Surgical Education Research: An IDEAL Proposition

To the Editor:

Since the publication of Richard Horton’s contentious commentary in The Lancet in 1996 likening surgical research to comic opera, much progress has been made with respect to the development of a coherent and methodologically appropriate standard for the conduct of surgical research studies. In September 2009, the publication of the IDEAL framework, designed and developed by methodologists, surgeons, trialists, and evidence-based medicine experts, intends to assist in the assessment of surgical innovation. Taking a page from the book of drug development trials, the Balliol Colloquia (as they called themselves) defined 5 stages of surgical innovation: innovation, development, exploration, assessment, and long-term. Each stage has a set of recommendations on how evaluation should be conducted, for example, research question, aim, patient base, and optimal study design. Common items for agreed standard definitions are also listed, such as grading of patient risk factors, scale of surgical insult, and scope and severity of complications. The bold claim was to “... transform the current liberal approach of surgical innovation into a structured process based on the scientific principles of evidence-based healthcare.”

A contributor to the IDEAL framework is senior author for 3 systematic reviews of the literature with respect to the innovation of surgical simulation, published within this Journal. The first in 2006 sought to compare 30 randomized controlled trials (RCTs) comprising 760 participants with respect to the effectiveness of surgical simulation. The quality of the RCTs was often poor, with resultant vague conclusions for the review. A further review published in 2008, and updated just this year, considered RCTs, which reported on skill transfer to the clinical environment after simulation-based training. Both reviews suggested the transfer of skills to the clinical environment, with the latter publication noting an increase in quality of study design, and a strengthened evidence base of the collective studies. Nonetheless, there were numerous limitations of the cited studies, that is, RCTs’ failure to report methods of randomization, allocation concealment, intention-to-treat analysis, and so on. Sample sizes were generally small, with power calculations reported in less than one third of studies. There was multiple testing of many variables, increasing the likelihood of type I error, endpoints of training were neither well defined nor consistent, and there was no data to demonstrate money saved through improved operating room efficiency or reduced risk to patients. The authors submit that future research studies are required with consistent training and assessment methods across studies to provide further insight into the benefits of simulation-based training.

In this journal, Arriaga et al report pilot testing of multicycle simulation training for operating room (OR) teams. Their study recruited 221 active OR staff from 4 Harvard medical centers to undergo a standardized 4- to 6-hour course focused upon teamwork and communication in the OR. Financial and administrative support came from the local malpractice insurer. Outcomes were based on a novel self-report survey following completion of training, with overwhelmingly positive responses from participants with regard to realism, challenge, and relevance of the simulation scenarios. A not dissimilar study recruited 288 senior medical staff (ie, surgeons, anesthesiologists, physicians, and nurses) to work as expert multidisciplinary teams within the UK Defence Medical Services’ Hospital Simulator, or HOSPEX. The training program encompasses the entire environment of a military hospital for 3 whole days, as preparation for war zone deployment. The simulation focuses upon high-level crisis management and nontechnical skills, in prehospital, emergency department, operating room, and intensive care environments. The IMPACT tool was used to measure participants’ skill in a pre-post manner, and again during deployment to the war zone hospital, as a measure of retention. The results from self-reported data revealed significantly positive improvements for decision-making, situational awareness, and patient care skills, with high levels of satisfaction with regard to the training exercise. At deployment there was no statistical decay in these scores, indicating maintenance of skills, though only 10% of subjects were followed-up to this stage.

Common to both these innovative studies are the interdisciplinary nature of the exercise, the engagement of staff physicians as subjects, structured, standardized and relevant training curricula, large numbers of participants, together with high-level organizational and financial support. It is understood that both these studies seek to report new paradigms in surgical simulation, which are commendable, well founded, and important additions to the literature. Nonetheless, the outcome measures are weak, and say more about the course rather than its effectiveness as a strategy to enhance clinical care. Arriaga et al state that the program’s impact needs to be followed up through outcomes measured in the OR, which is laborious, challenging, and expensive. The concern is that even if this is done, it will be impossible to know whether any improvement in patient outcome is attributable to the course, as there is no prospective control arm for this study.

Barsuk et al published groundbreaking work with regard to a simulation-based mastery learning program for central venous catheter insertion, comparing two adult intensive care units in a cohort manner. Not only were there fewer infections in the interventional intensive care units, but this was also a cost-effective strategy with a seven-fold return on investment. Neily et al reported a dose-response association between the implementation of a medical team training program and surgical mortality, in a retrospective analysis with a contemporaneous control group. While neither study was a prospectively performed RCT, both employed rigorous clinically relevant metrics, and have great merit in furthering the implementation of simulation-based training into modern practice.

In concert with the work of the IDEAL group, there is a need for researchers to describe a process for the conduct of high quality surgical education research. Agreed definitions and standards are required for validation and implementation of training and assessment strategies. The needle needs to move toward high quality multi-center studies, designed in a prospective manner, with outcome measures of relevance to clinicians, patients, institutions and the wider society. The design must consider future work with implementation scientists, policy makers, clinical staff and patients, to ensure widespread and definitive impact upon patient care. Rather than stifel innovation, a structured and scientifically rigorous framework can encourage an iterative process of research and development in surgical education, which has a defined pathway for clinical implementation.

