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Evaluation of on-the-job surgical training programme for clinical officers in Malawi

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Abstract

Background: Shortages of specialist surgeons in African countries mean that the needs of rural populations goes unmet. Task-shifting from surgical specialists to other cadres of clinicians occurs in some countries, but without widespread acceptance. Clinical Officer Surgical Training in Africa (COST-Africa) developed and implemented BSc surgical training for clinical officers in Malawi.

Methods: 17 trainees participated in the COST-Africa BSc training 2013-2016. This prospective observational study done in 16 hospitals compared crude numbers of selected numbers of major surgical procedures between intervention and control sites before and after the intervention. Volume and outcomes of surgery were compared within intervention hospitals between the COST-Africa trainees and other surgically active cadres.

Results: The volume of surgical procedures undertaken at intervention hospitals almost doubled (+89%, 2013-2015), and there was a slight reduction in the number of cases done in the control hospitals (-4%, 2013-2015), (p=0.059). In the intervention hospitals most general cases were done by COST-Africa trainees (61.2%) compared to other Clinical Officers (31.3%) and Medical Doctors (7.4%). Postoperative wound infection rates for hernia procedures at intervention hospitals were compared between trainees and Medical Doctors with no statistical difference found (p=0.065).

Discussion: The COST-Africa study demonstrated that in-service training ~~model for~~ of practicing clinical officers is safe and can greatly improve the surgical productivity of district level hospitals.

Introduction

The burden of surgically avoidable morbidity and mortality in low and middle income countries (LMICs) and steps towards achieving global solutions have been reviewed comprehensively by the Lancet Commission on Global Surgery (1). In sub-Saharan Africa ~~countries~~, in particular, one of the main issues is the shortage of specialist surgeons at the district level, which means that the needs of rural dwellers go unmet. One response has been task-shifting of basic essential surgery from surgical specialists to less specialised cadres of clinicians(2)(3). Malawi is one such country where ~~majority of~~ most surgical, obstetric and orthopaedic procedures are done by clinical officers (COs) (4)(5). COs are a cadre of non-physician clinicians who receive three years ~~of~~ basic training on how to diagnose and treat common conditions. Elsewhere, they are also

known as associate clinicians (1) and 'non-surgeons' (3)(6). Task-shifting of major surgery for common conditions to non-physician clinicians has taken place in between 30 (3)(6)and 41 LMICs(3).

Despite the task-shifting concept being generally accepted(1)(7), there are reported concerns about: its safety, efficacy, and the breakdown of professional roles (1)(2)(8)(9)(10)(11)(12); the perception that non-specialists are unable to master the required decision-making skills (13)(14); and unregulated 'task creep', where non-physician clinicians embark on surgery for which they are not trained(1). On the other hand, advocates of task-shifting (15)(16), point to the lack of alternatives for providing emergency life-saving surgery in remote and rural areas. Most published studies have reported comparable findings when a limited set of emergency obstetrical and general surgical procedures are performed by COs and medical doctors (MDs) (17)(9)(18)(19)(20). However, better evidence is needed on the feasibility and conditions for rolling out a safe surgical model based on non-physician clinician-performed surgery at district hospitals. Clinical Officer Surgical Training in Africa (COST-Africa) was a research project, funded by the European Union, implemented in Malawi and Zambia in 2011-2016. The aim of the project was to develop, implement and evaluate a training model for COs tailored to district level needs.

Surgical in-service training intervention

In Malawi, there is a historical shortage of MDs and a high reliance on COs (4). General COs have very limited surgical training offered to them as part of the Diploma in General Medicine (21)(22), which covers emergency obstetric cases and some minor procedures. Therefore, COST-Africa through the PI (EB) initiated consultations between the University of Malawi's College of Medicine, the Ministry of Health and other stakeholders to develop a curriculum for a Bachelor of Sciences (BSc) in General Surgery for this cadre. The COST-Africa team provided technical guidance and support. This led to the development and accreditation of a BSc in General Surgery programme for COs run by the College. Subsequently 5 other specialty BSc programmes for clinical officers were developed by the College.

