Research protocol for ethics approval (UoN-KNH ERC)

1. Project title:

The effect of Emergency Obstetric and Newborn Care training interventions on knowledge and skills of midwifery students prior to graduation in Kenya: A randomised control trial

2. Researchers

Name/ Organisation	Qualifications	Role in Study	Geographic Location
Charles Ameh LSTM	PhD, MB.BS, DRH, MPH, FRSPH, FWACS, FRCOG (OBGYN)	 Principal Investigator Study design (tools, SoPs data, management), development of intervention, ethics application, analysis, publications 	Liverpool UK
Helen Allott LSTM	FRCOG, MSc	Research administrator Liverpool—Development of intervention,—coordinationofimplementation of intervention and—external quality assurance	Liverpool UK
Fiona Dickinson LSTM	MSc, RNM	Research assistant Training of data collectors Preparation and distribution of data collection tools Monitoring of data collection Data cleaning Data analysis	Liverpool UK
Judith Maua LSTM	MiPH, RNM	Co-Investigator Kenya —Oversight for implementation of interventions, —liaison with participating institutions and data analysis and report writing —dissemination or results in Kenya.	Kenya
Pamela Godia LSTM Kenya	PhD	Co-Investigator Kenya —Oversight for implementation of interventions, —liaison with participating institutions and data analysis ad report writing —dissemination or results in Kenya.	Kenya
Joyce Mutuku LSTM	MPH, RNM, DRH	Research administrator Kenya —Coordination of implementation of intervention and data collection, —external quality assurance	Kenya
Dr Wangui M MoH Kenya	MBBS, MPH	Collaborator Monitoring of protocol implementation Publications	Kenya

3. Collaborating institutions:

- i. Centre for Maternal and Newborn Health (CMNH), Liverpool School of Tropical Medicine (LSTM), Pembroke Place, Liverpool, L3 5QA
- ii. Kenya Medical Training College (KMTC) Headquarters, Nairobi
- iii. LSTM Kenya office, PO Box 856-00606, Wilson Business Park, Nairobi
- iv. Reproductive & Maternal Health Services Unit, Ministry of Health, Nairobi, Kenya

4. Funding agency:

This work will be funded within an existing programme of work led by CMNH-LSTM and funded by DFID/UK Aid (Improving the Quality of Care for Mothers and Babies- Making it Happen in Kenya (MiH Kenya).

5. List of Abbreviations

BEmONC	Basic Emergency Obstetric and Newborn Care
CEmONC	Comprehensive Emergency Obstetric and Newborn Care
CMNH	Centre for Maternal and Newborn Health
DFID	Department for International Development
DHMT	District Health Management team
EmOC	Emergency Obstetric Complications
EOC&NC	Essential (Emergency) Obstetric Care and Newborn Care
КМТС	Kenya Medical Training Colleges
LSTM	Liverpool School of Tropical Medicine
MCP	Maternity Care Providers
MiH	Making it Happen
MNH	Maternal Newborn Health
MOH	Ministry of Health
RCT	Randomised Controlled Trial
SBA	Skilled Birth Attendant/Attendance
ТВА	Traditional Birth Attendance

6. Operational Definitions

N/A

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8. Abstract

Introduction: Kenya continues to experience a high burden of maternal and newborn death; maternal mortality was estimated at 510/100,000 live births in 2015. The provision of emergency obstetric and newborn care (EmONC) by skilled birth attendants is one of the global strategies to reduce maternal and newborn mortality and the Kenyan government has included this intervention as a priority in the National Health Strategy 2009-2015 as well as into the Second Medium Term Plan 2013-2017. EmONC is an approach that is successful in improving knowledge and skills both for trained health care professionals and at pre-service level, for midwifery and medical students⁵. There are no known randomized controlled trials (RCTs) of competency based training programmes that have focused on improving pre-service students' knowledge and skills compared to standard training.

Aim: To measure the effective of pre-service EmONC training interventions and self-reported confidence in performing EmONC skills amongst final year midwifery students in Kenya

Objectives. The two research questions to be answered in this study are 1) what is the effect of EmONC capacity building interventions on knowledge and skills of pre-service midwifery students? 2)_What is the effect of EmONC capacity building interventions on self-reported confidence to provide EmONC?

Methodology: Cluster randomized controlled trial with 2 intervention and 1 control arm, involving 12 Kenya Medical Training Colleges and 240 final year midwifery students

Expected outcomes: The primary outcome is the student knowledge and skill assessment score and the secondary outcome is the student self-reported confidence in performing EmONC skills. Generating evidence about the most effective way to train pre-service nurse-midwives will have a positive impact by optimizing available resources in low resource settings; implementing effective teaching methods for optimum student learning thereby enabling nurse-midwives to develop appropriate competencies prior to graduation and contribute to reducing mortality/morbidity of pregnant women and newborns.

9. Introduction

An estimated 289,000 maternal deaths, 2.6 million stillbirths and 2.4 million newborn deaths occur globally each year, with the majority occurring around the time of childbirth [1]. Kenya continues to experience a high burden of maternal and newborn death. Maternal mortality was estimated at 510/100,000 live births in 2015 [2], whereas recent estimates from the Kenya Demographic and Health Survey 2014 [3] indicate that child mortality has decreased to 52/1,000 live births. Maternal deaths represent about 15 % of all deaths of women in the reproductive age group (15-49 years), which translates to an estimated 6,000 to 8,000 pregnant women dying every year. 17% of direct maternal deaths are related to complications of abortion and 25% to postpartum haemorrhage [4].

The medical and surgical interventions to prevent this loss of life are known, and most maternal and newborn deaths are in principle preventable. The provision of emergency obstetric and newborn care (EmONC) by skilled birth attendants are internationally seen as appropriate means to reduce maternal and newborn mortality [5] and the Kenyan government has included this intervention as a priority in the National Health Strategy 2009-2015 as well as into the Second Medium Term Plan 2013-2017 [6].

