county level quarterly.

7. Document and share programme resultsand lessons learned for potential scale-up annually.

5. ROLES AND OBLIGATIONS OF THE KENYA MEDICAL TRAINING COLLEGES

1. Appoint a contact person who will liaise with Liverpool School of Tropical Medicine- Kenya on all matters related to this Programme M.o.U
2. Nominate two (2) members to serve in the Pre-service Training Taskforce for reviewing the KMTC curriculum for nursing/midwifery and clinical medicine practice
3. Include the pre-service EmONC trainings in the annual work-plans
4. Take custodian of the training equipment in the KMTCs (which remains a property of DFID)
5. Identify/select and release (in consultation with LSTM) 50midwifery and medical staff for training as master trainers to deliver the updated training syllabi (with minimal disruption to teaching/clinical services).
6. Select and release 250 midwifery, clinical medicine and clinical instructors for training on the updated syllabi/curricula
7. Support at least 50 pre-service institutions deliver competency-based EmONC training within the pre-service curriculum for (i) nurses, (ii) clinical officers
8. Contribute to the cost of the training, specifically costs related to the training venue. Trainings will be conducted 'on-site', in KMTC institutions and/or government venues. Hotels will not be used as training venues.
9. Collaborate with LSTM on monitoring/evaluation and conducting operational research on the effectiveness and lessons learned implementing the programme. This will include joint authorship and dissemination of findings.

6. SUSTAINABILITY

The program will develop the capacity of medical/nursing/midwifery and clinical educators to train and provide continuous professional development for pre-service training faculty through the new curriculum and syllabi. This will provide a critical step for the stewardship, ownership and implementation of the pre – service training to trainee healthcare professionals.

7. AMENDMENTS

Any provision of this **MOU** may be amended as need arises through mutual consent by the parties in writing.

8. ENTRY INTO FORCE

This **MOU** shall enter into force upon signature by both parties.

9. TERMINATION

1. Either party may terminate this MOU at any time by giving a written notice to the other party of one (1) calendar month of the intention to do so.
2. In the event of termination of this MOU, necessary steps shall be taken by Liverpool School of Tropical Medicine- Kenya to ensure that such termination is

not prejudicial to training and capacity building activities of healthcare providers that are in progress.

10. CONFIDENTIALITY

Each party agrees to hold the terms of this MOU and this collaboration (and related information and documentation) in confidence and not to disclose such information to any third party (other than to such party's legal and professional advisors) without the prior written consent of the other party. This paragraph shall not apply to any specific disclosures which may be required by law.

11. DISPUTE RESOLUTION AND GOVERNING LAW

Any disputes or misunderstanding that might arise in pursuit of the provisions of this MOU will be reported to, and amicably resolved by, the highest steering committee established for the implementation of this project. Where a dispute has not been amicably resolved the parties shall enter structured negotiations with the assistance of a mediator acceptable to both sides. Where mediation fails the parties shall settle the dispute through arbitration. The award of the arbitration shall be final and binding upon the parties.

In witness whereof, this Memorandum of Understanding has been executed by the parties by their respective hands on this ..28th..... day of ..May...2020

Signed

Name: **Lucy Nkirote**
Kenya Country Director
Liverpool School of Tropical Medicine - Kenya

Date: 28/05/2020

Name: **Prof. Michael Kiptoo**
The Chief Executive Officer
Kenya Medical Training College (KMTC) Headquarters

Date: 27.05.2020

Signed. (Witnesses)
SIMUKU DUNCAN, LSTM.

Date: 28.05.2020