17 COs were enrolled in the COST-Africa training from the pool of already practicing general COs from the Southern and Central region of Malawi. The COST-Africa BSc in Surgery was divided in three parts. Firstly, a four month (May to September 2013) theoretical training was provided at the College covering: biological and biomedical sciences, including medical microbiology, parasitology and host defences, principles of pharmacology and therapeutics, human physiology, principles of pathology, essential surgical skills, anatomy and research and statistical methods; and also participation in a *Surgeons without Borders* short course.

Secondly, surgical trainees were deployed in pairs to eight government district hospitals and received a hands-on training through a 24-month placement. During the placement (November 2013 to December 2015) CA-COs received fortnightly visits funded by COST-Africa from 26 specialist and trainee specialist surgeons based at the central hospitals in Blantyre and Lilongwe. During the visits they delivered practical 'on-the-job' training for CA-COs in common surgical, gynaecological and orthopaedic procedures, covering generic skills (e.g. perioperative care, infection and bleeding, sutures, suturing and instruments; sepsis and pus), as well as specific surgical procedures. The focus was on common emergency and elective procedures including, but not limited to, hernia and hydrocele repairs, abdominal surgery, ectopic pregnancies and hysterectomies. CA-COs were given lectures in applied surgery, anaesthesia, intensive care, primary trauma, obstetrics and gynaecology, common anorectal conditions, urology, blunt uro-genital trauma, ultrasound and urology. They were also trained in how to introduce surgical best practice at the district hospitals.

The rationale behind placing this training model at district level was to maximise the learning opportunities for CA-COs. At central hospitals surgeon specialist trainees and MDs ~~in~~ undergoing surgical training are the priority and they are the first to receive hands on training, leaving COs waiting for they turn. It was also considered beneficial for the whole district health service if the training took place on the job in the district.

Following completion of the district training, in January 2016 candidates returned to the two central hospitals for 8 months (until August 2016) to complete a third year of advanced surgical training. All students graduated with the BSc.

Methods

Study settings:

In Malawi 84% of its 18 million population live in rural areas (23), the highest rural population density in sub-Saharan Africa. A network of 24 government owned district hospitals and 23 faith-based district level hospitals provide surgical services to rural areas, where almost all surgery is undertaken by COs (23)(24). In urban areas of Malawi there are four central hospitals(25)(26), which are staffed by specialist surgeons. These hospitals manage both complex and common surgical cases, including simple cases some of which are referred from lower levels of care(27).

At the request of the Malawian Ministry of Health, the project focused on the Southern and Central regions, leaving out Northern region. All government district hospitals in these two regions (18 of 24 country-wide) were deemed eligible for inclusion as potential intervention hospitals. Faith-based facilities were excluded from the study following instructions from Malawi Ministry of Health (MoH). The capacity of district hospitals to deliver major surgery was assessed through a baseline situation analysis, which also informed the selection of hospitals that took part in the trial.

Students enrolled in the COST-Africa BSc programme were selected based on the following criteria developed by University of Malawi:

a. Malawi Schools Certificate of Education (MSCE), “O” Level, IGCSE or GCE with 6 credits which include English and Mathematics

b. A Diploma in Clinical Medicine or its equivalent from a recognised institution
c. at least two years working experience as a CO providing surgical and other clinical care at a district or rural hospital

Selection was independently done by the University of Malawi's Admissions Office with no involvement of the COST-Africa project. The cost of training the CA-COs was fully covered by the project. The trainees remained on government salaries, but received a monthly stipend (local equivalent to approximately 80 USD) funded by COST-Africa for collecting data for the project. The study was approved by the College of Medicine of Malawi and the Royal College of Surgeons in Ireland Research Ethics Committees.

Study design

Primary outcome measure

The COST-Africa primary outcome was the change in the combined number of index surgical procedures (salpingectomy, herniorrhaphy and hydrocelectomy) as a result of the intervention, comparing intervention hospitals with control hospitals. Index procedures were selected based on two criteria:

- Incidence (numbers of specific cases) undergoing surgery at district hospitals.
- Inclusion in the COST-Africa training curriculum.

