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An evaluation of the effectiveness of an updated pre-service midwifery curriculum integrated with emergency obstetric and newborn care in Kenya: a cluster randomised controlled trial

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Abstract

Introduction Quality midwifery education is central to improving midwifery service delivery and maternal and newborn health outcomes. In many settings, midwifery educators insufficiently prepared for their teaching role and deficient curriculum compared to international standards affect the quality of healthcare provided by the midwifery graduates. This study assessed the effectiveness of an EmONC enhanced midwifery curriculum delivered by trained and mentored midwifery educators on the quality of education and student performance in Kenya.

Methods A cluster randomised controlled trial in 20 midwifery colleges (12 intervention, 8 control colleges). Educators in both arms received training in teaching/EmONC skills to deliver the updated national midwifery curriculum. The intervention arm received additional 3-monthly post-training mentoring for 12 months. Educators' knowledge and confidence in EmONC/teaching skills was assessed before and after training and at 3, 6, 9 and 12 months. Teaching skills observations at baseline and endline in both study arms were also assessed. Knowledge, self-rated confidence and three OSCE in EmONC practical skills among final year midwifery students were assessed. Linear mixed effects models were used to evaluate the effect of intervention on educators and students.

Results Seventy four educators and 146 students participated. Training significantly improved educators' mean knowledge (61.3%-73.3%) and confidence to teach EmONC (3.1–4.2 out of 5). Observed teaching skills mean scores of educators in the intervention arm were significantly higher compared to those of controls at endline (89.4%-vs-72.2%, mean difference 17.2 [95%CI, 3.2–29.8]). Mean scores for students in the intervention arm were significantly higher than those in controls for knowledge (59.6%-vs-51.3%, mean difference 8.3 [95%CI, 1.6–15.0]) and the three skills assessed (means; mean difference (95%CI): shoulder dystocia (64.5%-vs-42.7%; 21.8 (10.8–33.9); newborn resuscitation (43.9% vs 26.1%; 17.8 (2.0–33.9); and maternal shock resuscitation (56.5%-vs-39.2%; 17.3 (8.0–26.0) and combined average skills scores (55.0%-vs-36.0; 19.0 (8.7–29.5).

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Conclusion Training and supportive mentoring improved the quality of educators' teaching pedagogy and EmONC skills and enhanced students' learning. Overall performance in EmONC knowledge and skills was significantly higher for students who were taught by trained and mentored educators compared to those who received training alone. Thus, a local mentoring system is effective to enhance learning and effectiveness of an EmONC-updated midwifery curriculum.

Keywords Midwifery, Emergency obstetrics and newborn care, Curriculum, Education, Kenya

Introduction

Midwives play a critical role in the reduction of preventable maternal and newborn mortality [1, 2]. When supported by interdisciplinary teams and working within an enabling environment, they can deliver up to 90 percent of essential sexual, reproductive, maternal, newborn and adolescent health interventions [3]. Their interventions can avert 67% of maternal deaths, 64% of newborn deaths and 65% of stillbirths [4]. Current estimates attribute up to one third of all maternal and neonatal deaths to poor quality maternal and newborn care [5]. Improving quality of care is key to achieving the maternal and newborn health sustainable development goals (SDGs). However, there is gross under investment in midwifery education and training in low- and middle-income countries (LMICs) that is affecting the quality of midwives produced and subsequent quality of care [3, 6].

Evidence shows that midwifery graduates are inadequately prepared with limited support and do not possess the requisite WHO and International Confederation of Midwives (ICM) competencies needed to function adequately as skilled health personnel after graduation [7–12]. Barriers to the quality midwifery education include: a deficient and largely didactic curriculum; educators are more confident with theoretical classroom teaching than clinical teaching; inadequate teaching resources; and lack of/insufficiently trained midwifery educators leading to inadequately skilled graduates [3, 7–11, 13, 14]. The 'Global Strategy on Human Resources for Health: Workforce 2030' calls for education strategies that should focus investment on trainers, for which there is good evidence of a high social rate of return. Consequently, it calls for priority on curricula to produce professionals capable of meeting local needs [15]. Skilled health personnel are defined as competent healthcare professionals (including midwives, nurses, obstetricians, paediatricians and anaesthetists) providing care during childbirth. The 2018 joint statement by WHO, UNFPA, UNICEF, ICM, the International Federation of Gynaecology and Obstetrics (FIGO) and other global bodies emphasize that these professionals should possess competencies (knowledge, skills and behaviours) to perform (as part of a team) all signal functions of emergency maternal and newborn care to optimize the health and well-being of women and newborns [16]. However, evidence suggests that majority of midwives gain basic skills – the ICM Competencies for Midwifery Practice – through in-service training and on-job experience than in pre-service training [17]. This leads to production of graduates that are inadequately prepared and less competent [10, 18]. Training of skilled health personnel in emergency obstetric and newborn care (EmONC) is an approach that is successful in improving knowledge and skills, clinical practice and MNH outcomes [19, 20].

Emergency obstetric and newborn care is defined as the collective minimum set of medical interventions (or bundle of care) required to prevent or manage the main obstetric complications (haemorrhage, pre-eclampsia or eclampsia, sepsis, complications of obstructed labour or abortion) and newborn complications (birth asphyxia) [19]. The Kenyan government has included this training as a priority in the National Health Policy 2014–2030 [21]. However, the focus has been on in-service EmONC capacity building [22–24]. A gap analysis of pre-service and in-service midwifery competency education in Lao People's Democratic Republic and Democratic Republic of Congo showed that basic emergency obstetric care, postpartum care, essential newborn care and post-abortion care competencies were either lacking or not fully covered in the pre-service training curriculum [25, 26]. In Afghanistan, only half (54 percent) of the midwifery educators were trained in EmONC [11]. To improve the effectiveness of periodic in-service EmONC training programmes, EmONC should be covered within pre-service midwifery and medical curriculum and adequately taught in training institutions.

The ICM's Global Standards for Midwifery Education (2021) and WHO, UNFPA, UNICEF and ICM's 'seven-step action plan to strengthen quality midwifery education' provides a clear framework of action to improve midwifery education. The key investments to achieve quality midwifery education include (i) strengthening educational institutions, practice settings and clinical mentors; (ii) strengthening faculty, standards and curricula; (iii) monitoring, evaluating, reviewing and adjusting; resources; (iv) educating students and quality improvement as key investments to result in competent midwifery graduates potentially contributing to achievement

of maternal and newborn health (MNH) SDGs and universal health coverage [13, 27]. The WHO outlines eight core competencies that midwifery educators must possess for quality education and training. These include maintaining current knowledge & skills in midwifery theory and practice, effective clinical teaching of midwifery care and facilitating learning [27]. Mentoring in nursing and midwifery education has been acknowledged as an effective system for developing competent and confident educators [28–30]. Where this has been implemented, international consultants who are the capacity 'builders' have largely designed and implemented the mentorship interventions for national participants. However, evidence of local/national co-designed and implemented midwifery educator mentoring programmes in low resource settings is limited [31].

Investments are urgently needed to improve the quality of midwifery education, and in particularly the knowledge and skills required for management of obstetric and newborn emergencies [8–11, 32–34]. The ICM recommend that at least 50 percent of midwifery education should be practice-based and provide experience in clinical and community settings [35]. Educators are required to structure curriculum and develop learning activities that enable midwifery graduates to learn the knowledge and develop skills and behaviours. These competencies promote the role of the midwife to assess, diagnose, act, intervene, consult and refer as necessary, including providing emergency obstetric and newborn care interventions during antenatal, labour, birth and the postnatal period [36].

Strengthened midwifery curriculum and faculty in Kenya

Midwifery education in Kenya is offered predominantly as integrated nursing and midwifery programs in mid-level training colleges and universities at basic and advanced levels (diploma, bachelor, masters and doctoral). Midwifery educators at both Kenya mid-level training colleges and universities are inadequately prepared to teach EmONC within the pre-service curriculum [37, 38]. To improve the quality of pre-service midwifery education and training, the Kenya Ministry of Health (MoH) in its Health Sector Strategic Plan 2018 – 2023 prioritised review of curricula to address emerging issues (including universal health coverage), strengthening the capacity and quality of pre-service faculty and clinical instructors on EmONC [39].

In 2016, Liverpool School of Tropical Medicine (LSTM) with funding from the United Kingdom's Foreign, Commonwealth and Development Office supported the Kenya MoH to strengthen the quality of midwifery education and training. These included a bundle of interventions that were shown to be effective in improving the knowledge and skills of final year midwifery students [40]. To ensure that the gains achieved are sustained, there was demand to invest through policy and regulation for delivery of high-quality care. Through the MoH-led Pre-service Taskforce, LSTM supported a detailed review of the national nursing and midwifery syllabus at the Nursing Council of Kenya and curriculum at Kenya Medical Training College (KMTC). Curriculum content integrating EmONC and teaching pedagogy were updated [38] and aligned with the WHO and ICM competencies for midwifery educators. The aim of the review was to facilitate a shift from the largely theoretical training to a competency-based skills training of an EmONC enhanced curriculum. This would provide a strong midwifery foundation and reduce the need for long duration and unsustainable EmONC trainings after graduation for midwives. This was followed by building/strengthening the capacity of the training institutions and midwifery educators to deliver the updated EmONC-enhanced curriculum through short and repetitive 'skills and drills' training and mentorship over time as these training modalities help to build layers of knowledge and skills in EmONC [22, 27, 28, 35]. Summary of the curriculum review and capacity strengthening interventions are summarized in Table 1.

