Generating evidence for surgical practice in Africa: The role of clinical research

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INTRODUCTION

Practicing surgery in a world that is often surrounded by uncertainties requires scientific evidence that will guide surgical management decisions. This is important in view of the growing phenomenon of malpractice and litigation often associated with surgical interventions. More so, the complexity of clinical care and particularly clinical surgical care has increased dramatically.[1] This increasing complexity has clearly led to increasing demand for sub-specialisation in various clinical surgical disciplines across the regions of the world. Maintaining a balance between the increasing demand for clinical surgical care and the need to be engaged in credible surgical research in order to generate evidence for improving clinical care outcomes is critical.

Evidence-based surgical practice therefore helps in improving precisions in management decisions and reduces the attendant risk associated with uncertainties based on clinical experience or opinions. Evidence-based decisions in surgical practice holds the promise of improving the quality of life of surgical patients, ensuring patient safety and satisfaction as well as having an overall impact on better surgical efficiency and reduction in costs for the patient, hospital management and the society in general.

Therefore, the need for surgical clinicians to engage in sound research activities cannot be overemphasised despite our limitations in resource poor settings in Africa. A survey of senior surgeon scientist showed that 38% had stopped carrying out research before turning 40 years. Of those who stopped, 73% reported that the increasing demand for clinical work was the reason for stopping.[2] It has been argued that this attrition in surgeon’s engagement in surgical research is related to inability to garner resources for research, rather than being primarily related to increasing work load. How then can we do research to generate evidence for better surgical practice in a region with limited financial resources? Should we just focus on our clinical work or we need to strike a balance? If clinical research is the gateway for generating evidence for better surgical practice, how then can we conduct credible research giving our limitations? This article explores various aspects of clinical research and its role in providing scientific evidence for surgical management decisions in Africa.

Clinical opinion or evidence-based surgical intervention

Evidence-based practice is the systematic, scientific and explicit use of current best evidence in making decisions about the care of individual patients. The highest level and grade of clinical evidence are drawn from systematic review of randomised controlled trials (RCTs)
and the lowest being evidence drawn from “expert opinion without a critical appraisal” [Table 1].

The greatest difficulties with RCTs in surgical practice is having to deal with ethical issues of withholding a surgical intervention known to be “effective” based on clinical experience for an experimental intervention not yet proven effective in clinical setting. However, RCTs are the gold standards in proven the efficacy and effectiveness of any intervention in medical practice. RCTs should therefore be designed and applied in selected surgical scenarios to provide evidence for improving surgical practice in Africa. For instance, what is the place for watchful waiting in the management of minimally symptomatic inguinal hernia in African men? If a survey is conducted to assess the opinions of African surgeons on the role of watchful waiting for this clinical scenario, the findings will be quite revealing and probably will end in a dilemma. There may be no consensus opinion among surgeons on this management option. A well-designed RCT is the only way for providing evidence for the effectiveness of this option in clinical practice. The RCT done by Fitzgibbons et al. on watchful waiting vs repair of inguinal hernia in minimally symptomatic men[3] provides evidence that watchful waiting is an acceptable management option for men with minimally symptomatic inguinal hernias. The trial also showed that delaying surgical repair until symptoms increase is safe because acute hernia incarcerations occur rarely. This trial was done in 5 North American centres among 720 men with minimally symptomatic inguinal hernias. Can we apply the findings of this RCT in the management of African men with “minimally symptomatic” inguinal hernias? The answer can only come through the design of similar RCT in a cohort of African men. If this is done, management decisions for this type of clinical scenario will be improved in our setting rather than basing our decisions on mere clinical experience, opinions or expertise. Moreover, in order to safeguard and ensure compliance with the first canon of medicine: “first do no harm”, we must engender a culture of clinical research in our hospitals to generate evidence for optimal surgical practice in Africa. Although clinical opinions are important, it often takes the lowest rung in the ladder of clinical evidence for optimal practice.

In the proceeding paragraphs, some of the roles of clinical research in surgical practice in Africa will be discussed.

1. Clinical research and surgical efficiency

Hospital survey data suggest a rising demand for surgical services faster than our ability to supply.[4] One of the areas that clinical research has proven to be beneficial to the practice of surgery is the application of evidence to improve surgical efficiency in the operating room.[5] This is critical in Africa as the demand for surgical services is rising faster than our ability to supply them. Surgeon-scientists could design and investigate various models of operation room (OR) practices and come up with innovative and more efficient surgical OR practice models that will reduce waiting times, improves patient throughput and over all surgical efficiency in our various surgical settings in Africa. Indeed, health system research which is the integration of epidemiologic, sociological, economic and other analytic sciences in the study of health services is a novel area of research that the African surgeon should seek to engage in. Health services research is usually concerned with relationships between need, demand, supply, use and outcome of health services. This aims at evaluation, particularly in terms of structure, process, output and outcome. The end result is improvement in service efficiency.

2. Clinical research and surgical principles

Clinical surgery is a rapidly developing specialty and innovative surgical principles and approaches in Minimal Access Surgery, Endoscopic surgical approaches in surgery and
Gynaecology, use of Laparoscopic banding techniques in surgical management of morbid obesity,\textsuperscript{[6]} stem cells in neurosurgical management of spinal cord injuries, Natural Orifice TransEndoscopic Surgery and many other novel approaches are by-products of well-designed clinical surgical research that have proven the effectiveness and the safe application of those techniques in current surgical practice. However, some of these innovative approaches have limited application in most settings of Africa. The African surgeon-Scientists therefore most understand what works well giving our peculiar setting as well as the characteristics of the African surgical patient. We can only have this unique understanding through well-designed clinical research in our settings in order to set unique guidelines and principles for managing surgical conditions in Africa.