For the primary outcome this study was designed as a randomised matched-pairs controlled trial (ISRCTN66099597). Pairs were formed based on principal component analysis, which created hospital pairs based on the following ranked criteria:

- Similar in volume of caesarean sections (CS).
- Surgical case-mix and caseload of major surgical procedures: total number of major surgical procedures, excluding CS, circumcision and bilateral tubal ligation. The major surgeries included were hysterectomy, ectopic pregnancy –salpingectomy, inguinal

herniotomy, herniorrhaphy-repair, prostatectomy, appendicectomy, stab wounds, GIT perforation, GIT resection anastomosis colostomy, laparotomy other, amputation arm leg, hydrocele excision repair, cataract and other major operations not included in preceding list.

- Similar-size of government grant, considered a good indicator of the size of the hospital.
- Distance to main referral hospital for referred surgical patients.
- Similar in number of COs whose current principal responsibility was to perform major surgery.
- Similar in functional capacity (infrastructure, steadiness of anaesthetic machine, anaesthetic staff, theatre nurses, availability of medical supplies).

After assigning ranks, the hospitals were paired with the nearest ranks for each criterion, with final pairs representing the best overall fit across the selected criteria. Table 1 lists the pairs of hospitals, where randomisation within pairs determined intervention and control hospitals. A simple physical randomisation method was applied using pieces of papers with hospitals names. The draw aiming for randomisation was done by a representative of Malawi MoH. The intervention group included all hospitals hosting CA-COs during their 2-year placement as part of the new BSc programme, while control hospitals only had regular COs. All hospitals initially selected for the trial completed the full study.

TABLE 1 HERE

Secondary outcome measures

A range of secondary outcomes was used to evaluate the effects of the intervention at different levels. Secondary outcomes had appropriate study designs, different from the RCT designed for the primary outcome.

Cross-sectional comparison was used to asses:

- Surgical productivity: in each intervention hospital the percentage of obstetric, general and other types of surgical procedures performed by CA-COs was compared with other surgically active COs and MDs.
- Quality of surgery: in each intervention hospital, perioperative mortality and wound infection rates of surgical cases prior to discharge were compared between CA-COs and MDs.

Surgical self-reported confidence was also compared before and after the intervention in CA-COs. Satisfaction with on-the-job training was measured upon completion of the full training using a survey tool developed by the COST-Africa team.

Tools and data collection

The initial situation analysis revealed lack of standardised routine surgical data collection tools at district level hospitals (DLHs). To overcome this obstacle, the project developed its own data collection instruments, building on and strengthening existing government's information system. In the intervention hospitals we introduced an extended theatre register (ETR). This was designed to capture basic data routinely collected in operating theatres (patient demographics, indication for surgery, procedure, type of anaesthesia, surgical team composition and outcomes), as well as additional variables such as: postoperative complications (wound infection, urinary infection, respiratory infection), date of discharge and health status at discharge and destination (home or referred to another hospital or dead). To prevent misclassifications, detailed lists of diagnoses and procedures were drafted with assigned codes. The COs were then tasked to code the conditions and procedures using these lists when transferring data from the hard copy register into MS Excel files (all COST Africa tools available at www.costafrica.eu/data-collection).

Surgical output data in control hospitals were collected using a bespoke form that captured diagnoses and procedures. Data collection in intervention hospitals was conducted by COST-Africa Clinical Officers (CA- COs), whilst in the control hospitals regular COs or theatre nurses were employed to collect the required information. At the end of the training programme, COST-Africa researchers visited all hospitals involved in the study, validating the data and correcting identified data errors.

The COST-Africa research team also developed its own instrument to measure the effect of the training on participants' self-reported confidence levels due to the lack of an already validated tool. The instrument contained questions about how confident ~~one~~ COs felt when conducting listed procedures unsupervised, using a Likert-type of scale where confidence levels were rated as low, moderate, high. The list of procedures included: hysterectomy, strangulated and non-strangulated inguinal, femoral and other types of hernia, salpingectomy, prostatectomy and exploratory laparotomy. Answers were coded 0-2, resulting in a scale of confidence with a maximum value of 20. This instrument was piloted and the final version was administered among CA-COs before the start of the district hospital attachment and again after the 24 months of in-service training.