Table 1 Improving quality pre-service midwifery education interventions in Kenya

Improving quality pre-service midwifery education interventions in Kenya
1. Reviewed the pre-service midwifery training syllabus at Nursing Council of Kenya
2. Reviewed the pre-service midwifery training curriculum at Kenya Medical Training College
3. Mapped out the training hubs/centres of excellence
4. Equipped/replenished the hubs' skills laboratories with EmONC training equipment
5. Mapped out the national level midwifery educators as master trainers (MTs)
6. Trained 50 MTs on the updated syllabi and master training (3-day virtual and 2-day face-to-face)
7. Trained 313 midwifery educators in the training colleges across the country on the updated curriculum (2-day virtual and 2-day face-to-face)
8. Mentoring of educators on teaching methodologies and EmONC skills

WHO's action 7 of the 7-point action plan "Monitor, evaluate, review and adjust" is critical to strengthen quality midwifery education [13]. Although there have been two studies evaluating the effectiveness of EmONC training for pre-service students, generalising the results are limited by the type of participants included (medical students and interns) and weak study designs [41, 42]. Besides, evaluations on the effectiveness of an updated EmONC-enhanced pre-service midwifery curriculum, faculty development and institution strengthening, on the quality of midwifery education and students' performance in LMICs are limited.

The objective of this study was to assess whether training and supportive mentoring improves the quality of teaching, knowledge, and the confidence of the midwifery educators in delivering an updated competency-based curriculum in Kenya. Additionally, the effect of this educator focused intervention on students' knowledge and skills in EmONC was evaluated. The study is important as it (i) addresses a major gap in pre-service curriculum content against ICM standards for midwives [8, 10, 11, 33, 43] (ii) addresses a major gap in faculty development for effective quality teaching and practice [8, 32, 37, 38, 44] (iii) integration of EmONC within the pre-service midwifery curriculum to equip nursing and midwifery graduates with essential EmONC competencies as skilled health personnel as recommended by ICM and WHO at graduation [8, 33, 36, 45] (iv) potentially reduces the need for longer duration and resource-intensive in-service EmONC trainings after graduation required for optimal skilled care at birth [32, 46, 47] and (v) provide a strong foundation for targeted regular, short and structured mentoring to strengthen midwifery educators' capacity to deliver a competency-based midwifery education curriculum [48].

Methods

Study design

This was a cluster randomized control trial design prospectively registered at the International Standard Randomised Controlled Trial (ISRCTN 14203188 (09/12/2020)) with mixed research methods conducted in 20 KMTCs. This robust design is widely used to evaluate the effectiveness of interventions applied to groups of individuals and provides high-quality evidence as a rigorous tool to examine cause-effect relationships between an intervention and outcome [49, 50]. In this design, the unit of randomization is a group of individuals (like a school), where the entire group is assigned to a single treatment condition [51]. The college (KMTC) was the unit of randomization as the interventions were targeted to groups of educators in the intervention and control arm colleges. Midwifery educators from both arms received training on the teaching pedagogy and delivery of the updated EmONC-enhanced curriculum. Educators in the intervention arm received additional mentoring and peer support on teaching and EmONC skills every three months for one year (summarized in Table 2). Effectiveness was assessed at the Kirkpatrick level 1 (participant's reaction including experiences in implementing the updated curriculum), level 2 (change in knowledge, confidence and skills) and level 3 (change in behaviour; applying learned knowledge and skills) [52]. The outcome measures were: knowledge, confidence and teaching/EmONC skills over the different time periods. Students' performance in knowledge, confidence and practical skills in EmONC after their midwifery modules but before their final qualifying examinations and graduation was also assessed. Difference in outcome measures in both study arms for educators and students were assessed. The Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting cluster-randomized trials were followed (Fig. 1) [53].

A rich description of experiences, barriers and perspectives of midwifery educators, mentors and students implementing the updated emergency obstetric and newborn care-enhanced pre-service midwifery curriculum were also explored (Kirkpatrick level 1). Findings are reported in a separate nested qualitative study within the cluster randomised controlled trial [54].

Randomization

Two levels of randomization were implemented. First, colleges, stratified by former eight provinces as regions, were assigned by simple, random allocation by manually drawing lots without replacement to the intervention or the control arm as the number of participating institutions was small. The lead researcher and corresponding author (independent and not a faculty member of KMTC) with two KMTC representatives performed the random allocation of colleges to study arms. The process included generation of the random allocation sequence, allocation concealment, and implementation of the random allocation sequence. Sixteen [16] colleges were randomly allocated to either intervention or control arm in a ratio of 1:1. Four colleges designated

Table 2 Interventions educators received in the trial

Intervention colleges	Control colleges
Training on teaching pedagogy and EmONC skills	Training on teaching pedagogy and EmONC skills
3-monthly mentoring visits including - Teaching observations and debriefing - EmONC skills teaching support	

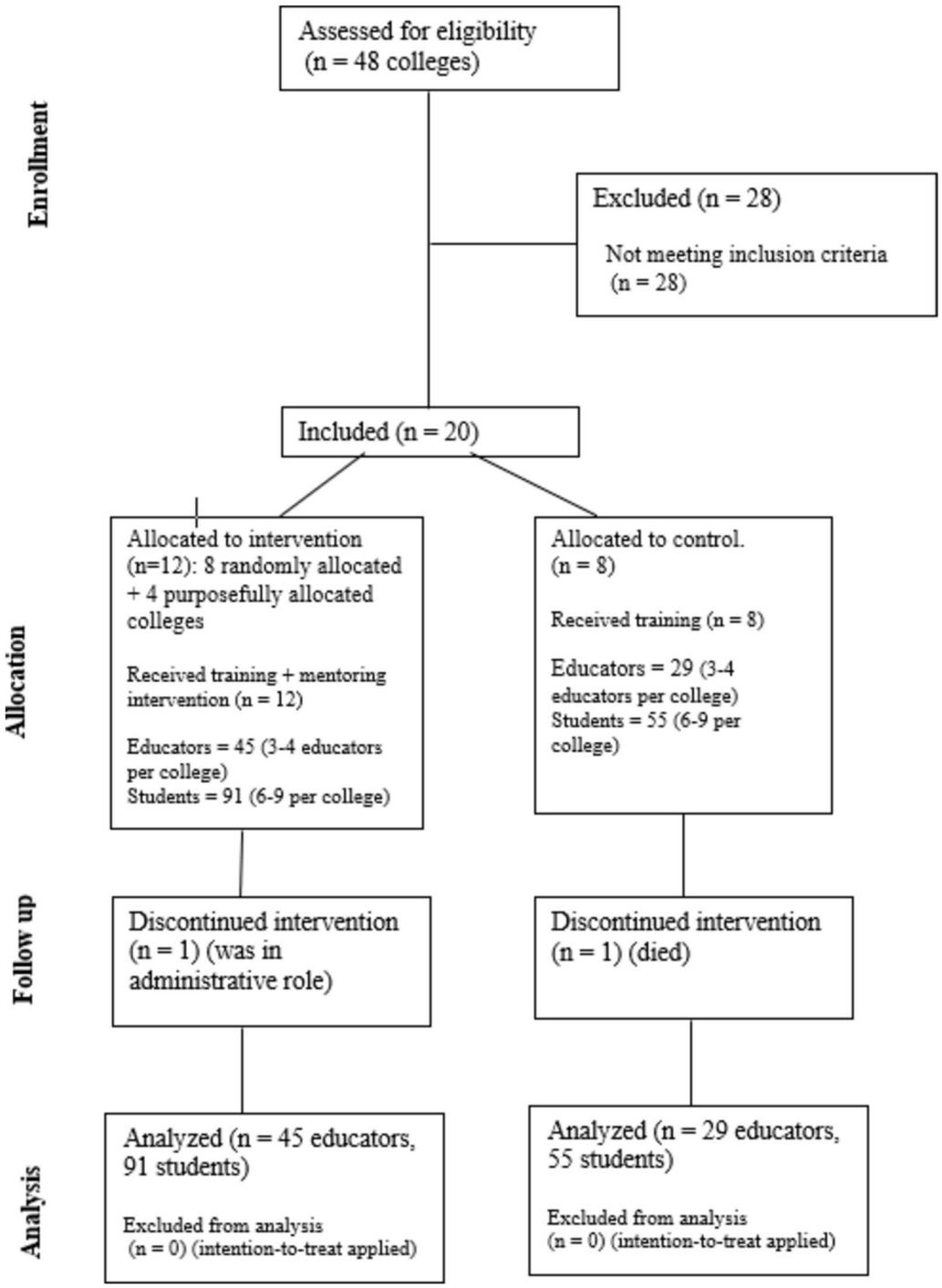

Fig. 1 CONSORT diagram showing the flow of participants through each stage of a randomized trial

as training hubs because of their central location and accessibility to other colleges in the region were purposefully allocated to the intervention arm. These training hubs did not have comparative advantage over the other colleges in technical and infrastructural capacity. Importantly, there were no statistically significant differences in mean scores in the last common national examinations for midwifery modules taken by all the colleges between the 12 interventions and 8 control colleges (54.8% vs 59.0%, $p=0.111$) or the 4 hubs, 8 interventions and 8 control colleges (55.7%, 54.4% and 59.0% respectively, $p=0.272$).