There is a need to build the capacity of health-care providers in low resource settings to recognize and manage complications during pregnancy, childbirth and the post-partum period. Skills-and-drills competency-based training in skilled birth attendance and EmONC is an approach that is successful in improving knowledge and skills both for trained health care professionals and at pre-service level, for midwifery and medical students [5]. Despite this evidence, few studies have formally evaluated the impact of EmONC training interventions at pre-service (undergraduate) level prior to graduation [7-11]. Previous studies have predominantly focused on the training of medical and nursing students in high income settings [7-10] with only one study undertaken in a low resource setting that focused specifically on emergency obstetric care training [12]. The benefit of competency based training including improved knowledge and skill outcomes and clinical practice behaviours have been clearly demonstrated [7-13]. However, a lack of robust methodologies and small sample sizes limit the quality of the studies [8].

To date, there are no known randomised controlled trials (RCTs) of competency based training programmes that have focused on improving pre-service students' knowledge and skills compared to standard didactic techniques, that are still widely used in many low resource pre-service institutions. This full-scale cluster RCT tests the effectiveness of a short, competency based training intervention that has been shown to be feasible and acceptable to pre-service and in-service students across South East Asia and sub Saharan Africa [5].

10. Research questions

What is the effect of EmONC training interventions on knowledge and skills of pre-service midwifery students?

What is the effect of EmONC training interventions on self-reported confidence to provide EmONC?

11. Objectives of the study

- 1. To determine the effect of Emergency Obstetric and Newborn Care (EmONC) training interventions on knowledge and skills of pre-service midwifery students.
- 2. To determine the effect of Emergency Obstetric and Newborn Care (EmONC) training interventions on students self-reported confidence to provide EmOC.

12. Methodology

A multicentre cluster randomised controlled trial (RCT), to evaluate the impact of EmONC training interventions on the knowledge/skills of final year midwifery students, and self-reported confidence in EmONC skills, prior to graduation. The cluster, randomised trial design is likely to minimise contamination between intervention and control arm participants.

Emergency obstetric Care Training Interventions

The four EmONC training interventions are

- a. EmONC training for midwifery teachers: Midwifery teachers/lecturers are trained in the LSTM 5-day EmONC course (5).
- b. Training of EmONC trainers for midwifery teachers: Midwifery teachers/lecturers are trained to use evidence based EmONC training methods and content. Training in EmONC (a-above) is a pre-requisite to this training.
- c. Supply of EmONC training equipment for skills laboratory: Supply of EmONC training equipment and technical support to set-up and use the skills labs by LSTM technical team.
- d. Supportive supervision/mentorship: 3-monthly visits to supported KMTCs to facilitate the use of evidence based EmONC training methods and content by LSTM technical team.

Intervention and control groups

There will be two intervention (partial or full EmONC training interventions) and one control group (no EmONC training intervention):

1. **No EmONC intervention**: Training colleges that have received NO previous EmONC training interventions from LSTM.

2. Partial EmONC intervention: Training colleges that have SOME EmONC training interventions.

3. **Full EmONC intervention**: Training colleges that have received ALL the EmONC training interventions from LSTM.

Primary outcome

The primary outcome is the student knowledge and skill assessment score.

The assessments will involve 40 multiple choice questions and four scenario-based learning activities and four Objective Structured Clinical Examinations (OSCE) stations using obstetric and newborn models. The process will take 80 minutes in total and will be administered by three research teams supervised by experienced researchers from LSTM.

Secondary outcomes

The secondary outcome is the student self-reported confidence in performing EmONC skills.

Confidence will be measured using a 5-point Likert scale for self-report of confidence levels in performing six skills: maternal resuscitation, newborn resuscitation, administering of magnesium sulphate for pre-eclampsia,

recognition and initiation of treatment for sepsis, manual vacuum aspiration and recognition and initiation of treatment for post-partum haemorrhage. Similar Likert scale has been used in a population of final year medical students and medical interns in South Africa and Rwanda [12, 13]. The Likert scale questionnaire will be administered after the knowledge and skills assessments for all groups (<u>Additional file 6: Student post</u> <u>assessment questionnaire</u>).



<u>Clusters:</u> Kenya Medical Training College

— 4 KMTCS per group <u>**Participants:**</u> Final year midwifery students

Outcome measures

- a. Primary: Difference in knowledge and skills
- b. Secondary: Difference in confidence to provide EmONC

Data collection

Selection of Study participants

Study participants will comprise all final year midwifery students in selected Kenya Medical Training Colleges (KMTCs). This year group was selected as they will have completed all of their midwifery clinical placements and are preparing for graduation as first year nurse-midwives. Midwives form the core of maternity care providers in Kenya. The clusters will be the KMTCs, each has approximately 60 final year midwifery students.

Research team

Three research teams each lead by an experienced researcher, supported by an administrative assistant and will have eight data collectors/assessors each. It is estimated that data collection at each cluster will last half a day and that data collection will be completed in one week. Each research team will collect data from four KMTCs.

All teams will receive a two-day training on the study protocol prior to data collection (See work plan in <u>Annex</u> <u>1</u>). The teams will collect data from KMTCs included from any of the three groups within regions allocated to that team. The teams will be blinded to the study characteristic of each cluster, this will only be known to the PI. The PI will not be involved in data collection (See <u>Table 1</u> for roles of the research team members).

