Summary description of project context and objectives.

The large and largely neglected burden of surgically avoidable morbidity and mortality in low and middle income countries (LMICs) and the steps to achieve global solutions have been reviewed comprehensively by the Lancet Commission on Global Surgery. There are shortages of specialist surgeons in most African countries, and few work at the district level, which means that the surgical needs of rural dwellers go unmet. One response has been task-shifting of surgical responsibilities from surgical specialists to other clinician cadres. In Malawi, half of surgical, obstetric and orthopaedic procedures are done by clinical officers (COs).

COs are a form of non-physician clinician (NCP), also known as associate clinicians and ‘non-surgeons’, who have been the backbone of clinical care services for rural dwellers in Africa for decades, working at health centres and district hospitals. COs undergo three years basic clinical training and can diagnose and treat most of the common major diseases that present to district hospitals. Their qualifications, which are not recognised in Europe or North America, make it difficult for them to emigrate.

Task-shifting of major surgery for common conditions to non-physician clinicians has taken place in over 30 LMICs. However, the case for promoting surgical task shifting is neither generally accepted nor has it been adequately justified as a mainstream model for making surgery accessible in rural settings that lack specialist surgeons, even if it is often a life-saving measure, as in the case of obstetrical emergencies, strangulated hernias and some acute abdominal emergencies. The Lancet Commission cited “.... concerns about safety, efficacy, and the breakdown of professional roles”; the perception that non-specialists are unable to master the required decision-making skills; and unregulated ‘task creep’, where non-physician clinicians embark on surgery for which they are not trained. On the other hand, advocates of task shifting, point to the lack of alternatives for providing emergency life-saving surgery and unmet need for basic elective surgery in remote and rural areas.

Clinical Officer Surgical Training for Africa (COST-Africa), funded under the European Union’s Seventh Framework Programme (grant agreement 266417), is a 5-year trial, 2011-16. It aims to design, implement and evaluate a scalable surgical training programme so as to demonstrate the effectiveness, cost-effectiveness and feasibility of COs delivering major surgery at district hospitals in Malawi and Zambia, trained and supervised by specialist surgeons.

Objectives

1. (a) Work with national policy makers and other national stakeholders to ensure that COST-Africa becomes embedded within and helps to support national policy priorities for surgical training of clinical officers in Malawi and Zambia.

   (b) Conduct a situational analysis to map the distribution and types of current district level surgical services; measure surgical capacity and gaps to be addressed; and establish surgical information systems at district hospitals for measuring surgical outcomes in Zambia and Malawi.

2. Design and implement ethically reviewed surgical training interventions for Clinical Officers which include centralised training, in-service training, supervision and quality control, leading to the scale-up of elective and essential emergency surgical care in district and rural hospitals.

3. Measure the effectiveness and impact of the intervention at the levels of health worker, patient, health facility and district population, using a cluster randomised controlled trial design where similar hospitals are paired and one of each randomly assigned to
intervention and control arms.

4. Establish the cost-effectiveness of the intervention.

5. Support national and regional policy makers in developing career paths and retention strategies aimed at surgically trained Clinical Officers and specialist surgeon-trainers.

Description of the work performed since the beginning of the project and the main results achieved so far.

By prioritising engagement with national decision makers (Permanent Secretaries and national directors) and alignment with national training plans and programmes, COST-Africa is now embedded at national policy levels in Malawi and Zambia. It has accredited and rolled out a national BSc in Surgery for COs in Malawi; and has strengthened the surgical component of a national training programme for COs in Zambia. Thereby, COST-Africa has contributed substantively to establishing a career path for COs to retain them to work at African district hospitals. Despite the challenges, including government-requested scale ups from 1/3rd to 2/3rd of Malawi’s districts and increase in coverage from 3 to 8 provinces in Zambia, COST-Africa has sustained a rigorous programme of ethically approved research.

In Period 1, national surgical curriculums were agreed, situation analyses were conducted, surgery-capable district hospitals identified and hospitals were randomly allocated to intervention and control arms. COs were selected nationally in Malawi and allocated to intervention hospitals, where they received 2 years of in-service training from visiting surgeons. In Zambia, COST-Africa surgical skills’ training was added to a national CO training programme and graduates were deployed to intervention hospitals, often after long delays (due to a politically challenging environment), where visiting surgeon supervisors provide training and oversight to ensure safe surgery.

Data collection tools (see http://www.costafrica.eu/data-collection.html) include the baseline situation analysis Tool A, an Annex A used to collect 12 months of retrospective data on major surgery from all intervention and control hospital operating theatre (OT) registers; and Tool B1 – an extended OT register used by COs to record and transmit an expanded set of monthly surgical data from intervention hospitals. A core set of similar data is collected by data associates at control hospitals. A B3 ‘critical event’ tool, developed from Tool A, captures hospital factors that enable or obstruct district hospital surgery. A B4 ‘adverse event’ tool records intra- or post-operative mortality and surgical complications. Data are reviewed by visiting surgeons, who are responsible for ensuring patient safety, and are transmitted to the local and European researchers who undertake initial data cleaning and instigate action, where needed.