Information on the relevance and quality of the training model was collected through a bespoke structured questionnaire administered among CA-COs at the end of the training programme. It contained questions about overall satisfaction with different aspects of the COST-Africa training and questions about specific roles (teaching, management, administration) CA-COs undertook while training in district hospitals.

Statistical analysis

Differences in the primary outcome before and after the intervention between intervention and control hospitals were examined comparing the crude numbers of index procedures performed, Relative percentage changes were compared using t-test. Chi-square tests were

used to examine differences in surgical productivity between CA-COs and other surgically active cadres (COs and MDs). The analysis focused on ~~one~~ a 24 month time point: 2014-2015.

Postoperative wound infection rates at intervention hospitals were compared between CA-COs and MDs using Fisher's Exact Test. This comparison was considered important, because COs at district level hospitals often provide surgery in the absence of medically trained staff. Therefore, MDs can be considered a valid comparator when the quality of service is measured. The analysis was undertaken for hernia procedures (n=559), serving as an example of the most commonly performed general surgical procedure at district level in sub-Saharan Africa(28)(24).

Before and after the training, differences in means of self-reported surgical confidence in performing operations unsupervised, measured on a scale (0-20 max), were ~~was~~ compared using paired t-test. All tests were two-tailed and statistical significance was set at $p< 0.05$

Descriptive statistics were used to analyse results of the survey assessing CA-COs satisfaction with the COST-Africa on-the job BSc training programme.

Results

Productivity

There was a substantial (89%) increase in the numbers of major index surgical cases undertaken in intervention hospitals during the two-year period of CA-COs in-service training compared to control hospitals with only regular COs (Table 2).

TABLE 2 HERE

Analysis of individual pairs of hospitals revealed that there was no clear pattern for the primary outcome. In five out of eight pairs, the intervention hospitals outperformed the control ones, in

some cases to a considerable extent, in the percentage change in numbers of index procedures undertaken (table 3). Statistical significance was not observed (p=0.059) however the effect size was large (Cohen's d=1.03).

TABLE 3 HERE

Most cases of major general surgery (n=7870) were done by the COs trained under COST-Africa. Whereas, other COs, who were not undergoing COST-Africa training and who were between 5 and 15-fold more numerous than CA-COs, mainly undertook 'Obstetric' and 'Other' surgical cases (see footnote) Table 4.

TABLE 4 HERE

Analysis of the average number of procedures per clinician, by the three cadres of surgical clinicians, showed a higher surgical workload on the part of CA-COs at most district hospitals, as presented in Table 5.

TABLE 5 HERE

Quality of surgery: outcomes and safety

There was a lower incidence (proportion) of wound infections among surgical cases performed by CA-COs compared with those done by MDs, ~~even~~ although the difference ~~is~~ was not statistical significance (p=0.065) (Table 6). No surgical death was recorded.

TABLE 6 HERE

Surgical confidence

There was a statistically significant increase in average surgical confidence scores reported by CA-COs between time 1 (M=9, SD=5.5) and time 2 (M=14,6 SD=3.4); $t(16)=-5.4$, $p < .001$.

Perception of the COST-Africa training

Almost all COST-Africa trainees (15/16) reported a 'very positive' experience from taking part in the COST- Africa training. The main benefits reported were: improvements in surgical knowledge and skills (9/16), appreciation of the financial support (paid tuition fees and a scholarship paid by the project) to undertake the training (7/16), and taking part in the research component through learning about data collection and analysis (6/16).

Respondents indicated that working in district facilities made them responsible for training other clinicians in various aspects of surgical care (pre, intra and postoperative care) (16/16). All CA-COs provided on-the-job training at their hospitals to interns, nurses and other COs interested in surgery.

Discussion

The ideal staff cadre for the delivery of complex health care, including surgery, is ~~that of~~ medical doctors. However, in countries like Malawi, which has the second ~~lowest~~ highest patient-doctor ratio in the world and where most district hospitals do not have medical specialists (31), maintenance of this standard would mean that no essential surgery would be available for rural populations. In the interim, there is an urgent need to develop, evaluate and implement sustainable solutions to fill this gap and to address the unmet surgical burden of disease. COs (non-physician clinicians) are often the main, if not the only, providers of surgical

care in rural areas, so it is important to find ways to support them in this role and to strengthen their capacity to ensure rural populations have access to safe and quality surgical services.