Name/ Organisation	Qualifications	Role in Study	Geographic Location
Charles Ameh LSTM	PhD, MB.BS, DRH, MPH, FRSPH, FWACS, FRCOG (OBGYN)	 Principal Investigator Study design (tools, SoPs data, management), development of intervention, ethics application, analysis, publications 	Liverpool UK
Helen Allott LSTM	FRCOG, MSc	Research administrator Liverpool — Development of intervention, — coordination of implementation of intervention and — external quality assurance	Liverpool UK
Fiona Dickinson	MSc, RNM	Research assistant — Training of data collectors	Liverpool UK

Table 1: Research team

Name/ Organisation	Qualifications	Role in Study	Geographic Location
LSTM		 Preparation and distribution of data collection tools Monitoring of data collection Data cleaning Data analysis 	
Judith Maua	MiPH, RNM	Co-Investigator Kenya	Kenya
LSTM		—Oversight for implementation of interventions,	
		—liaison with participating institutions and	
		-dissemination or results in Kenya.	
Pamela Godia	PhD	Co-Investigator Kenya	Kenya
LSTM Kenya	—Oversight for implementation of interventions,		
		—liaison with participating institutions and	
		-dissemination or results in Kenya.	
Joyce Mutuku	MPH, RNM,	Research administrator Kenya	Kenya
LSTM	DRH	-Coordination of implementation of intervention and data collection,	
		-external quality assurance	
Dr Wangui M	MBBS, MPH	Collaborator	Kenya
MoH Kenya		 Monitoring of protocol implementation Publications 	

Research team leaders will be LSTM Liverpool and trained EmONC Course Directors from Kenya. The PI will ensure that the research team members are blinded to the research characteristic of interest for the included clusters.

Research team members will be EmONC Master Trainers based in regions outside the regions where they will be collecting data from.

Inclusion ad exclusion criteria

All participants in this trial will be final year Kenya Medical Training College midwifery students.

Training colleges that do not have a final year cohort of nurse-midwifery students will be excluded from the sampling frame

After analysing data from the institutional screening form and excluding KMTCs without final year midwifery cohort, Colleges will be given unique identification numbers by the PI and then grouped into the 3 groups. Then the PI will use a computer to generate random numbers to select 4 KMTCs per study arm (constituent with the sample size calculation). This concealment will only be revealed after analysis to the research team. These groups are based on predefined study characteristics (See page 6).

Sampling framework

The sampling frame includes all 47 counties in the country to ensure a large enough sample is obtained. Including training colleges from different areas across the country will also help ensure the generalisability of the findings. After excluding KMTCs without final midwifery cohort, the colleges will be given unique numbers by the PI and placed in the 3 groups, based on the predefined study characteristics (see intervention and control groups section above).

Sample Size

<u>**Table 2**</u> below indicates the number of individuals that would be required in an individually randomised RCT to detect specified differences as a function of the standard deviation (s.d.) and the numbers of clusters of size 60 that would be needed to detect the same differences for inter cluster correlation (ICCs) ranging in value between 0.1 and 0.3.

If the s.d. is 10% and the minimum difference between study arms that is of interest is also 10% (i.e. the ratio is 1:1) then 22 participants would be needed in each arm of the study, if individually randomised. If the ICC is as low as 0.10 then four Colleges (and 60 participants in each group of the study and a total of 240 participants) would suffice. However, if the ICC is 0.3 then 12 clusters would be required in each arm of the study. If a power of 80% is sufficient then 8 Colleges per arm would suffice even if the ICC is as large as 0.3. However, a smaller difference in effect of EmONC training interventions is likely to be of interest. If a difference of only 6% is of interest and the ICC is 0.10 then the number of KMTCs required per study arm would be 12 for 90% power.

Ratio of minimum	Power	Number per arm for	Number	of clusters	with 60 per
detectable	require	an individually	cluster fo	r various I(CC values
difference: s.d.	d	randomized RCT	0.1	0.2	0.3
1:1	90%	22	4	8	12
	80%	16	3	6	8
1.25:1	90%	14	3	5	7
	80%	11	2	4	6

Table 2: Sample size determination

Ratio of minimum	Power	Number per arm for	Number	of clusters	with 60 per
detectable	require	an individually	cluster fo	r various I(CC values
difference: s.d.	d	randomized RCT	0.1	0.2	0.3
0.8:1	90%	33	6	12	17
	80%	25	5	9	13
0.6:1	90%	59	12	21	31
	80%	44	9	16	23

Since this will have to be a cluster RCT with each College assigned to each group, it will be necessary to account for variability between sites in the analysis. Therefore, the greater the number of sites that can be used the better. Given the uncertainties about the potential levels of variability between Colleges and within Colleges in the assessment performance, a minimum of 12 Colleges will be included in the study.

The cells in the table which are shaded indicate sample sizes not exceeding 12 Colleges per arm, from which it can be seen that there would be 90% power to detect a difference of 6% with this sample size if the ICC is 0.1. If it is 0.2 then a difference of 8% would be detectable and if the ICC is 0.3 then a difference of 10% would be detectable.

On the basis of having 12 KMTCs will be selected for the study, there will be four randomly selected clusters in each of the study groups.

Stratification and randomisation

The training colleges in each of the groups will be randomly allocated, using computer generated random numbers until the group size is achieved. The group characteristic will only be revealed to the rest of the research team after analysis (14).

Recruitment and consent

Consent will be obtained at institutional level and at participant level. Institutional consent will be obtained four weeks before data collection while participants will receive the study information sheet one week before the data collection and signed consent be obtained on the day of data collection. If an institution declines participation, another randomly selected cluster from that group of the sample frame will be used to replace it (See <u>Additional</u> <u>file 1-4</u>: institutional and participant consent form and study information sheet)

Before the start of each knowledge and skills assessment/training course, the participants will be asked to read the consent form and information sheet, check their willingness to participate and record that on the consent form. We will ensure that two copies of the consent form is handed out to the participants who wish to proceed with the study prior to the assessment are signed. One copy is to be given to the participants and the other will be securely filed.

At registration prior to the assessment, each study participant will be given a unique identification number that consists of the institutional code and the participant number. This will be used on both pre and post assessment questionnaires (see <u>Additional file 5 and 6</u>) to be completed by the participant, also on the knowledge and skills assessment sheets.

Data management and analysis

All data will be managed in accordance with the LSTM internal data management policy and protocols.