One area of concern in surgical practice in Africa is the continuing problem of post-operative surgical infections. Basic science research has helped the understanding of molecular behaviour of microbes and how they mediate surgical infectious diseases and have led to novel approaches to prevention of pre- and post-surgical infections.\textsuperscript{[7]} Indeed, clinical research trials have shown the effectiveness of peri-operative hyper-oxygenation in the prevention of surgical infections during surgical procedures involving the gastrointestinal tract.\textsuperscript{[8-11]} We may not have the right environment to conduct high-tech bench research to understand the biology of microbes, but could do prospective studies to investigate epidemiologic predictors of surgical infections in our settings. Clinical research in these areas has contributed to setting practice guidelines on optimal antibiotic prophylaxis during surgery, etc. In the field of obstetrics and Gynaecology, clinical research has contributed to development of principles and practice guidelines\textsuperscript{[12]} for vaginal birth after Previous Caesarean sections, non-peritoneal closure after pelvic surgeries etc.

3. Clinical research, Quality of care, patient safety and satisfaction

One of the principal roles of clinical research in surgical practice is to ensure quality improvement in surgical care which ultimately affects patient safety and satisfaction. Setting minimum benchmarks for delivering surgical care services is critical in ensuring quality of care and safeguarding patient safety and satisfaction in various surgical settings in African. The landmark report by the National Institute’s of Medicine 2000: To Err is Human,\textsuperscript{[13]} emphasises the need to set benchmarks in medical care in order to safeguard quality of care and patient safety. Surgical units in Africa should engage in health outcome research and audit of our surgical practice standards in order to determine if we are maintaining quality of service delivery or otherwise. One principal outcome used in tracking quality of surgical care is morbidity and mortality patterns associated with various surgical diseases and their management modalities. We could also compare surgical outcomes of certain conditions in different hospital settings in order to determine hospital-level and operator-related factors in surgical outcomes. This will help in tracking hospital performance and also upgrading standards of practice aimed at maintaining quality of care and patient safety in our practices. The study by Chang \textit{et al.} identified substantial variation in the mortality rates of infants with gastroschisis, even after risk adjustment in low-complexity cases.\textsuperscript{[14]} They also argued that the disparity in outcome is suggestive of a disparity in operative practices and quality of care in the treatment of these infants. Clinical research, particularly surgical outcome research, could help in determining predictors of quality improvement of surgical care in Africa.

4. Clinical research and cost-effectiveness of surgical interventions

It has been commented that more than 70% of the revenue generated in some academic medical centres around the world come from clinical surgical services.\textsuperscript{[15]} Since most surgical services are often expensive, the need to consider the issues on cost and effectiveness of such services cannot be overstated. It will be rather “too expensive” to
subject patients to surgical procedures that add little or no value to quality of life. Effectiveness in this context refers to the quality of life gain by undergoing a particular surgical procedure. It could also be measured in terms of the disability-adjusted life years (DALYs) averted by the surgical intervention. A surgical procedure that improves the quality-adjusted life years (QALYs) or reduces the DALYs for a patient per unit cost for the procedure is generally considered cost-effective. Surgical procedures that result in deterioration in QALYs gain or increases DALYs are not cost-effective even if the absolute cost for the procedure may seem “very cheap” or affordable. In order for surgical practice in Africa to be “cost-effective”, we need to conduct basic outcome research to understand the effectiveness or value of certain surgical interventions in a given surgical scenario. Again, in order to maintain the first canon of medicine: “first do no harm”, we must engender a culture of clinical research in our hospitals to generate evidence for optimal, quality, safe and cost-effective surgical practice in Africa.

CONCLUSION

From the preceding paragraphs, it is quite clear that we need to engage in clinical research in order to generate evidence for better surgical practice in Africa. The challenge is the capacity of our residents and young surgeons to understand the basic methodology and concepts in research. We must therefore advocate to our government and healthcare policy makers to see the value of investing in capacity building for better conduct of clinical research in our various health settings. The comment of Kenneth Kaushanky,[16] 2004, on the value of research in our academic medical centres sums it all. He advocate that “we must teach residents that the singular discovery of new knowledge can sometimes impact tens of thousands of patients; we must nurture our fellows and junior faculty members, providing them the tools of the trade and instilling in them the tremendous excitement that comes from bringing effective therapy to patients. And because teaching can impact these constituencies, we must teach the public about the values and processes and power of biomedical science, replacing the fear of things unknown with a renewed enthusiasm for the reward and potential made possible by strong support for clinical investigation”.

We all need to think carefully and place research as a valued commodity for the government and health policy makers to see and also search for ways to incorporate responsible conduct of clinical research into the fabric of our health institutions in Africa.

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## Table 1

Grades of recommendation and levels of evidence

| Grade of recommendation | Level of evidence | Interventions                                           |
|-------------------------|-------------------|--------------------------------------------------------|
| A                       | 1a                | Systematic review of randomised controlled trials      |
|                         | 1b                | Individual randomised controlled trial                 |
| B                       | 2a                | Systematic review of cohort studies                    |
|                         | 2b                | Individual cohort study                                |
|                         | 3a                | Systematic review of case-control studies              |
|                         | 3b                | Individual case-control study                          |
| C                       | 4                 | Case series                                            |
| D                       | 5                 | Expert opinion without explicit critical appraisal or based on physiology or bench research |