~~In~~ Our study ~~we~~ tested an innovative 36-month surgical training programme for COs, ~~COST-Africa,~~ mainly involving practical in-service training at district hospitals. The findings of our study suggest that 'on-the-job' surgical training of COs is effective, as it has been reported elsewhere in Africa (17)(29)(5)(30). Two follow-up cohorts of COs have already entered the BSc in Surgery programme at the College of Medicine of the University of Malawi, developed by COST-Africa. This is an important achievement in terms of sustainable solutions to remedy the health workforce crisis that deprives rural populations of critical life-saving surgical care, in Malawi and other countries in the sub-Saharan Africa region(3).

Large-scale controlled trials of major health systems interventions are relatively unusual in sub-Saharan Africa (31)(37)(32). The main strength of this study is its design and scale. COST-Africa was designed and implemented through Malawi's public sector system and two of Malawi's three regions (16 of 24 district hospitals) were included in the trial. The intervention was delivered to government employed COs as part of their routine district hospital clinical duties; and real-life, district hospital routine data collection systems were used to gather output and outcome data (31). The research consortium partners concluded that it was neither feasible nor desirable to interfere with normal hospital and operating theatre practice by introducing parallel data collection systems (31); and instead augmented and strengthened the reliability of the existing routine data systems.

No inclusion or exclusion criteria were used to screen patients or qualify their eligibility to benefit from the intervention (31), which increases the generalisability of the findings. All patients with a surgically treatable condition presenting at a district intervention hospital could benefit from the intervention; and the case management was determined by the attending CO on duty at the time, who decided whether to operate, observe or refer the patient.

Evaluating large scale health systems interventions applying methodologies best suited for the evaluation of medical interventions, such as the randomised controlled trial (RCT), ~~may lead to~~ encounter multiple challenges(33). The positive change in the intervention arm of the study was not observed in all pairs of hospitals, and the statistical comparison was not significant, however the effect size was large. We hypothesise that the lack of statistical significance is rather an attribute of a very small sample size (n=16), 16 of all 27 government district hospitals in Malawi, ~~rather than the intervention was not effective~~ given the large effect size(34). Several factors influenced the effectiveness of this in-service training model and are reported in details in another publication (35). Firstly, some intervention hospitals experienced severe shortages of essential surgical equipment and supplies, rendering delivery of surgical services, as well as delivery of the training, impossible at times. This was outside the control of the project, because ensuring availability of surgical infrastructure, equipment and consumables was the sole responsibility of the local authorities. The COST-Africa intervention was designed to have an effect on human resources only, and no project funds were committed to filling gaps in material resources. Secondly, some control hospitals were approached by once-off foreign-led projects boosting the numbers of surgeries done in the duration of the study. Thirdly, in some intervention hospitals, COST-Africa trainees were required to perform other duties outside of the operating room, including clinical and administrative tasks. This impacted on their ability to concentrate on surgery, undermining the primary outcome measure of the trial.

In most intervention hospitals surgical caseloads, when compared with other surgically active COs and MDs, were highest for COs undergoing COST-Africa training. In a separate publication we documented how other COs abandoned their surgical duties when CA-COs arrived, and the project encountered challenges to motivate general COs (35). Particularly interesting is the low surgical productivity of medically qualified staff, who in some hospitals performed almost no surgery in the two-year study period, a finding observed in other studies in the region(7). In most intervention hospitals COST-Africa trainees performed more general surgeries than other COs (who were on average ten-fold more numerous) and were far more surgically productive than MDs. This suggests that surgical ‘task-shifting’ was acceptable at government owned

district level facilities in Malawi, where qualified medical staff, who would be seen as more senior than COs, in some hospitals delegated almost the entire responsibility for general surgical care to the COST-Africa COs.