Knowledge and skills assessment scores will be calculated by one of the data collectors/assessors and this will be cross checked by another data collector/assessor. Data will be manually entered into a study database. Checks will be built into the database to disallow entry of impossible values. Student questionnaires will be scanned into FORMIC data capture system and uploaded for analysis. A randomly selected 10 % of the questionnaires and knowledge and skill test results entered will be checked by a second research team member to ensure data quality. Only the study team will have access to the final trial dataset that will be stored on a password protected networked drive.

Data Analysis

The data (final assessment score for each student and student confidence score) will be analysed using a mixed effects linear model, with random effects for student, nested in cluster (KMTC), and cluster, nested within study arm, and a fixed effect for study arm.

Analysis of variance using cluster scores for knowledge and skills will be performed and p value will be set at less than 0.05

Odds of score of 80% or more score in Group A vs C, B vs C (Group A control, Group B partial EmOC Group C Full EmONC) will be performed.

Data monitoring

The study will not have a data monitoring committee as the risks of harm are minimal and effectiveness will not be able to be determined until the end of the study so no earlier stopping points are expected.

Monitoring safety

No adverse events are anticipated during data collection. At the end of each assessment, members of the research team will discuss the performance of the group and debrief the group with emphasis on demonstrating correct skills assessed, deemed to have been wrongly performed by the participants. Poorly performed skills will not be attributed to any participant during the group debriefing.

Protocol changes

Any important changes to the protocol will be reported to the LSTM and Kenyatta Research and Ethics committee.

Study limitations

The effect of cluster randomisation is to increase the size of standard errors and hence widen the confidence intervals and increase the p values, compared with a study of the same size using simple randomisation (15). However, to answer the primary research question, the unit of analysis is the cluster (KMTC) and the null hypothesis is that EmONC training interventions at these institutions has no effect on the knowledge and skills of final year midwifery students, therefore there will not be any difference in the scores between the intervention and control arms of the study.

A fundamental assumption is that trained KMTC tutors have remained in post, EmONC equipment provided are still available and functional.

During site preparation, we shall collect information on proportion of midwifery tutors trained in EmONC, availability and functionality of EmONC equipment, identify institutions with EmONC support from other sources, number of final year midwifery students and number of KMTC midwifery teachers/educators

KMTCs may feel obliged to participate because of directive from HQ but the institutional information sheet will clearly state that they may chose not to participate. The same applies to final year students in each cluster.

The group of KMTCs that have never received any intervention will be offered full 5 day EmONC training for their tutors and final year students after data collection.

Potential disruption of studies at the KMTCs, the study will last about 4 hours in each site and the week of the study will be agreed in advance with the institution but actual date confirmed only a week to data collection.

There may be concerns of confidentially of test results by final year students and heads of institutions.

Participants will be reassured about the confidentiality of their individual marks, this will not be disclosed to their lectures or head of institution or KMTC HQ. They will be informed that mean score in each group will be compared and identify of the institutions in each group will not be known outside the research team. Lectures from the clusters will not participate in data collection but will have the option of sitting in the group debriefing after data collection/assessment.

13. Research policy and ethical standards

An ethical issue would be protecting the confidentiality of the people involved in the knowledge and skill assessments and the questionnaires. Also blinding the identity of each cluster to members of the research team and the public when disseminating the results.

In order to minimize these potential breeches of confidentiality, all data will be anonymised during data collection and analysis and when preparing reports so that responses cannot be traced to individual respondents. Unique identifiers will be used in place of individual's names and KMTC. Participation without coercion or fear will be ensured throughout the process. Hard copies of all data will be kept in locked cupboards and soft copies on password-protected computers so that people that are not part of the project team do not have unauthorised access to the data.

We will strictly adhere to the LSTM's Code of Practice for Research Conduct in designing and implementing the evaluation. The LSTM's Code of Practice for Research Conduct expects all researchers to understand and apply the following principles:

- Being open, honest and fair, including properly attributing the contribution made by others
- Providing leadership and co-operation in research, including the appropriate supervision and mentoring of young researchers
- Appropriately recording and reporting research, allowing ready verification of the quality and integrity of the research data
- Appropriate dissemination, application and exploitation of the results of research
- Compliance with relevant regulations or policies, whether legal, institutional or other, which govern particular aspects of research
- Professional participation only in work which conforms to accepts ethical standards and which ensures the safety of all those associated with the research
- Participation only in work which the researcher is competent to perform
- Avoidance of real or apparent conflicts of interest
- Strict maintenance of the confidentiality of all those involved

14. Dissemination

A report will be prepared for each participating KMTC containing the overall findings, and each KMTCs anonymised school-level knowledge and skill assessment results.

A full report of the study will be provided to the trial funder, the Kenya Ministry of Health and the Kenya Pre-Service National Taskforce Committee. Papers reporting on the main outcomes will be published in peer reviewed journals. If the findings show the intervention to be effective the intervention will be written up as a guidance document for KMTCs. This will be shared with the Kenya Ministry of Health and the Pre-Service National Taskforce Committee.

Addendum

Following initial data collection and in order to fully inform both research questions, additional data from key informants (KMTC administrators and teachers) is required. (Additional file 7: KMTC Institutional Information 2). The additional information will be collected by members of the research team, who will either visit or contact by telephone, all 12 study sites over 2 weeks, to collect data from key informants. Appointments with relevant institutional staff will be arranged in advance, to ensure minimal disruption of KMTC activities, and it is anticipated that administering the data collection will last no more than one hour per institution.

Descriptive analysis of KMTC institutional Information 2 questionnaire will be carried out by members of the research team, to fully interpret the analysis from the initial data collection.

Annex 1: Timetable of the proposed research

The estimated time-frame within which the assignment will be completed in 2 years as outlined below.