The four training hubs acted as host centres where trainings for educators across the country were conducted (activity 6 and 7 in Table 1). To account for the randomisation in clustering, sensitivity analyses for robustness of the results were planned (described in the data analysis section). Secondly, educator participants from the same college were assigned to different tests on each assessment period by simple random allocation (see details in the knowledge assessment section).

Blinding/masking

Midwifery educators were not blinded because the intervention required their overt participation. Colleges were randomized to study arms rather than individuals to avoid contamination among educators in the same college. The master trainers, mentors and data collectors were mutually exclusive. Double blinding was applied in the assessment of students. Both students and data collectors were blinded to the intervention and so did not know whether the colleges were intervention or control sites during the assessments. Data collectors were also not aware of the mentoring intervention that had been completed in the colleges prior to the assessments. Only the lead researcher and corresponding author accompanying the data collectors was aware of the study arms. Importantly, the status of the colleges was concealed throughout the assessments and the lead researcher did not participate in the actual assessments of students.

Study setting

This study was conducted in the KMTC, the largest public tertiary institution with 72 campuses strategically located nationwide. Diploma in nursing and midwifery (Kenya Registered Community Health Nursing) is the predominant programme offered in 52 campuses although certificate and higher diploma programmes are also offered in a few select campuses. A single academic calendar (for all courses offered in KMTC) and nursing and midwifery curriculum is developed at the KMTC Headquarters in Nairobi and is used across all the KMTC campuses for training of nurse midwives in Kenya. Each campus has faculty recruited and posted from the KMTC Headquarters, except for additional clinical instructors/preceptors required (with the approval of the KMTC Headquarters) at the respective hospitals to support clinical training of students. The graduates of the KMTC account for more than 85 percent of the middle level workforce in the health facilities in Kenya [55]. Each KMTC has two intakes of 50 students each per year (March and September), thus approximately 50 final year midwifery students are expected to graduate annually. The training of midwifery educators on the Nursing Council of Kenya approved updated pre-service midwifery EmONC-enhanced curriculum was conducted in four LSTM established KMTC training hubs in the country.

During training, student midwives go for clinical placements in the maternity and newborn health wards under the guidance of their educators or clinical instructors/preceptors. Each campus is attached to either a level 4 (sub-county/district), 5 (county/regional) or 6 (national) health facility providing comprehensive EmONC services for clinical placements. High volume lower-level health facilities may be used to supplement clinical training of midwifery students especially when there are insufficient numbers of obstetric and newborn emergencies for training.

Intervention

The updated national midwifery curriculum review

The predominant Kenya Registered Community Health Nursing (KRCHN) taught in all campuses and the Kenya Registered Nursing and Midwifery (only taught in select campuses) curricula for training of nurse midwives in Kenya were reviewed and updated with EmONC and approved by the Nursing Council of Kenya. The previous 3.5-year KRCHN curriculum was last reviewed in 2013. The new updated nursing and midwifery curriculum is a 3-year programme with a combined 1232 h for theory teaching and 4033 for practical learning and experience. Midwifery alone has 231 h for theory teaching and 1526 h for practical learning and experience in the skills lab; mother and child health clinic; antenatal, intrapartum (labor ward) and postnatal wards; newborn unit; obstetrics operating theatre and 40-h block dedicated to EmONC skills training. The LSTM Emergency Obstetric Care and Newborn Care Skilled Health Personnel training package was used. This package has been used by LSTM in collaboration with the Ministries of Health in over 15 LMICs to strengthen the capacity of maternity care providers for quality EmONC provision [19]. The review included updates in the training guidelines on the related modules (covering teaching content, time allocated for theory and skills teaching & practice, teaching/learning resources, teaching methods aligned to the intended learning outcomes), assessment tools and strategies and student clinical practice training logbooks. The midwifery content was updated and aligned to the ICM's four essential competencies for midwifery practice: general competencies; pre-pregnancy and antenatal; care during labor and birth; and ongoing care for women and newborns [56]. The content included Communication using the SBAR (Situation, Background, Assessment & Recommendation) approach, respectful maternity care, focused antenatal care (FANC) 4 visits to WHO 8 ANC contacts, updates on EmONC signal functions, WHO

safe surgical checklist, modified early obstetric warning systems and updates on current maternal shock recommended management. Other key concepts introduced/updated were: care of mothers after traumatic birth or perinatal loss, postpartum family planning, menstrual hygiene, community midwifery, teenage pregnancy, male partner involvement and maternal and perinatal deaths surveillance and response (MPDSR). In addition to the content, the updated curricula included principles of adult teaching and learning focusing on stimulating participatory teaching methodologies – simulation/skill demonstration using low fidelity mannequins, scenarios and role plays for effective learning. Other updates included facilitating online teaching and learning; students' assessments and providing effective feedback; academic writing; critical thinking and appraisal; presentation skills; flipped classroom teaching, peer learning and support in teaching. Following curriculum review, the table below summarizes the interventions educators in the trial received in the study (Table 2).

Training of midwifery educators on the updated midwifery curriculum

Midwifery educators were upskilled on delivery of the updated EmONC-enhanced curriculum in a two-part (virtual and face-to-face delivery) capacity building workshop in May 2021 (during the COVID-19 pandemic). The training components are listed below: -

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

Part 1 was a two-day virtual facilitated workshop of 8 h for the theoretical component (including an additional module on 'facilitating online teaching' as part of the COVID-19 containment measure and modification to pre-service teaching). Additional details on the virtual training are reported in a separate paper [38]. Part 2 was a two-day face-to-face facilitated workshop of 19 h for the skills-based component. This practical component was preceded by 13 h of self-directed learning of the emergency obstetric and newborn complications, and teaching pedagogy. The training was delivered by a Kenya MoH approved multidisciplinary group of experienced EmONC master trainers, course directors and quality assurance officers. The training content was delivered through the simulation based medical education, active and participatory teaching methods – short lectures, role plays, plenary/small group discussions, scenarios and skills drills using various low-fidelity mannequins and equipment. Each small group/skills breakout session had 7–8 participants to allow for sufficient time for hands-on skills training, return demonstrations and skills transfer. Targeted mentorship support sessions were also held for participants who needed some extra guidance/demonstration for certain skills or sessions. At the end of the training, the LSTM EmONC Skilled Health Personnel training package (facilitator manual) was shared with each of the educators as an additional resource to support teaching of EmONC at their institutions.

Mentoring support intervention

Evidence from a multi-country longitudinal study on knowledge and skill retention with 3 monthly assessments for 1 year showed knowledge and skills retention up to 1 year. In addition, midwives who attended all the four assessment and debriefing sessions had statistically significant better retention of skills but not knowledge compared to those who attended one or two assessments only [46].

A group of 10 experienced EmONC faculty consisting of educators and clinical staff were recruited and trained as mentors. Educators were from midwifery institutions not included in the study and they did not form part of the master trainers who supported the training interventions of educators in Table 1. They received a virtual one-day mentorship training facilitated by the corresponding author and an LSTM – UK senior MNH specialist with experience in EmONC capacity strengthening and pedagogy. Training focused on introduction to mentoring, building effective working relationships, giving effective feedback, handling difficult situations during mentorship, and teaching pedagogy. The training used interactive lectures, discussions and case studies.

Mentors were facilitated with a transport, resource and meals/accommodation allowance in line with Government of Kenya guidelines, to conduct a one-day mentoring visit for educators (mentees) in the 12 intervention colleges. This was completed every three months for a period of 12 months in the institution's skill lab. Prior to the mentorship sessions, the mentor and mentees had a phone call discussion, identified priority needs/skills for support and their availability at the campus for onsite support. In addition, the self-reported feedback by the mentees in the online questionnaire completed every three months also informed the priority areas for mentoring support. Mentoring sessions targeted the participating educators in the study as a group within the institution and lasted on average between 2 – 4 h per educator mentee per institution. Mentoring sessions focused on teaching skills, EmONC skills and drills and

giving effective feedback to promote learning among students especially on performance of critical lifesaving EmONC skills or scenarios. The EmONC skills and scenarios included performance of complicated births – breech, shoulder dystocia, assisted vaginal birth (vacuum extraction), perineal tear/episiotomy repair and maternal/newborn resuscitation, pre-eclampsia/eclampsia, maternal shock among others. During the mentoring sessions for EmONC skills, mentees had a skill run through to check practice, gaps and opportunities to standardize practice. The mentor demonstrated the skill using the 4-staged approach and allowed a return demonstration from each of the mentees to check learning and mastery. As this was a mutual relationship, skills assessment forms were not completed although the EmONC facilitator manuals were used on every skill to ensure compliance and mastery of the steps. After each return demonstration, debrief and peer supportive feedback was provided by fellow mentees and mentor to strengthen good practices and promote confidence for skills transfer to the students during teaching. Mentors and mentees also formed a community of practice using the WhatsApp platform to support peer-to-peer learning and ongoing mentoring. At the end of the mentoring visit, debrief sessions were held by the mentor, mentees and the campus administration as necessary. The debrief provided feedback and areas that needed institutional support to promote quality teaching and learning. On occasions where the corresponding author was not present at the mentoring visit, the mentor recorded and shared field notes on key strengths observed, areas for further support and the action points agreed with the mentees.