Longer term patient survival and quality of life outcome evaluations are being implemented in four intervention hospitals in Malawi, following discharge post-caesarean section and hernia repairs; and surgical referrals from districts to the central hospital in Malawi are being evaluated for appropriateness. Data collection for costing studies has been completed in Malawi and is ongoing in Zambia.

Our correspondence letter to the Lancet Global Health has been published. “The evidence needed to make surgery a Global Health priority”, LANGLH, 3, 12, e741, Dec 2015 and a full manuscript of our study design is under review in the journal TRIALS – see Appendix 2 of our request for a grant extension.

Preliminary analysis and final hospital visits to validate data and conduct interviews, to interpret research findings, have started in Malawi. Three abstracts were accepted for oral presentations at the COSECSA scientific conference in Blantyre, Malawi, December 2015:
1. The effectiveness of the COST-Africa Clinical Officer surgical training model in Malawi shows a 31% increase in numbers of hernia and hydrocele repairs and salpingectomies in intervention versus control hospitals.

2. The COST-Africa supervision model in Zambia will present initial lesson learning on these processes.

3. Estimates of the cost of district-level surgery and costs of scale-up in Malawi.

By Month 60, COST-Africa will be in a position to start to disseminate on a large scale and engage with national, regional and global stakeholders to ensure maximum research into policy and practice.

Expected final results and their potential impact and use (including the socio-economic impact and the wider societal implications of the project so far).

(i) District hospital and patient end points

(i) (a) surgical outputs
The numbers and incidence density, per district population, of surgical cases conducted in intervention compared with control hospitals; and the numbers and population incidence densities of total major surgical cases and specific cases – herniorrhaphies, hydrocoelectomies and salpingectomies.

(i) (b) appropriate surgical referrals
In Malawi, measurements of quality of surgically related patient-referrals received at the QECH central hospital, comparing surgical practice across 4 intervention and 4 control district hospitals in the Southern region.

(i) (c) mortality and morbidity – patient level data:
Measurements of district hospital secondary end points: post-operative complications prior to hospital discharge in Malawi and Zambia. In Malawi, post-discharge patient level end points are being measured in 4 selected intervention hospitals: post-discharge post-caesarean section mortality of mother and baby; and patient quality of life measurements, pre- and post-inguinal herniorrhaphy.

(i) (d) surgical task shifting
compositions of surgical teams, identifying the roles of COST Africa CO/MLs as lead surgeons, assistant surgeons and anaesthetists in Malawi and Zambia, providing insights into surgical task shifting and cascade effects.

(i) (e) process measurements:
Analyses of (i) ‘adverse events’, ie cases of major peri-operative complications including mortality; and (ii) ‘critical events’, ie events that impact (usually negatively) on district hospital surgical output. These will provide insights into contextual factors determining surgical outputs.

(i) (f) District hospital costs of selected surgical procedures
Comparisons of costs of district and tertiary referral hospital surgery; estimates of costs of surgery as a proportion of total district hospital cost; costs of selected index cases of surgery (unit costs); and estimates of cost implications of scaling up surgery at district hospitals. Also estimates of direct and indirect cost for households / patients seeking and obtaining surgery.

(ii) Clinical officer / Medical Licentiate end points and stakeholder perspectives

(ii) (a) Estimates and changes in levels of self-reported surgical experience, confidence and skills of COST Africa trained COs/MLs prior to deployment, during and at end of intervention.
(ii) (b) In-depth interviews to explore and analyse CO/ML experiences, evaluate the effects of the intervention on their practice, inform future scale-up models; and generate insights on COs/MLs career trajectories and intentions.

(ii) (c) In-depth interviews with surgeons, district and national stakeholder to explore and inform future scale-up models.

(iii) Patient health outcomes
See (i) (c) above.

Potential applications:
COST-Africa is delivering a fully-costed and tested model that will provide African countries with a trained and retainable surgically competent NCP (CO/ML) who can deliver a safe essential surgery package to neglected rural populations. It also is demonstrating the potential for a new role for Africa's scarce resource of specialist surgeons, as trainers and supervisors of district clinicians, to help retain specialists in Africa.

By March 2016 (Month 60 and project end), COST-Africa will be uniquely well placed and poised to engage with national ministries in Malawi and Zambia; with African decision makers, supported by the College of Surgeons of East, Central and Southern African (COSECSA) and with the global surgical community. COST-Africa is filling a major evidence gap identified by the Lancet Commission on Global Surgery and will contribute to transforming the health and protecting the lives of some of the poorest populations of Africa who have least access to basic elective and emergency surgery.

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