Tasks and deliverables			2018			2019		
	2017							
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
Preparatory Phase			_		1	1	1	
Development of study protocol, data collection tools, consent forms and information leaflets	X	X						
Letter of support – KMTCs, MOH Kenya		X						
Ethics submission LSTM		X						
Ethics submission – Kenya			X					
Trial registration			X					
Study site preparation, institutional consent and participant information sheet				X				
Training Phase			1		1	1		
Training of research team on study conduct				X				
Data Collection phase			1				l	
Data collection in all sites over 7 working days				X				
Post data collection phase: Training for control group, data analysis, results and dissemination								
EmONC Training courses for control group					X			
Data entry, cleaning and analysis					X			
Preparation of results for final dissemination – publication and presentation						X	X	
Dissemination to stakeholders								X

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16. Consent forms and data collection tools

Additional File 1: Institutional Information Sheet

- Additional File 2: Institutional Consent Form
- Additional File 3: Student Information Sheet
- Additional File 4: Student Consent Form
- Additional File 5: Student pre-assessment questionnaire
- Additional File 6: Student post-assessment questionnaire

Additional File 7: KMTC Institutional Information 2

The effect of Emergency Obstetric and Newborn Care training interventions on knowledge and skills of midwifery students prior to graduation in Kenya: A randomised control trial

a. Institutional screening form

Version 1: 2017

Date of data	
collection	
Name of College	
<u> </u>	
Country	
Region	

- 1. Availability of final year midwifery students for 2018: Yes No
- 2. If Yes, how many students? _____
- 3. No. of midwifery lectures and clinical supervisors____
- 4. Since 1st January 2014, has your College had any of the following EmOC capacity intervention implemented

S/No.	EmONC training capacity building intervention	Yes	No
1.	EmONC training of midwifery lecturers and clinical supervisors (as participants and Master trainers)		
2.	Mannequins for EmONC training based on national EmONC curriculum		
3.	Supportive supervision of midwifery lecturers and clinical supervisors after EmONC training		
4.	Other EmONC training capacity building intervention. If Yes please specify:		

5. Estimated proportion of current staff/students trained in EmONC (based on Kenya national EmONC training curriculum)

S/No	Proportion trained	Staff and supervisors	2018 final students
1.	Less than 25%		
2.	More than 25% but less than 50%		
3.	50% to less than 75%		
4.	More than 75% to 100%		

6. If no EmONC training equipment was provided to the institution since 2014, does the institution have a complete set of EmONC training equipment based on Kenya Ministry of Health EmONC training curriculum and guidelines?

Yes_____ No_____

- 7. Any student Self Efficacy Scale (SSE) survey conducted during the period of training of the current final year cohort? YES______ No_____
- 8. If yes, comments about student Self Efficacy Scale (SSE) survey conducted: Frequency, type of tool used etc

Study title: The effect of Emergency Obstetric and Newborn Care training interventions on knowledge and skills of midwifery students prior to graduation in Kenya: A cluster randomised control trial.

Institutional Information Leaflet

We have randomly selected your institution to take part in a research study because you have a final year midwifery student cohort potentially benefiting from Emergency Obstetric and Newborn Care training interventions, provided by the Liverpool School of Tropical Medicine (LSTM) in collaboration with the Kenya Ministry of Health to at Kenya Medical Training Colleges. Although consent for the study has been obtained from KMTC headquarters in Nairobi, Ministry of Health and the research and ethics committees of KNH/UoN, and LSTM, I will like to describe the study and the involvement of your institution, in other to obtain institutional consent.

I will go through the information sheet with you and answer any questions you have. This should take about 10 minutes. Ask me if there is anything that is not clear.

Purpose of this study

We are carrying out a research study to find out the effect of EmONC training interventions (training of tutors in EmONC, strengthening of EmONC skills laboratories, supportive supervision for EmONC trained midwifery tutors) on knowledge and skills of final year midwifery students in KMTCs.

Why have you been invited?

Your institution has been invited to take part in a research study because you have a final year midwifery student cohort potentially benefiting from Emergency Obstetric and Newborn Care training interventions, provided by the Liverpool School of Tropical Medicine (LSTM) in collaboration with the Kenya Ministry of Health to at Kenya Medical Training Colleges

Do I have to take part?

If you choose not to take part it will not make any difference to your inclusion in the EmONC training interventions in future or put you or your institution at any disadvantage. You can withdraw from this study at any point. All identifiers will be removed from the test scores and these will not be shared with your staff, students, institution, KIMTC HQ or the MoH.

What will happen to me if I take part?

If you agree to take part in this study, you will be asked to complete a consent form and your institution will be given an Identification (ID) Number. The name of your institution will **NOT** appear in any of the research documents, results are dissemination materials.

Final year midwifery students will be asked to complete the following tests that are based on the knowledge and practical skills in the EmONC training package:

- 1. A knowledge assessment of 40 multiple choice questions.
- 2. A skills assessment using 4 scenarios based activities and 4 skills assessments using obstetric and newborn models.

This will take approximately 80 minutes in total.

They will also be asked to complete pre-and post assessment questionnaires asking about the midwifery training they have received so far and their self-assessed confidence in providing EmONC after graduation.

The tests will take place within your institution and your staff will not be involved in the assessments. Sixty final year students will be assessed in two batches of 60 and the assessments will be completed within 4 hours.

The date of the assessment will be communicated 1-2 days in advance (January to March 2018).

Compensation

Your institution or students will not receive payment for your involvement in this study.

What are the possible disadvantages and risks of taking part?

There are no known risks to participating in this study. We have designed the study to ensure that you are not at any risk, your staff will not be involved in the assessments and results will not be shared with them or published with your institutions or student's identity elsewhere.

What are the possible benefits of taking part?

There are no immediate benefits to you taking part in this study. However, your involvement in the study will help us to understand effect of the EmONC training interventions in improving the knowledge and skills of students compared to the standard curriculum. The results can potentially result in recommendations to improve the standard curriculum in pre-service midwifery education in Kenya.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time, and you do not need provide a reason. If you do withdraw from the study, we will need to use the data collected up to your withdrawal.

Will my taking part in this study be kept confidential?

All the information about your institution and students will be handled in confidence, stored securely in cabinets and on password protected computers. Your data will be looked at by responsible and authorised personnel and representatives from regulatory authorities only.

What will happen to any data I give?