Teaching observations and support

The college teaching timetable/plan for the nursing and midwifery classes was shared by the mentees with the mentor two weeks prior to the teaching observations for the mentor's independent planning and identification of the session/s to observe. Sessions involving an EmONC signal function/skill/procedure/content were selected for observation. Structured direct observation of teaching sessions (theoretical or practical) and support by mentors for midwifery educators were conducted in the intervention arm of the study at 3, 9 and 12 months after the training. Key elements of good quality teaching and learning were observed including: (1) teaching style, (2) use of visual aids, (3) teaching environment and (4) student involvement using a standardized observation checklist [57]. Direct observation 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 [58, 59]. This allowed the educators to be observed in their natural environment without interfering in their process of teaching the students. Debrief and support through peer review and reflection formed part of the normal practice for the educators to strengthen their teaching skills. Mentee educators had a one-on-one opportunity to self-evaluate their teaching and received supportive constructive feedback from the mentor to improve effective teaching practices and learning. LSTM's lead researcher and associate fellow in the United Kingdom Higher Education Academy based in Nairobi Kenya conducted quality assurance visits to some of the mentoring sessions for all mentors.

Eligibility of training institutions

The eligibility criteria for training institutions included: (i) Evidence of teaching and examined students on the midwifery curriculum in the five years preceding 2020 (regulatory and institutional curriculum review is conducted every five years) and (ii) Have at least three midwifery educators so that routine school calendar was not disrupted during the training period.

Sample size determination, colleges and participants

Colleges and educators

The design involved randomisation of colleges 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 were used, thereby enabling the changes within participants to be measured. The Shiny app (https://clusterrcts.shinyapps.io/rshinyapp/) developed by Karla Hemming for cluster randomised trials was used for sample size calculation [60]. Relevant data on which to base selection of the values for use in sample size / power calculations were not available. It was assumed that intra-cluster correlations coefficient (ICC) (the correlation between responses of different educators within the same college in a given assessment occasion) was 0.1 and that cluster autocorrelation (CAC) (the correlation between means for a given college on different assessment occasions) and individual autocorrelation (ICA) (the correlation between scores for a given lecturer on different assessment occasions) were both at 0.8 when eight colleges were randomly allocated to each group to give a high power to detect any differences in outcomes. The primary outcome (change in knowledge scores) was measured on a continuous scale and a standard deviation of 20% assumed (the baseline mean score on average was assumed to be 50% implying that two thirds of responses would be between 30 and 70% and almost all would be between 10 and 90%). The mean (SD) number

of educators who participated at each college was assumed to be 3 (0.6) based on available staffing levels per eligible college. It was therefore estimated that 36 and 24 educators will participate in the intervention and control groups respectively. Consecutive sampling was used for selecting the available educators until the sample size was achieved. It was assumed that the improvement with training is from 50 to 60% and that with the additional support it would be 78% [61–63]. With CAC and IAC both as high as 0.8 and the within period ICC of 0.1, a 89% power would detect a difference of 18% in a total of 8 randomized colleges to each arm participating in the study. As these assumptions were based on the value of the intra-class correlation coefficient, a minimum of 60 educators were eligible for participation in the study.

Students

Final year nursing-midwifery students (KRCHN March 2020 class), the first group to be taught the updated EmONC-enhanced curriculum participated in the study to evaluate the effectiveness of implementation of an updated pre-service midwifery curriculum. This group had completed the midwifery theory and skills sessions including clinical rotations and experience in the wards and waiting to write their final college qualifying examinations and graduation. Thus, this was the preferred group for assessing any association between delivering the updated pre-service midwifery curriculum by trained and mentored educators and the knowledge and skills of students in EmONC before graduation.

Each participating college was estimated to have between 36 and 57 students. Using the estimated number of students per college (N), we determined the number of strata (S) to be formed and the number of excess students (R) and used 6 as the minimum number of students to participate per college so that S = (N-R)/6, where S and R were both integers and $R < 6$. Each strata had a complete set of 6 students within the same rank of overall performance mean score in the previous common examination completed. The excess students (R) were removed from the list following ranks that were symmetrically arranged, so that ranking the best highest or lowest yielded the same selections to give the final number of students to participate in the college as 6S. After removing the excess students to form a complete stratum of 6 students per stratum per college, a college had either 36, 42, 48 or 54 eligible students to participate, depending on the total class population which ranged between 36 and 57 students. Students to participate per college ranged from 6 – 9 depending on the student population in the class.

Data collection

Midwifery educators' assessments

Recruitment of educators

After randomisation of colleges, a contact list of all eligible nursing and midwifery educators from each college was shared with the lead researcher. The lead researcher then shared an online participant information sheet with the study details and consent form with all the eligible educators. After consent, the lead researcher allocated a unique identifying number to each of the participants. Each participant kept their number safe for use on subsequent assessment occasions.

Knowledge and confidence among midwifery educators

Knowledge and confidence of midwifery educators to teach EmONC and apply different teaching methodologies in both study arms were assessed over time through an anonymous online questionnaire designed using a secure online platform. Knowledge was assessed for both study arms simultaneously immediately before the start of the virtual/online training (baseline), immediately after the face-to-face training and at 3, 6, 9 and 12 months after training from a questions bank developed for this study. The lead researcher administered the online questionnaire using email and/or WhatsApp application at each assessment occasion. Ten multiple choice questions (MCQs) were used on each occasion. The knowledge questions used at baseline and immediately after the training were similar. Four distinct tests of knowledge questions (denoted by T1, T2, T3 and T4) were used in the subsequent assessments. Participants were allocated to four groups of 18 each (denoted by G1, G2, G3 and G4). Participants from the same college were each randomly allocated to one of the four groups to ensure that at least participants from the same college were not completing a similar test at any given assessment occasion to minimize chances of potential consultations. Each participant was assessed on four occasions, once per test in each assessment round. The groups were all assigned to a sequence in which the four tests were used on the four assessment occasions.

The lead researcher made reminders to complete the knowledge questionnaire through phonecalls, whatsapp or text message. He also maintained an updated color-coded tracker designed in MS Excel for the research assessments that informed the reminders to be made for completion of the questionnaire.

Teaching skills among midwifery educators

This was completed by a study team comprised of eight experienced EmONC faculty of midwives, obstetricians and selected midwifery educators trained as master trainers. This group did not participate in the training

intervention of educators in Table 1 to prevent bias during follow-ups. They received a 4-h orientation and training on the use of the online data collection checklist at a pre-observation planning meeting to ensure there is clarity and agreement on how to score and complete the tool.

Structured direct observation of teaching sessions (theoretical or practical) for midwifery educators were conducted in the two study arms a month before the training (baseline) and a month after the intervention (endline). A pre-designed online structured direct observation checklist for teaching methodologies was utilized to assess the educators' teaching skills in a class session with midwifery students. There was an underlying assumption when using structured observation techniques that the observers understand the phenomena to be studied [57]. They were blinded on the study arms and did not know nor participated in the training or mentorship intervention implemented. Importantly, they were allocated to colleges from the regions different from where they worked to minimize possible chances of bias in the scoring. Before the teaching session, the observer and educator clarified the objectives of the observation as a quality improvement opportunity and informed verbal consent was obtained to participate (and record as appropriate) in the teaching session. An educator was observed and independently scored by one observer. The observer also summarized key notes for debriefing during the constructive/supportive feedback session with the educator at a separate private location in the absence of the students. Consented video recordings of teaching sessions were also taken and shared with the lead researcher for verification of accuracy of the scoring of the sessions at the end of the day's assessment.

Institutional assessment

This was also conducted at baseline and endline period. Using a structured institutional assessment form, data on the infrastructure (skills lab equipment), student support for clinical experience and clinical supervision was collected. The observers assessed the availability and readiness/functionality of the EmONC teaching equipment in the skills lab using a pre-designed checklist within the assessment form. During the endline observations, the observers also held a private and confidential discussion with the student representatives from different clinical rotation groups members of the class. The focus was to understand how students are prepared for clinical placement experience, clinical supervision and mentoring during placements at each institution as part of teaching and learning experiences. Findings on institutional assessment are reported and published in the nested qualitative study within this RCT [54].

Students' assessments

The assessments aimed to check the achievement of essential midwifery competencies through knowledge check and direct observation of three skills using objective structured clinical examination (OSCE). The skills were managing shoulder dystocia, postpartum haemorrhage and birth asphyxia (newborn resuscitation) as some of the leading complications of childbirth in Kenya and globally.

Students' assessments were conducted at least two weeks after completion of the final clinical rotations in maternity, newborn and gynaecology departments for their clinical experiences. These assessments were completed between December 2022 and March 2023 due to varied clinical rotation completion times determined by the number of students per college and limited hospitals for clinical placement for each college. During the assessment week, the lead researcher officially communicated with the college administration to make available the skills lab or classroom venue and target class of students for the monitoring of implementation of the updated curriculum for a full day. This was meant to ensure that no disruption to the ongoing teaching sessions for other classes on the day owing to the limited available classes for teaching. The nature of the monitoring of implementation was not disclosed to the administration and educators to minimise any prior preparation of students for the assessments.