Cook (another IDEAL co-author) offers a useful classification for surgical RCTs, ie, exploratory for the early assessment of new trials, explanatory to assess the intervention in favorable conditions, and pragmatic to inform clinical decision making through evaluation of the intervention in a realistic clinical setting. Whilst Cook focuses upon describing RCTs, in the context of surgical education trials those described by Arriaga et al and Arora et al would be considered exploratory in nature. High-quality RCTs to...
assess the impact of simulation for surgical skills training would be an example of explanatory trials.12-13 Pragmatic RCTs are more difficult to perform, and absent in the surgical education literature. It is notable that neither of the aforementioned studies on central venous catheter insertion or team training were prospective RCTs, though have had an important impact upon clinical care.8-10 Arriaga et al11 rightly contest that high reliability industries such as aviation and nuclear power have incorporated simulation into their practice without definitive evidence to prove its effect. Whilst factually correct, it is not the overall assertion that simulation is not a good idea for surgeons and their patients. The statement by Champion and Gallagher in 2003 that ‘bad science in the field of medical simulation is all too common’ is unlikely true today, but there is more work to be done.11-12 We need to take a page from the IDEAL framework to develop a strategy, structure and definitions to assist in the undertaking of high quality surgical education research. A simple start point might be to suggest that the educational idea should have a specific goal, which through development and exploration can be shown to be efficacious in terms of learner and patient-level outcomes. The educational intervention should then undergo rigorous assessment in comparison to traditional learning strategies, which is further validated and potentially refined through long-term study of clinically relevant outcome measures.

This model would serve to take surgical education research to the next level in terms of its quality and impact. Not only would this benefit scientists working in this field, but also assist researchers who are not cognizant of the subject matter to accurately appraise its scientific quality. Funding bodies and agencies would be more confident of the nature and potential impact of proposed research trials. Such a strategy would engage surgical educationalists to effectively collaborate with relevant technology developers, trial methodologists, outcomes analysts, patient safety specialists, health economists, and implementation scientists in search of a common goal—how to assess and implement innovation in surgical education. This process can enable institutions, regulatory bodies, policy makers and society to confidently appraise the value of surgical education to improve care for all surgical patients.

Rajesh Aggarwal, MD, PhD, MA, FRCS
Department of Surgery
University of Pennsylvania
Philadelphia, PA
rajesh.aggarwal@uphs.upenn.edu

REFERENCE


REPLY

The letter by Rajesh Aggarwal is a timely wake-up call to subject surgical education and simulation to the rigorous surgical scientific approach supported by the IDEAL recommendations.1 Worldwide surgical education remains largely “eminence” rather than “evidence”-based. This is despite the cost of a surgical education representing substantial expenditure in time and resources for trainees, surgeons, hospitals, governments, and patients. As more financial constraints and patients’ expectations demand an efficient and safe surgical experience, attention must be directed at how to deliver a high-quality, reliable, comprehensive, and assessable surgical education.

The challenge is clear but the solutions are less obvious. Hospitals and training programs continue to try to blend a service and training model for surgical education. Much of surgical training and skill/competence is gained osmotically through experience and serendipitous patient and disease encounters. Individualized educational programs are rarely in place and are frequently time-based, not competence-based, programs. Recent research projects in Toronto into competence-based surgical training seemed to have been successful but are not yet widely adopted.2

To concentrate relevant surgical experience and provide objective assessment, simulation efforts have been increased in the recent years.3 As has previously been documented, many of the studies published around surgical simulation continue to have few subjects and are often lacking clear outcome measures. As Rajesh Aggarwal infers in his letter, the argument that it is not necessary to wait for proof of the value of simulation can no longer be used. We have the approaches, methodology, means, and questions to conduct “exploratory” and “pragmatic” randomized controlled trials of approaches to surgical education and simulation. Simulations have been developed to train and assess technical, interpersonal, and operative team skills, yet many programs largely rely on the century-old apprenticeship model that was administered to most current training programme directors.

As surgeons, we strive to put our patients’ best interests foremost. Our surgical journals, such as the Annals of Surgery, celebrate often small improvements in patient outcome. The challenge for both academic and practicing surgeons is to rigorously study the best models of surgical education possible in 2014 and publish the methods and outcomes compared with the “control group” with increased reference to demonstrated improved patient safety, total cost, and efficient use of the trained and training surgeon.

The next generation of trainee surgeons should be highly competent in appropriate simulation tasks, able to dwell on weaknesses, and then to progress quickly through to mastered surgical skills. The trainee should work in programmes that ensure adequate exposure.

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to an appropriate range of complexity of clinical problems and skills. Such education and training can be offered if the will and data are made available. The model proposed by Aggarwal deserves consideration.

Guy Maddern, MBBS, MS, MD, PhD FRACS
The Queen Elizabeth Hospital
University of Adelaide Discipline of Surgery
Woodville, South Australia
guy.maddern@adelaide.edu.au

REFERENCES