- Data / samples will be anonymised (for this study, and for storage for future studies)
- Data will be stored securely by LSTM for five years and then destroyed

What will happen to the results of the research study?

The findings from this study will be produced as a written report that will be distributed to in-country and international stakeholders. The findings will also form the basis for one or more peer-reviewed papers. Publication of the results from this study will not include any information which would enable anyone or institution taking part to be identified.

Study Conduct

The Sponsor is ultimately responsible for the safe conduct of the study and the well-being of participants. Any unforeseen circumstances will be reported to the Sponsor and dealt with appropriately.

Complaints

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [+254-705 804 276, +254-706 258 481, +44 (0) 151 705 3706]. If you remain unhappy and wish to complain formally, you can do this by contacting [Professor Anasthasia Guantai on +254-020 2726300-9 Ext 44355 or Dr Angela Obasi on +441517053102]. Details can be obtained from [Judith Maua Ong'yi].

Sponsorship and Funding

This researched is sponsored by Liverpool School of Tropical Medicine and has been reviewed and been approved by LSTM Research Ethics Committee and Kenyatta National Hospital Research and Ethics Committee.

It is funded by Department for International Development United Kingdom.

Contact Details

Researchers

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2. Name: Judith Maua Ong'ayi (Co-investigator Kenya)

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Research and Ethics Committees

 Name: Professor Anasthasia Guantai (Chair) Address: Kenyatta National Hospital/University of Nairobi Ethics and Research Committee College of Health Sciences

Email: uonknh_erc@uonbi.ac.ke

Telephone: +254-020 2726300-9 Ext 44355

Name: Dr Angela Obasi (Chair)
 Address: Liverpool School of Tropical Medicine, Research and Ethics Committee

Email: Angela.Obasi@lstmed.ac.uk

Telephone: +44 (0) 151 705 3102

b. Additional file No.2

Version 1 13.10.2017

The effect of Emergency Obstetric and Newborn Care training interventions on knowledge and skills of midwifery students prior to graduation in Kenya: A randomised control trial

Institutional Consent Form CONFIDENTIAL

Study Title: The effect of Emergency Obstetric and Newborn Care training interventions on knowledge and skills of midwifery students prior to graduation in Kenya: A cluster randomised control trial.

	Study Site: Kenya
Principal Investigator: Charles Ameh	Unique ID

	If you agree with each statement, please INITIAL the box provided	
1.	I confirm I have read and understood the information sheet dated.24/08/2017	
	(Version 001) for the above study. I have had the opportunity to consider the	
	information, ask questions and have had these answered satisfactorily.	
2.	I understand that participation in this study is voluntary and I am free to withdraw	
	my institutions consent at any time, without giving a reason, without any penalties.	
3.	I understand that data collected during the study may be looked at by individuals	
	from LSTM and from regulatory authorities. I give permission for these individuals	
	to have access to my records.	
4.	I hereby declare that I have not been subjected to any form of coercion in giving this	
	consent.	
5.	I agree to the data about my institution collected in this study being stored for further	
	use in the future. (delete if not applicable)	
6.	I agree to take part in this study.	

Signing this declaration does not affect your right to decline to take part in any future study.

Date

Signature

Name of person taking

Date

Signature

Consent

When complete: 1 copy for Institutional Head; 1 copy (original) for research

c. Additional file No.3

Study title: The effect of Emergency Obstetric and Newborn Care training interventions on knowledge and skills of midwifery students prior to graduation in Kenya: A cluster randomised control trial.

Participant Information Leaflet

We would like to invite you to take part in a research study because you are a final year student at a Kenya Medical Training College potentially benefiting from Emergency Obstetric and Newborn Care training interventions, provided by the Liverpool School of Tropical Medicine (LSTM) in collaboration with the Kenya Ministry of Health. Before you decide, we would like you to understand why the research is being done and what it would involve for you. **I will go through the information sheet with you and answer any questions you have.** This should take about 10 minutes. Ask me if there is anything that is not clear.

Purpose of this study

We are carrying out a research study to find out the effect of EmONC training interventions (training of tutors in EmONC, strengthening of EmONC skills laboratories, supportive supervision for EmONC trained midwifery tutors) on knowledge and skills of final year midwifery students in KMTCs.

Why have you been invited?

You have been invited to take part as you will be on the LSS-EOC training course and we are asking all those who are attending for the training to take part.

Do I have to take part?

We have invited you because you are a final year student at a Kenya Medical Training College potentially benefiting from Emergency Obstetric and Newborn Care training interventions. If you choose not to take part it will not make any difference to your inclusion in the EmONC training course or put you or your institution at any disadvantage. You can withdraw from this study at any point. All identifiers will be removed from the test scores and these will not be shared with your tutors, institution or the MoH.

What will happen to me if I take part?

If you agree to take part in this study, you will be asked to complete a consent form and you will be given an Identification (ID) Number. We will ask you to write this ID number in the space provided on the front of every test you complete (for the practical skills test, please give this number to the faculty assessor). You will **NOT** need to write your name or any other personal details anywhere on the test papers.

You will be asked to complete the following tests that are based on the knowledge and practical skills in the EmONC training package:

- 3. A knowledge assessment of 40 multiple choice questions.
- 4. A skills assessment using 4 scenarios based activities and 4 skills assessments using obstetric and newborn models.

This will take approximately 80 minutes in total.

We will also ask you to complete a questionnaire asking about your training experience so far and your self-reported confidence in providing EmONC after training.

The tests will take place within your institution and your teachers/tutors will not be involved in the assessments. We will ask you to stay in the room once a test has started and until the test has finished and that you do not copy anyone else's answers during the tests.

Compensation

You will not receive payment for your involvement in this study.

What are the possible disadvantages and risks of taking part?

There are no known risks to participating in this study. We have designed the study to ensure that you are not at any risk, your teachers will not be involved in the assessments and your individual results will not be shared with them or published with your identity elsewhere.

What are the possible benefits of taking part?