Nine midwives and obstetricians working as midwifery educators in public or private training institutions and/or in clinicals and experienced EmONC faculty, blinded to the intervention implemented and study arms, participated in the assessment of students across the 20 colleges. For assessors from public training institutions (KMTC), they were selected from colleges not participating in the study. Again, each of the assessors participated in the assessments in the regions where they did not work to minimize chances of possible bias. As much as possible, each midwife was paired with an obstetrician for the assessments per college. A total of eight pairs of assessors all selected from the nine assessors completed the assessments in the 20 colleges.

The team of assessors were oriented on the sampling procedure to be used for students, the assessment checklists and the study procedures on the assessment day in a virtual 4-h preparatory meeting. They were also reminded of their duty of confidentiality during the assessment period.

Recruitment of students

Students who participated in the assessments were only identified on the morning of the day of the assessments

in the college. The two assessors and the lead researcher together with the available midwifery educators in the college held an introduction meeting with the students from the participating class. Details about the assessment as part of the monitoring of implementation of the updated curriculum and two debrief sessions (assessors and students only then assessors, students and educators) were provided. The brief meeting emphasized voluntary participation, privacy and confidentiality (anonymous identification) during the participation. After the introductory meeting, the two assessors applied the systematic random sampling to select the students to participate. The last written examination results list for students for each college (year 2 semester 2 common exams for all colleges) was used to rank the students. With every strata having six students ranked from highest to lowest, a random number was selected to determine the student rank to be selected in each of the strata (in this study, every 4th ranked student per strata was selected and enrolled). If any selected student from the list was not available or did not opt to participate, another substitute student from the same stratum was selected. This followed a sequence of sampling that was strictly followed until the sample size was reached. Informed verbal and written informed consent were obtained for all student participants. The ranking of each student substituted was recorded. The students were not aware of their rankings, strata and others being approached. A total of five substitutions were made (two in the intervention and three in the control colleges).

Student knowledge and confidence in EmONC assessment

Selected and consented students were then taken to the set skills lab or private classroom to complete the registration form for administrative purposes only. After registration, they were each assigned a unique identification number to be used on all the assessment forms. The lead researcher shared the online knowledge assessment survey through a link on a WhatsApp group specifically formed for the participating students only for the day on their mobile phones which was completed in no more than 60 min. Backup mobile phone/tablets and internet was provided by the lead researcher as necessary. When each student completed the knowledge assessment, the link to the questions on WhatsApp as well as the history in the mobile phone browsers were deleted to avoid chances of students sharing the assessment questions with their colleagues not participating in the study.

Student skills assessments

This was completed after the knowledge test. Assessors first assembled and prepared the equipment to be used for the assessment in the skills lab. They also had a brief run through the skills using the checklists provided and clarified any inconsistencies to minimize variations in the scoring of students.

Each student was assessed on the same skill by the two independent assessors using the checklists at the same time. The lead researcher served as the administrator responsible for managing the OSCE assessment process for the students. The college educators did not participate in the equipment preparation or administration process as a blinding strategy to the skills to be assessed. Students who had completed the OSCE were isolated in a separate private room from those who were yet to complete the same OSCE. The student's mobile phone was collected as they entered the assessment room by the lead researcher. These were given back between OSCEs and at tea/lunch breaks to prevent leakage of information on what was being assessed but also allow them attend to emergencies as necessary.

Debrief sessions

After completing the knowledge and OSCE assessments, a debrief session was first organised between the evaluated students and assessors. This was a confidential discussion between the research team and the students. During this debrief, students had an opportunity to provide and receive feedback on the assessments completed including how skills teaching and ward/hospital placements for clinical experience were conducted in the institution. Where there was need to correct practice on the OSCEs not well performed, the assessors took the students through the skill demonstration and supervised return demonstration to master the skill. A second debrief between the research team, educators/administration and the students assessed was conducted. This was a short discussion about 15 min where students and research team provided feedback and the day's experiences to the administration. Overall performance was discussed including the strengths observed and potential areas for improvement for both students and educators. Key highlights on the specific skills noted to be poor were demonstrated for educators privately and informed about the designed midwifery educator CPD program to be rolled-out (published in separate study [64]) in the country to refresh and strengthen their teaching skills. Performance scores in the knowledge or OSCEs were not disclosed during the debrief meetings. Field notes were taken during the debrief sessions which also included students' experiences with the skills lab simulation teaching, supervision and teaching during clinical rotations. Member check/participant validation for rigor and trustworthiness of the data was conducted by the lead researcher. Importantly, these sessions were not recorded to allow free expression of students on their experiences.

Data collection tools

The designed self-rating tools used for the students and educators' assessments were highly reliable and valid to assess the desired competencies.

Student assessments

An online written knowledge examination (20 MCQs) and three objective structured clinical examination (OSCE) skills/scenario checklists were developed for assessing EmONC skills. The checklists were adapted from the updated LSTM's EmONC facilitator manual [65] and the Kenya Basic Paediatric Protocols [66]. For confidence in performing EmONC skills, a 0 – 5 self-rated confidence assessment tool for performance of 10 select EmONC skills was used. The skills were: partograph use; performing physiological birth; active management of third stage of labor (AMTSL); newborn resuscitation; maternal hypovolemic shock and resuscitation; administering Magnesium Sulphate in eclampsia; vacuum assisted vaginal birth; managing shoulder dystocia; manual vacuum aspiration; and episiotomy/perineal tear repair. The internal consistency of the 10 items, a measure of reliability of the survey tool, was excellent and acceptable with a Cronbach's alpha = 0.953). All the 10 items in the tool were valid with Pearson correlation values (ranging from 0.780 to 0.896, $p < 0.001$) greater than the critical value = 0.159 ($p < 0.001$) at 95% confidence interval. Thus, the tool was reliable and valid to assess the competencies achieved in EmONC for the students.

Educator assessments

Two 0 – 5 self-rated confidence assessment tools were used (i) for teaching of 11 select EmONC skills – the 10 listed above for students plus the modified early obstetric warning scores (MEOWS) charts (ii) using seven teaching and learning strategies – lecture method, simulation/demonstration; facilitating scenarios; facilitating small group discussions; peer teaching and support; giving effective student feedback and facilitating online teaching. The internal consistency of the 11 items in the assessment of confidence in teaching EmONC tool had an excellent Cronbach's alpha = 0.940; and Pearson correlation values ranging from 0.442 to 0.845, all values greater than the critical value = 0.230 ($p < 0.001$). The seven items in the confidence in using teaching strategies tool had an excellent Cronbach's alpha = 0.930 and Pearson correlation values ranging from 0.715 to 0.885, all greater than the critical value = 0.230 ($p < 0.001$) at baseline, thus considered acceptable to test the self-rated competencies of educators in delivering the updated EmONC-enhanced curriculum to students.

Teaching observations

The checklist had 27 items focusing on (1) preparation and teaching style – 9 items, (2) use of visual aids – 7 items, (3) teaching environment – 5 items and (4) student involvement in teaching and learning – 6 items. The checklist was 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 [67, 68].

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 [69], different sets of 10 questions selected randomly from a bank of developed questions were administered to all participants. A single set of questions were administered at each assessment time. The bank of knowledge MCQs were developed by the course experts with rich experience as EmONC faculty. The questions were validated and standardized by the course experts and piloted among EmONC trainers, midwifery educators and postgraduate midwifery students who did not participate in designing the MCQs. This was 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 [70].

Item analysis was integral in this study and was conducted for all test items for assessment to provide indicators which test the quality of assessment (i.e. item difficulty, item discrimination & distracter analysis) [71, 72]. 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 [71, 73–75]. In this study, questions with a difficulty index of 30% or more were retained in the question bank.

Use of online data collection tools in Google Forms with setting for all fields mandatory before proceeding to the next question ensured that no data were missed during data collection.

Study contamination

The lead researcher actively monitored potential cross contamination by transfer of educators to participating study colleges. There were no inter-arm transfers of participating educators (from intervention to control or control to intervention study arm), thus no study

contamination. However, there were two intra-arm transfer of educators in each arm (intervention to intervention and control to control study arms).

Data entry and analysis

Data from the online surveys was extracted in Microsoft Excel 2016, cleaned and exported to SPSS 28 for statistical analysis [76]. Analyses were performed based on the intention-to-treat principle, and all available data were included in the analysis. Performance scores for educators in knowledge (10 MCQs for each test) and observed teaching sessions (27 items) were converted to percentages. Average of educators' confidence (rated on a 0 – 5 Likert scale) to teach 11 select EmONC skills was calculated out of a total maximum of 5 for each educator at all assessment periods. The Shapiro–Wilk/Kolmogorov–Smirnov tests of normality of data were performed for relevant data variables to determine the parametric/non-parametric tests to compare the scores between the two study arms.