Surgical safety is of paramount importance in any surgical training programme(36). Our analysis supports findings from other studies(19)which have demonstrated the safety of surgical 'task-shifting' from qualified medical staff to trained non-physician clinicians. Higher percentages of wound infections were registered in cases done by MDs; others have proposed as~~, but~~ a possible reason ~~may be~~ the higher complexity of cases usually performed by MDs(37), though this less plausible in our study, where MDs did little surgery. A deeper analysis of the comparative safety of using surgically trained non-physician clinicians in district hospitals is described in a separate paper, where we demonstrated that surgical outcomes following hernia repairs by COST-Africa COs in the districts were as good as those undertaken at central level hospitals in Malawi(38).

In the course of the training no intra- or post-operative surgical death was recorded in the intervention hospitals, which can also be regarded as a measure of safety of the evaluated model. This finding, however surprising, was confirmed through data validation, interviews with surgical staff and consultations with surgical supervisors who participated in the delivery of the training. The population who receives surgical care in Malawi is young, and district hospitals perform only relatively basic procedures(24) what may explain low surgical mortality rates.

The trainees acknowledged and highly appreciated the design of the COST-Africa BSc programme, its implementation and opportunities for personal development that it offered them. These results demonstrate the overall good fit of the COST-Africa in-service training model with the reality of living and practicing in rural Malawi. Satisfying the needs of district level practitioners is in line with results of studies looking at factors motivating clinical staff to practice in rural areas: supervision, career progression opportunities, financial motivation and personal development(39)(40)(41). However, a follow-on situation analysis undertaken one

year after CA-COs graduated found high levels of attrition (publication forthcoming) and retention of trained practitioners at district hospital level remains the major challenge to meeting the surgical needs of rural populations.

In conclusion, COST-Africa developed, implemented and evaluated Malawi's first postgraduate surgical training programme for non-physician clinicians. The training model has proved to be effective and has been embedded within the mainstream educational programmes offered by the University of Malawi's College of Medicine. However, there are ~~many~~ serious risks endangering the long term success of the model, including the absence of ~~There is no~~ career paths for COs in Malawi after obtaining the BSc in Surgery, which is similar to the situation of other NPCs in the region(42)(17). More research needs to be done to develop retention strategies for surgically able COs to prevent them from diverting to other professions away from the operating room. Lastly, long term impact of surgical 'task-shifting' needs to be investigated to address existing concerns about 'professional dilution' and compromised quality of care for rural populations (43).

Limitations

This study has several limitations. Firstly, the findings on effectiveness are statistically non-significant. However, the scale of the project, where two thirds of all district government hospitals were allocated to intervention or control groups, together with the large observed effect size allow, in our view, for a good level of generalisability and outweighs this limitation.

Another shortcoming concerns the quality of evaluation of safety of the training which was done for one complication (wound infection) for one procedure only (hernia); also, the comparison should have been done between COs and qualified surgeons. The reason why hernias were picked for this study was because hernia repairs are relatively complex procedures for the skill level of surgical trainee and they constitute 60% of all cases of general surgery done at district level. There is no qualified surgeon stationed at district level in Malawi,

and we found comparison of outcomes between cadres working at district and central level unjustified, because of a possibility of confounders beyond our control.

The use of routine data systems, with data recording being undertaken by clinicians might raise questions about data reliability and reporting bias leading to unreported complications, mortalities or over/under-reported numbers of surgeries performed. Challenges with using routine surgical data collection systems in SSA are also well documented(1). However, follow up visits by COST-Africa researchers to hospitals to validate all collected data and to conduct interviews of a wide range of hospital staff, would (we contend) have revealed under-reported cases of general surgery perioperative mortality. The researchers typically found two registers (surgical and anaesthesia) where cases operated on were being recorded, and by comparing these two registers case by case they mitigated to a reasonable extend the problem of reporting bias. Moreover, we contend that the in-depth interviews of a range of different district hospital staff (manuscript under review) we conducted would have revealed any undisclosed surgical mortality or issues with reliability of recording surgical data. Such mortality was detected and reported in the case of emergency obstetrical interventions, but was unrelated to surgical treatment. Also, there was a uniformed operating theatre register in all intervention hospitals introduced by the project and a project-designed form in control hospitals capturing volumes of procedures performed.

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