There are no immediate benefits to you taking part in this study. However, your involvement in the study will help us to understand effect of the EmONC training interventions in improving the knowledge and skills of students compared to the standard curriculum. The results can potentially result in recommendations to improve the standard curriculum in pre-service midwifery education in Kenya.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time, and you do not need provide a reason and this will not affect your studentship. If you do withdraw from the study, we will need to use the data collected up to your withdrawal.

Will my taking part in this study be kept confidential?

All the information about you will be handled in confidence, stored securely in cabinets and on password protected computers. Your data will be looked at by responsible and authorized personnel and representatives from regulatory authorities only.

What will happen to any data I give?

- Data will be anonymised (for this study, and for storage for future studies)
- Data will be stored securely by LSTM for five years and then destroyed

What will happen to the results of the research study?

The findings from this study will be produced as a written report that will be distributed to in-country and international stakeholders. The findings will also form the basis for one or more peer-reviewed papers. Publication of the results from this study will not include any information which would enable anyone taking part to be identified.

Study Conduct

The Sponsor is ultimately responsible for the safe conduct of the study and the well-being of participants. Any unforeseen circumstances will be reported to the Sponsor and dealt with appropriately.

Complaints

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [+254-705 804 276, +254-706 258 481, +44 (0) 151 705 3706]. If you remain unhappy and wish to complain formally, you can do this by contacting [Professor Anasthasia Guantai on +254-020 2726300-9 Ext 44355 or Dr Angela Obasi on +441517053102]. Details can be obtained from [Judith Maua Ong'yi].

Sponsorship and Funding

This researched is sponsored by Liverpool School of Tropical Medicine and has been reviewed and been approved by LSTM Research Ethics Committee and Kenyatta National Hospital Research and Ethics Committee.

It is funded by Department for International Development United Kingdom.

Contact Details

Researchers

3.	Name: Address:	Dr Charles Ameh (Principal Investigator) Centre for Maternal and Newborn Health, Liverpool School of Tropical Medicine, Pembroke Place Liverpool UK L3 50A
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4.	Name: Address:	Judith Maua Ong'ayi (Co-investigator Kenya) LSTM Kenya, Wilson Business Park Kenya
	Email:	Judith.Maua@lstmed.ac.uk
	Telephone:	+254-705 804 276 or +254-706 258 481

Research and Ethics Committees

3.	Name:	Professor Anasthasia Guantai (Chair)									
	Address:	Kenyatta National Hospital/University of Nairobi Ethics and Research Committee									
		College of Health Sciences									
	F U										

Email: uonknh_erc@uonbi.ac.ke

Telephone: +254-020 2726300-9 Ext 44355

 4. Name: Dr Angela Obasi (Chair) Address: Dr Angela Obasi (Chair) Liverpool School of Tropical Medicine, Research and Ethics Committee
 Email: Angela.Obasi@lstmed.ac.uk
 Telephone: +44 (0) 151 705 3102

d. Student Consent Form CONFIDENTIAL

Additional file No.4

(version 001 13/10/2017)

The effect of Emergency Obstetric and Newborn Care training interventions on knowledge and skills of midwifery students prior to graduation in Kenya: A randomised control trial

Study Title: The effect of Emergency Obstetric and Newborn Care training interventions on knowledge and skills of midwifery students prior to graduation in Kenya: A cluster randomised control trial.

Principal Investigator: Charles Ameh	Study Site: Kenya
	Unique ID

If you agree with each statement, please INITIAL the box provide	d
1. I confirm I have read and understood the information sheet dated.24/	08/2017
(Version 001) for the above study. I have had the opportunity to cons	sider the
information, ask questions and have had these answered satisfactorily.	
2. I understand that participation in this study is voluntary and I am	free to
withdraw consent at any time, without giving a reason, without any per	nalties.
3. I understand that data collected during the study may be looked	d at by
individuals from LSTM and from regulatory authorities. I give permis	ssion for
these individuals to have access to my records.	
4. I hereby declare that I have not been subjected to any form of coercion in	n giving
this consent.	
5. I agree to the data about me collected in this study being stored for fur	ther use
in the future. (delete if not applicable)	
6. I will gift these samples so that they may be used for future ethically a	pproved
research. (delete if not applicable)	
7. I agree to take part in this study.	

Signing this declaration does not affect your right to decline to take part in any future study.

Name of participant	Date	Signature	
Name of person taking	Date	Signature	

Consent

When complete: 1 copy for participant; 1 copy (original) for research

e. Additional file No.5

The effect of Emergency Obstetric and Newborn Care training interventions on knowledge and skills of midwifery students prior to graduation in Kenya: A randomised control trial

Student pre-assessment questionnaire

Date Today	Day	Month	Ye	ar																
Gender:	Male	F	Female				A	.ge:]	Parti	cipar	nt Nu	mber	:			
]									
County coo	de: Institution																			
code:																				
1. Numbe 2a. Have	er of months to you completed	gradua ł EmON	tion? NC trair	ning	with	in y	our 1	midv	wife	ry cur	ricu	lum	? (If N	lo, go] Ye to Q2c	s c and f] No inish c	D	onnaire	:)
2b. What	topics did the	course(s) cove	r? (P	leas	e pu	t a c	ross	X r	next to	o all	that	app	oly)						
	Adult Resuscita Resuscitation Management Ha Sepsis	ation Ne Ecla aemorrha	wborn umpsia ge				[[[V M B M	acuum Ianual reech E Ianager	Deli Rem Delive	very noval ery of Al	of PH/I	Plac PPH	eenta					
	Managing Obste	etric Com	plication	IS			[M C	lanagin ompleti	ig coi	mplic partog	cation graph	ns of 1s	abor	tion				

Other	(please specify:)	
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2c. When did you receive EmOC training as part of your midwifery training?

Never	In the first year	In the second year	In the third year	In every year
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2d. Was there a 'hands on' EmONC training session where you practiced on obstetric and newborn mannequins before clinical experience in the maternity/labour wards?