Descriptive statistics were computed for change in knowledge, confidence in teaching EmONC and teaching skills over time among educators. Changes in scores immediately after training were compared with pre-training (baseline) scores using the Wilcoxon signed rank tests. Differences between the study groups for knowledge and self-rated confidence in teaching EmONC skills and applying different teaching methodologies to facilitate learning were explored using independent samples t-test. Similar differences within each study groups for different time points was explored using the paired t-test. To explore the effect of intervention on knowledge and confidence of educators in EmONC and teaching skills accounting for clustering, the recommended linear mixed effects models were used with random effect for cluster (colleges) [77, 78]. Fixed effects were study arm, quarter periods (3, 6, 9 and 12 months), and the interaction between quarter and study arm, and covariates were baseline and immediately after training scores. To compare observed teaching skill scores among educators at baseline (before training) and endline (12 months), a simpler linear mixed effects model used only terms for cluster and study arm. Effect estimates/mean differences, 95%CI and *p*-values are reported.

Students' knowledge test (20 MCQs) and three OSCE skills: shoulder dystocia – 16 items, managing hypovolemic shock in postpartum haemorrhage – 33 items and newborn resuscitation – 22 items scores were converted to percentages. For the skills, the average score between the two assessors was calculated to give the overall score for the skill, named 'Skill score'. This was repeated for all the three skills. The inter-rater reliability (a measure of agreement between the two assessors/raters, measured by Kappa statistic) for the eight pairs of assessors for the skills assessment was calculated per skill. This ranged between Kappa = 0.818 to 0.947 ($p < 0.001$) for newborn resuscitation, Kappa = 0.723 to 1.0 for shoulder dystocia ($p < 0.001$) and Kappa = 0.735 to 0.92 ($p < 0.001$) for management of postpartum haemorrhage, all showing good and acceptable agreement between the assessors.

A cumulative average score was calculated for the three skills weighted equally and named 'skill average.' The average of the student's confidence (assessed on a 0 – 5 Likert scale) in performing the 10 EmONC skills was also calculated. To test the effect of the intervention on students' scores, a simpler linear mixed effects model used only terms for cluster and study arm. Effect estimates/mean differences, 95%CI and *p*-values are reported. *P*-values < 0.05 were considered statistically significant.

Sensitivity analyses were performed on the effect of intervention on educators to determine the consistency between the findings for the (i) 16 randomly allocated colleges in a ratio of 1:1 for intervention and control and (ii) 20 colleges (12 intervention inclusive of the four colleges designated as training hubs allocated and treated as intervention colleges and 8 control colleges) for robustness of the findings [79].

Results

Midwifery educators

Baseline characteristics of midwifery educators

There was no evidence of difference in the educators' baseline characteristics between the study arms for age, gender, educational level, previous training in EmONC and the previous performance mean score in the last common midwifery examinations ($p > 0.05$). The majority of the educators had previous EmONC training ($n = 43$, 58.1%) and more than 2 years since last training ($n = 38$, 81.4%) (Table 3).

Educators' knowledge, confidence and teaching skills during intervention by study arm and period

There was a statistically significant improvement in the mean scores of educators' performance in knowledge from baseline to immediately after training by 12.0% (SD ± 14.9 (95%CI, 8.6 – 15.6, $p < 0.001$). In the subsequent quarters, the performance of the educators was almost similar to scores immediately after the training. There was a mean (± SD) improvement in the self-rated confidence in teaching EmONC skills and applying different teaching pedagogy to facilitate learning from baseline to immediately after the training of 1.1 (± 1.4) (95%CI, 0.8 – 1.5, $p < 0.001$) and 0.5 (± 1.2) (95%CI, 0.2–0.8, $p < 0.001$), respectively. Consequently, the subsequent quarters' confidence ratings were similar to the ratings immediately after the training in both study arms. There

Table 3 Baseline characteristics of the educators in the study arms in the study arms

		Intervention (*N* = 45)	Control (*N* = 29)	Total (*N* = 74)	*P*-value
Age (years)[a]	Range	28—63	33—63		
	Mean (SD)	46.53 (9.55)	47.55 (8.21)	46.93 (9.0)	0.638
	Median (IQR)	47.0 (16)	48.0 (13)		
Gender	Male	17 (37.8%)	8 (27.6%)	25 (33.8%)	
	Female	28 (62.2%)	21 (72.4%)	49 (66.2%)	0.366
Education level	Higher diploma	6 (13.3%)	5 (17.2%)	11 (14.9%)	
	Degree	31 (68.9%)	19 (65.5%)	50 (67.6%)	
	Masters	8 (17.8%)	5 (17.2%)	13 (17.6%)	0.889
Trained EmONC before	Yes	27 (60.0%)	16 (55.2%)	43 (58.1%)	
	No	18 (40.0%)	13 (44.8%)	31 (41.9%)	0.719
Time after EmONC training	Less than 6 months	1 (3.7%)	2 (12.5%)	3 (7.0%)	
	6–12 months	3 (11.1%)	1 (6.3%)	4 (9.3%)	
	13–24 months	1 (3.7%)	0 (0.0%)	1 (2.3%)	
	Over 24 months	22 (81.5%)	13 (81.3%)	35 (81.4%)	0.58
Last common midwifery exams mean score (SD)[a]		54.8% (4.6)	59.0% (6.7)		0.111

Chi-square tests for associations performed

[a] Independent samples t-tests

was no evidence of statistically significant differences in the knowledge scores, self-rated confidence in teaching EmONC skills and applying different teaching methodologies to facilitate learning between the study groups at each time point.

For the directly observed teaching sessions, the performance scores of educators in the study arms were similar at baseline although there was a 20.5% ($p=0.003$) improvement in the intervention arm compared to a 3.6% ($p=0.634$) improvement in the control arm (Table 4).

Effect of training on educators' knowledge and confidence to teach EmONC

Midwifery educators' knowledge and self-rated confidence to teach EmONC skills and applying different teaching methodologies improved significantly immediately after the training from 61.3% to 73.3% ($p<0.001$), 3.0 to 4.2 (<0.001) and 3.7 to 4.2 ($p<0.001$) respectively (Table 5).

Effect of mentorship intervention on educators' knowledge, confidence and teaching skills

Using the quarterly scores as the dependent variable, quarterly periods, study arm, and interaction between quarterly periods and study arm were not significantly associated with the quarterly performance scores for knowledge or confidence in teaching EmONC skills or applying different teaching pedagogy ($p>0.05$).

The intervention improved the observed teaching skills of educators. The observed teaching skill scores of educators in the intervention arm were significantly higher compared with those of controls at endline (mean difference, 17.2; 95%CI, 3.2–29.8, $p=0.018$). For every unit increase in the immediate post-training knowledge score by the educators, there was a significant 0.3 increase in the knowledge due to the mentorship intervention (mean difference, 0.3; 95%CI 0.1–0.5, $p=0.001$). Consequently, for every unit increase in the baseline confidence to teach EmONC skills, there was a significant 0.2 increase in the confidence due to the mentorship intervention (mean difference, 0.2; 95%CI 0.1–0.4, $p=0.004$) (Table 6).

There was no evidence of a statistical difference between the effect of intervention in the results of the sensitivity analysis for 16 randomly allocated colleges and 20 colleges (12 intervention and 8 control) for educators' EmONC knowledge, confidence in skills and observed teaching scores and thus the results remain robust (Supplementary table).

Students

Demographics

A total of 146 students sampled from the intervention arm ($n=91$, 62.3%) and the control arm ($n=55$, 37.7%) participated in the study. Majority of the students in study were females ($n=104$, 71.2%) with no differences in gender distribution between the study arms (females, intervention, $n=66$, 72.5%; control, $n=38$, 69.1%, $p=0.657$).

Table 4 Educators' knowledge, confidence and teaching skills scores by study arm and period

Knowledge (%)	Intervention		Control		Combined (I&C)		*P*-value
	Mean	SD	Mean	SD	Mean	SD	
Baseline	63.3	17.7	59.0	17.4	61.3	17.5	0.300
Immediately after training	75.4	14.0	70.3	16.1	73.3	15.0	0.167
3 months	71.6	13.8	72.1	12.9	71.8	13.4	0.820
6 months	68.6	15.5	71.8	14.7	69.9	15.2	0.467
9 months	71.4	17.4	67.9	16.2	70.0	16.9	0.456
12 months	70.2	17.0	66.1	13.7	68.9	15.6	0.279
Confidence in teaching EmONC skills (0 – 5)							
Baseline	3.2	1.2	2.9	1.0	3.0	1.1	0.286
Immediately after training	4.1	1.2	4.3	0.8	4.2	1.0	0.656
3 months	4.1	1.1	4.2	0.5	4.1	0.9	0.695
6 months	4.1	0.9	4.0	1.0	4.0	0.9	0.562
9 months	4.0	1.1	4.0	0.9	4.0	1.0	0.975
12 months	4.1	1.0	4.2	0.6	4.2	0.8	0.569
Confidence in teaching pedagogy (0 – 5)							
Baseline	3.9	0.9	3.5	1.0	3.7	0.9	0.089
Immediately after training	4.2	0.9	4.3	0.8	4.2	0.9	0.725
3 months	4.4	0.7	4.5	0.4	4.4	0.6	0.424
6 months	4.1	1.0	4.3	1.0	4.2	1.0	0.352
9 months	4.1	1.0	4.4	0.7	4.2	0.9	0.190
12 months	4.1	1.1	4.4	0.8	4.2	1.0	0.154
Observed teaching skills (%)							
Baseline (13 and 8 sessions observed in intervention and control arms respectively)	68.9	18.8	68.8	16.7	68.8	17.6	0.984
Endline (12 months) (16 and 10 sessions observed in intervention and control arms respectively)	89.4	11.0	72.2	16.7	82.8	15.6	**0.004***

* $P < 0.05$ statistically significant

Table 5 Change in knowledge and confidence in teaching EmONC immediately after the training

Parameter	Pre-test		Post-test			
	Mean	SD	Mean	SD	Z	*P*-value
Knowledge in EmONC (%)	61.3	17.5	73.3	14.9	−10.573[b]	**< 0.001***
Confidence to teach EmONC skills (0 – 5)	3.1	1.1	4.2	1.0	−11.085[b]	**< 0.001***
Confidence in applying different teaching methodologies (0 – 5)	3.7	0.9	4.2	0.9	−7.130[b]	**< 0.001***

[b] Based on negative ranks of the Wilcoxon tests

*$P < 0.05$ statistically significant

Students' EmONC knowledge and skills performance

The intervention arm showed significantly higher knowledge and skill estimates compared to the control arm. Although the combined average mean score for the three skills was low (mean 47.8%, SD ± 16.9), the scores were significantly higher in the intervention arm (mean 55.0%; SD ± 15.8) compared to the control arm (mean 36.0%; SD ± 11.1), $p = 0.001$.

There was an 8.3% (95%CI, 1.6–15.0) mean difference in the knowledge scores between the two study arms (59.6% vs 51.3%, $p < 0.018$). Consequently, the mean scores for the three OSCE skills in the intervention study arm were 21.8% (95%CI, 10.8–33.9), 17.8% (95%CI, 2.0–33.9) and 17.3% (95%CI, 8.0–26.1) higher for shoulder dystocia (64.5% vs 42.7%, $p = 0.001$), newborn resuscitation (43.9% vs 26.1%, $p = 0.03$) and maternal shock

Table 6 Linear mixed effects of mentorship intervention by period and study arm

	Parameter	Estimate	95%CI (lower and upper levels)		T statistic	*P* – value
Knowledge						
Quarters						
	3 months vs 12 months	6.3	-0.1	12.6	1.944	0.053
	6 months vs 12 months	6.3	-0.2	12.7	1.920	0.056
	9 months vs 12 months	1.8	-4.6	8.2	0.550	0.583
Study arm	Intervention vs control	3.2	-3.8	10.3	0.911	0.363
Training	Baseline scores	0.0	-0.2	0.1	-0.280	0.781
	Immediately after training scores	0.3	0.1	0.5	3.457	**0.001***
Confidence to teach EmONC skills						
Quarters						
	3 months vs 12 months	-0.1	-0.4	0.2	-0.492	0.623
	6 months vs 12 months	-0.3	-0.6	0.0	-1.799	0.073
	9 months vs 12 months	-0.3	-0.6	0.1	-1.563	0.119
Study arm	Intervention vs control	-0.2	-0.6	0.2	-0.798	0.426
Training	Baseline scores	0.2	0.1	0.4	2.947	**0.004***
	Immediately after training scores	0.2	0.0	0.3	1.977	0.052
Confidence in applying different teaching pedagogy						
Quarters						
	3 months vs 12 months	0.0	-0.3	0.4	0.207	0.836
	6 months vs 12 months	-0.1	-0.5	0.3	-0.617	0.538
	9 months vs 12 months	-0.1	-0.5	0.3	-0.334	0.739
Study arm	Intervention vs control	-0.3	-0.7	0.1	-1.374	0.171
Training	Baseline scores	-0.1	-0.3	0.1	-1.198	0.235
	Immediately after training scores	0.1	-0.1	0.3	1.074	0.287
Observed teaching skills						
Study arm	Intervention vs control	17.2	3.2	29.8	2.614	**0.018***

**P*<0.05 statistically significant

resuscitation (56.5% vs 39.2%, $p=0.001$) respectively compared to the control arm. Newborn resuscitation skill scores were below 50% in both study arms. Mean scores in the three OSCE skills by students in the control arm were all below 50%. There was no evidence of a difference in the self-rated confidence of students in performing EmONC skills between the two arms (3.3 vs 2.9, $p=0.182$) (Table 7).

Table 7 Students' performance in EmONC by study arm

	Intervention (*N*=91)		Control (*N*=55)		Total (*N*=146)		Estimates			
	Mean	SD	Mean	SD	Mean	SD	Mean difference	95%CI	t	*P*-value
Knowledge (%)	59.6	12.9	51.3	10.0	56.5	12.5	8.3	1.6–15.0	2.610	**0.018***
Skills scores (%)										
Shoulder dystocia (%)	64.5	19.3	42.7	14.8	56.3	20.7	21.8	10.8–33.9	4.057	**0.001***
Newborn resuscitation (%)	43.9	22.5	26.1	16.6	37.2	22.2	17.8	2.0–33.9	2.359	**0.030***
Maternal shock resuscitation (%)	56.5	15.8	39.2	11.7	50.0	16.6	17.3	8.0–26.1	3.961	**0.001***
Skills average (%)	55.0	15.8	36.0	11.1	47.8	16.9	19.0	8.7–29.5	3.850	**0.001***
Confidence in EmONC skills (mean score, 0 – 5)	3.3	1.3	2.9	1.3	3.2	1.3	0.4	−0.2–1.0	1.388	0.182

* *P*<0.05 statistically significant

There was no evidence of a difference between the effect of intervention in the results of the sensitivity analysis for 16 randomly allocated colleges and 20 colleges (12 intervention and 8 control) in students' EmONC knowledge and skills and thus the results remain robust.

Discussion

This study assessed whether educator specific skills training and additional mentoring support improves the midwifery educators' quality of teaching of an EmONC-enhanced national midwifery curriculum and students' learning. Key findings demonstrated that training midwifery educators in teaching pedagogy and EmONC skills significantly improved their immediate knowledge in EmONC (61.3 – 73.3%) and confidence to teach EmONC (3.1 to 4.2 out of 5), $p < 0.001$. There was no evidence of a difference in the observed teaching skill scores of educators in both study arms at baseline. However, these scores were significantly higher at endline for educators who received training and mentoring support compared to those who received training alone (mean difference, 17.2; 95%CI, 3.2–29.8, $p = 0.018$). Performance scores for students in the intervention arm were significantly higher than those in controls for knowledge (mean difference, 8.3 [1.6–15.0]) and the three OSCE skills assessed (mean difference (95%CI): 21.8 (10.8–33.9) for shoulder dystocia, 17.8 (2.0–33.9) for newborn resuscitation and 17.3 (8.0–26.0) for maternal resuscitation. There was no evidence of a difference in the self-evaluated confidence of students to perform EmONC skills detected between the study arms.

Midwifery educators' baseline knowledge, teaching skills and confidence to teach EmONC skills improved immediately after training. Similar findings have been reported in other EmONC training studies suggesting that the intervention addressed a competency gap [19, 37, 63, 80].

Mentoring had a significant impact on the observed teaching skills of educators at endline in the intervention group. Our findings are similar to other studies which concluded that mentoring reinforces knowledge and skills [81, 82]. Our results underscore the value of targeted mentoring in improving and retention of competencies as opposed to training alone which improves knowledge and skills immediately after training [9, 37, 38, 46]. Designing sustainable and effective continuous professional development interventions for midwifery educators has the potential to address competency gaps. This approach can reinforce effective classroom and clinical teaching and enhanced students' learning of maternal and newborn health competencies.

Overall students' performance in knowledge and skills was sub-optimal. Generally, the students in intervention colleges had higher scores in both knowledge and skills compared to those in control colleges. Our findings are similar to a cross-sectional study in Ethiopia which assessed the competence of midwifery students at graduation [83]. Evidence shows that an increase in knowledge on simulation skills teaching is associated with an increase in practice of simulation [84]. Therefore, we argue that educators in the intervention colleges benefiting from regular mentoring improved and delivered effective teaching in midwifery modules leading to higher performance by students compared to the control group. The poor student performance is symptomatic of the suboptimal clinical education and shortcomings experienced by students as reported in our nested qualitative study within this RCT [54]. Thus, students are inadequately prepared for the full range of midwifery practice particularly for managing obstetric and newborn emergencies. Insufficient clinical environment for learning, inadequate training period and limited exposure to high-risk maternity situations, obstetric and newborn emergencies limit the opportunities to experience the full range of midwifery skills thus hindering learning and acquisition of essential competencies in EmONC [85, 85–93]. This finding demonstrates that students require support in knowledge and skills acquisition and mastery to graduate as competent skilled health personnel.

The students' self-rated confidence level was high in all study groups, while the skills and knowledge remained poor. The low students' scores in knowledge and skills are similar to other studies conducted on EmONC skills among midwifery students [94, 95]. This poses a potential serious risk for the prospective clients receiving suboptimal care. Applying Miller's pyramid of clinical competence, use of direct observation of procedural skills, demonstration (through OSCEs or simulations) and work-based or performance practice techniques should be integrated within the pre-service curriculum used to teach and assess clinical competence [96]. Besides the simulation teaching in classroom, students should be given opportunities to practice by actual performance of the EmONC skills under supervision and support to acquire the confidence and expected clinical competencies. When used effectively and accompanied by appropriate feedback, these practical-based techniques enhance the learning skills of the student, enhances students' motivation and helps educators to evaluate their activities – the hallmarks of effective evaluation of clinical competence [94, 97]. Short targeted pre-service training before graduation, short in-service/on-job training and mentoring by experienced skilled health personnel has been effectively used to address competence gaps in maternal and newborn health for new graduates [83, 98, 99].