Never	Yes	No

Additional file 6

The effect of Emergency Obstetric and Newborn Care training interventions on knowledge and skills of midwifery students prior to graduation in Kenya: A randomised control trial

Student self-reported questionnaire version

001 13.10.2017

Casey-Fink Readiness for Practice Survey tool

This survey is to examine senior midwifery students' perceptions of readiness for professional practice regarding emergency obstetric and early newborn care

There are four sections, please complete all sections

Section 1: General/Demography information

Institutional study code		
What year of midwifery training are you in?		
Duration of midwifery module		
Number of hours per week of clinical training (hours spent in obstetric wards)		

Did your midwifery training module contain the following topic? Please respond Y/N/don't know for each EmONC topic			
EmONC topics	Yes	No	Don't know
Newborn resuscitation with bag and mask			
Assisted vaginal delivery (vacuum delivery)			
Management of post- partum haemorrhage			
Management of severe pre-eclampsia and eclampsia including use of magnesium sulphate			
Manual removal of placenta			
Blood transfusion			
Peri operative care			

Section 2

Please identify the top three EmOC skills/procedures they are uncomfortable performing independently. Please report about level of comfort/confidence in performing these EmOC skills/procedures using a Likert scale (1=strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree).

S/No	EmOC skills/procedures	Level of comfort/confidence in performing	Other comments
1			
2			
3			

Section 3

1. What were the reasons for choosing nursing/midwifery as a profession?

2. What could be done to help you feel more prepared to enter provide emergency obstetric care after graduation.

Section 4

From the list of twenty items below, please report about your level of comfort/confidence in activities using a Likert scale (1=strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree) performing key nursing/midwifery

		Level of comfort/confidence in performing
	Clinical Problem Solving	
1.	I feel confident communicating with medical doctors	
2.	I am confident in my ability to problem solve	
3.	I use current evidence to make clinical decision	
4.	I am comfortable communicating and coordinating care with interdisciplinary team members.	

5.	I feel comfortable knowing what to do for a dying patient	
6.	I feel comfortable taking action to action to solve problems	
7.	I feel confident identifying actual or potential safety risks to my patients	
	Learning Techniques	
8.	Simulations (including use of EmONC mannequins) have helped me feel prepared for clinical practice	
9.	Writing reflective journals/logs provided insights into my own clinical decision-making skills	
	Professional Identity	
10.	I feel comfortable communicating with patients and their families	
11.	My clinical instructor provided feedback about my readiness to assume RN role	
12.	I am comfortable asking for help	
13.	I am satisfied with choosing nursing as a career	
14.	I feel ready for the professional nursing	
	Trials and Tribulations	
15.	I am comfortable delegating tasks to the nursing assistant	
16.	I have difficulty documenting care in the electronic medical record	
17.	I have difficulty prioritizing patient care needs	
18.	I feel overwhelmed by ethical issues in my patient care responsibilities	
19.	. I have difficulty recognizing a significant change in my patient's condition	

KMTC institutional Information 2 version 1: 201/10/2018

Date of data	
collection:	
Name of KMTC:	KMTC code:
County	
Interviewer:	

Received information sheet?	Yes/No
Consent to be interviewed?	Yes/No
Happy for discussion to be recorded?	Yes/No

All questions relate to the cohort of students who completed their studies in May/June 2018.

Students

 On what basis were this cohort of students selected? (previous education, test, ability to pay fees, Govt. sponsorship, external, what proportion of each?)

Skills labs and training equipment (mannequins)

- 1. Do you have a skills lab or room for conducting practical training sessions in your KMTC?
 - a. when was it established/equipped? ____
 - b. Was it available when this cohort did their EOC training?
- 2. If no, do you have access to one elsewhere (and if so where)?
- 3. How frequently is it used as part of the teaching?
- 4. Can students access it at other times and if so, how often do they use it?
- 5. Is there a full set of EOC equipment in the skills lab, if not, what's missing?
- 6. Is it in good working order or is any of it damaged? (please give details) _____
- 7. Who is responsible for maintaining the equipment? _____

8. Any other comments about use of the skills lab

Teaching space

- Do you have sufficient classroom space for all your teaching sessions including both theoretical and practical sessions?
- 2. If not, please give details.
- Do you have sufficient chairs/desks in reasonable working condition for students use during teaching sessions?

Teaching content

- 1. Which EOC topics are usually taught to students?
- 2. Are these taught as Theory/didactic, Practical (mannequins), Bedside? (please give details of each)

S/No.	Торіс	Mode of teaching (Theory/didactic,
		Practical (mannequins), Bedside

Midwifery teaching

- 1. How many KMTC staff are involved with teaching midwifery modules? _____
- 2. Which members of staff are involved in teaching midwifery modules?
- 3. At what point during the course are these taught? (please give details)______
- In the last 5 years, what training/updating in EOC have these members of staff received? (please give details who, when, where, what, by whom) ______

Clinical placements

- 1. How are students received generally when they go out on clinical placements (Orientation, specific mentor or tutor allocated)?
- 2. Have you had any problems with students not being well received? (please give details)
- Do members of KMTC staff carry out clinical supervision with students when they are out on clinical placement?
- 4. If so, how often and for how long? _____

EOC training course (Groups A & B only)

- 1. What was covered in the EOC training course you attended?
- 2. What content did you find most useful and why? ______
- 3. What content did you find least useful and why?_____
- 4. What teaching methods were used on the course that you attended?
- 5. In terms of the teaching methods what did you find most useful? _____
- 6. In terms of the teaching methods what did you find least useful? _____
- 7. Has attending the course changed the way in which you teach your students? (please give details)

8. What could be improved? _____

- 9. What worked best?_____
- 10. What was most relevant to your students? ______
- 11. What was most useful in developing teaching materials/curriculum?______
- 12. Have you attended any other EOC trainings? Please give details (when, by whom, what was covered).
- 13. Are there any other topics which you think should be included? (please give details)