A mentoring approach implemented by an interdisciplinary team of clinical skilled health personnel and academic mentors was a successful intervention in strengthening the capacity of educators. This collaboration is relevant as the classroom teaching should mirror the clinical environment for students during clinical placements. This blend also promotes pre-service and in-service collaboration and sharing of updates, a key ingredient for a strengthened health system for training of competent skilled health providers. This is also an opportunity to integrate and strengthen the support system for students' learning and mastery of skills during their clinical placements [9, 32]. Although there is demonstrated value for mentoring of educators, overall institutional investments and reinforcements in clinical education are urgently needed to improve the overall quality of teaching and practice. Provision of up-to-date national guidelines are essential to standardise practice on specific skills such as newborn resuscitation and provide an opportunity for midwifery educator continuous professional development [54, 100]. Midwifery students should be supported through structured mentoring and clinical teaching during clinical rotations by clinically and educationally competent staff, to ensure they gain mastery of the expected ICM and WHO midwifery competencies.

Study strengths and limitations

To the best of our knowledge, this is the first study in Kenya assessing the implementation of an updated pre-service midwifery curriculum in both educators and students. Use of cluster trial was useful as interventions were targeted at 'higher level' clusters/colleges rather than the individual, as it was not possible to avoid interaction between individuals within the same cluster [101]. The independent randomisation of colleges to study arms allowed independent recruitment and minimized possible introduction of selection bias common with cluster randomised trials if the process is done by individuals from the same institution [102]. Although two college representatives were present in the process of cluster selection to ensure an open and transparent process, the research lead who was not a faculty member with no prior knowledge of the clusters ensured strict adherence to the randomisation process and allocation. There was no contamination between those receiving the intervention and those who are not thus no dilution bias introduced, a key strength achieved with cluster randomization of colleges [102]. The study design was further strengthened by the blinding of data collectors to the intervention and study arms. This minimised the chance of bias being introduced. Importantly, mentors who supported the mentoring visits to the colleges and the data collectors/assessors were mutually exclusive. In addition, students participating in the assessments were only selected in the morning of the assessments and were not aware of the other colleges participating in the assessments. We acknowledge that it is difficult to maintain an effective blinding of the students and assessors regarding the intervention status of the colleges. Even though there is a chance that educators and students could communicate about the assessments with other colleges, there were no regular systematic patterns observed in students' performance of the skills during the assessments in the colleges strengthening that blinding was effectively maintained. There was no evidence of a difference in the self-rated confidence among educators and students in EmONC between the study groups. Self-rating is subjective, and individuals are likely to be biased in their self-assessment. However, triangulation through multiple assessments techniques (self-assessment, knowledge questions, teaching observations and skills/OSCEs) provided a robust evaluation criterion for impact of interventions on educators and students' competencies and strengthens the credibility of the findings [103–105]. There was no deviation in the scoring of the recorded teaching video sessions (by the lead researcher) between the lead researcher and the assessors, strengthening the credibility of the findings.

The four colleges that served as the training hubs were included in the intervention arm. These colleges were selected due to their central geographical locations and academic performance. Also, they did not benefit from additional resources or intense educational programmes to introduce a bias in favour of the intervention group. The sensitivity analyses performed demonstrated that the effect of the intervention under different scenarios (with 20 or 16 colleges excluding the four training hubs) was unchanged thus this strengthens the robustness and credibility of the findings [79]. The use of linear mixed models in analysis lead to data analyses with greater validity and enable accurate and informative interpretation of results toward higher reproducibility of experimental findings [77]. Our findings are generalizable to other institutions with similar settings. However, the small sample size of colleges, educators and students that participated in the trial and teaching observations collected means that the findings should be interpreted with caution. The Hawthorn's effect is a major drawback with direct observation as a method of data collection. However, this was necessary to observe the 'where' and 'when' of the ongoing process/situation/behaviour rather than relying on what people say they did. The Hawthorn effect was minimized by assuring the educators and students that the purpose of the study was to improve the process and not pass judgment on performance. Educators were informed about the benefits of peer observation

and feedback as a valuable tool in improving the quality of education and encouraged to adopt this practice, even prior to being observed during the study. This was also a self reflection tool intended to support them in celebrating their growth and continuing to strengthen their skills teaching practice [106].

Implications for practice

This study has demonstrated that institutional-based mentoring is an effective strategy for midwifery faculty development. The implemented interventions in this study – curriculum review and update, capacity strengthening of educators through training and mentoring and teaching using interactive teaching methodologies – and an enabling environment through provision of EmONC teaching equipment and supportive supervision as reported in a separate study [95] serve as a foundation for a sustainable strategy to effectively implement a competency-based curriculum in similar settings. The collaboration and synergy of teaching and clinical faculty as clinical mentors in the teaching of midwifery is a potential pathway for greater returns on investments. Preceptor support during clinical placements is critical and should be integrated within pre-service training to facilitate and promote students' learning and clinical experience to address maternal and newborn mortality prevention. To remain updated in teaching and practice to effectively deliver the updated curriculum, educators require regular targeted opportunities for continuous professional development. This approach of regular short targeted mentoring sessions provides a foundation for a sustainable and cornerstone strategy for future continuous professional development capacity strengthening. Diploma midwifery graduates in Kenya do not have internship period to build their clinical competencies. The Kenya MoH EmONC training and mentorship package developed for mentors and mentees provides a useful resource for educators and students to regularly update their clinical skills and practice [107].

Our findings indicate that for effective evaluation of mentorship or other training programmes, multiple methods should be used to minimise bias and improve credibility of the assessments. Like any training programme, it is also key to understand the experiences from implementers (educators) and recipients (students) for effective implementation of the updated competency-based curriculum [52]. The experiences of midwifery educators and students were explored, and findings are reported in a separate nested qualitative study within the RCT [54]. Overall, the findings from this study, provide lessons to inform relevant policy and training regulation changes in the country for skilled health personnel. However, the effect of these interventions on health outcomes are unknown and further research investments are required.

Conclusion

The training and regular mentoring interventions were effective in improving the quality of educators' teaching skills which enhanced student learning experience. Strengthened educators through mentoring support in applying interactive teaching methods contributed to higher performances in EmONC knowledge and skills for students in the intervention colleges. Although our results are promising, overall students' performance was sub-optimal and additional mentoring support is needed to further improve their knowledge and clinical competence in EmONC before and after graduation. Institutional investments are needed for educators to update/improve their competencies regularly through mentoring and other continuous professional development opportunities to enhance student learning. This has the potential to improve the quality of teaching and student learning required for effective teaching as we have reported. Future studies should evaluate the cost-effectiveness of implementing an EmONC-enhanced pre-service curriculum by trained and mentored educators on maternal and newborn health outcomes.

Supplementary Information

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Supplementary Material 1.

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Authors' contributions

DNS, HA and CA conceived the idea and designed the study protocol; designed the mentoring intervention and data collection tools. DNS administered the assessments, performed data extraction, cleaning, analysis and interpretation of the results, drafted the primary manuscript, reviewed and prepared it for publication. PN, AU, CW, LW, LN, ET, IB, EN, CB and SBZ participated in the design of the study procedures and substantively reviewed the drafts and final manuscript. CA obtained funding for the study, provided oversight in investigation, analysis, interpretation and substantively reviewed the manuscript drafts. All the authors read and approved the final manuscript.

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Data availability
The datasets generated and/or analysed during the current study are not publicly available due to the confidentiality of the data but are available from the corresponding author on request.

Declarations

Ethics approval and consent to participate
The study was reviewed and approved by Liverpool School of Tropical Medicine's Research and Ethics Committee (REC 20–050), Moi University/Moi Teaching and Referral Hospital Institutional Research and Ethics Committee (IREC) (IREC FAN: 0003764), Kenya Medical Training College (KMTC/ADM/74/Vol VI) and the National Commission for Science, Technology and Innovation (License No: NACOSTI/P/21/8931). Consent was received at various levels. Details about the study were communicated by the KMTC Headquarters to all the participating colleges' administration for institutional entry and required support. Study participants (educators) received an electronic detailed study information booklet containing all information about the study (including recording of teaching sessions as appropriate) and consent form two weeks before the commencement of the study. Secondly, a print copy of the same participant information sheet was issued to each participant and a written informed consent was obtained at the start of the face-to-face training sessions. A written informed consent was obtained from the students who participated in the study. Participation was strictly voluntary with an explicit option to withdraw at any time with no consequences. Those who opted not to participate in the study were not denied the training. Confidentiality was maintained throughout the study using the anonymous identity codes assigned to the study participants (educators and students). The study carried no risk to the participants as their identity was concealed throughout, study results (knowledge or skills scores) were not shared with the administration and participation in the study did not form part of their performance appraisal. Assessments, interview discussions and debrief meetings were conducted in a designated private space within the colleges.

Consent for publication
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Competing interests
The authors declare no competing interests.

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