



Strategies to improve clinical research in surgery through international collaboration

*Kjetil Søreide, Derek Alderson, Anders Bergenfelz, John Beynon, Saxon Connor, Dan L Deckelbaum, Cornelis H Dejong, Jonathan J Earnshaw, Patrick Kyamanywa, Rodrigo O Perez, Yoshiharu Sakai, Desmond C Winter, and the International Research Collaboration in Surgery (IRIS) ad-hoc working group**

Lancet 2013; 382: 1140–51

*Members listed in the appendix

Department of Gastrointestinal Surgery, Stavanger University Hospital, Stavanger, Norway (Prof K Søreide MD);

Department of Clinical Medicine, University of Bergen, Bergen, Norway (Prof K Søreide); University

Hospital Birmingham NHS Foundation Trust, University of Birmingham College of Medical and Dental Sciences, School of

Cancer Sciences, Academic Department of Surgery, Queen Elizabeth Hospital, Birmingham, UK

(Prof D Alderson MD); Department of Surgery, Skåne University Hospital, Lund, Sweden (Prof A Bergenfelz MD);

Department of Colorectal Surgery, Abertawe Bro Morgannwg University Trust, Swansea, UK (Prof J Beynon MS);

Department of Surgery, Christchurch Hospital, Christchurch, New Zealand (S Connor MBChB); Centre for

Global Surgery, McGill University Health Centre, Montreal, QC, Canada (D L Deckelbaum MD);

Department of Surgery, University Hospital Maastricht and NUTRIM, School for Nutrition, Toxicology and Metabolism, Maastricht University, Maastricht, Netherlands

(Prof C H Dejong MD); Department of Vascular Surgery, Gloucestershire Royal Hospital, Gloucester, UK (J J Earnshaw DM); Department of Surgery, Faculty of Medicine, National University of Rwanda, Butare, Rwanda

(P Kyamanywa MD); Department of Gastroenterology, Colorectal Surgery Division, University of São Paulo School of Medicine, Brazil (R O Perez MD);

Department of Surgery, Kyoto University, Kyoto, Japan (Prof Y Sakai MD); and Department of Surgery, St Vincent's University

More than 235 million patients undergo surgery every year worldwide, but less than 1% are enrolled in surgical clinical trials—few of which are international collaborations. Several levels of action are needed to improve this situation. International research collaborations in surgery between developed and developing countries could encourage capacity building and quality improvement, and mutually enhance care for patients with surgical disorders. Low-income and middle-income countries increasingly report much the same range of surgical diseases as do high-income countries (eg, cancer, cardiovascular disease, and the surgical sequelae of metabolic syndrome); collaboration is therefore of mutual interest. Large multinational trials that cross cultures and levels of socioeconomic development might have faster results and wider applicability than do single-country trials. Surgeons educated in research methods, and aided by research networks and trial centres, are needed to foster these international collaborations. Barriers to collaboration could be overcome by adoption of global strategies for regulation, health insurance, ethical approval, and indemnity coverage for doctors.

Introduction

About 11% of the global burden of disease can be treated by surgery, and 80% of deaths from surgically correctable disorders occur in low-income and middle-income countries.^{1,2} About 235 million major surgical procedures are done every year worldwide.² By contrast with the number of operations, few patients are enrolled in trials; for example, less than 1% of patients with cancer in California, USA, enrol in cancer trials.³

Key messages

- More than 235 million patients worldwide undergo surgery every year, but very few are enrolled in surgical clinical trials
- Benefits of global research collaboration include faster recruitment of patients, and larger trials with more generalisable results
- Barriers to collaboration could be overcome by adoption of common, global strategies in regulation, insurance, ethical approval, and indemnity
- Surgeons educated in specific research methods, aided by surgical research networks and trial centres, should foster collaboration in international research
- International research collaboration in surgery between developed and developing countries should result in capacity building and quality improvement, and mutually enhance surgical care
- Low-income and middle-income countries increasingly report much the same surgically treatable diseases (ie, cancer, cardiovascular disease, and metabolic disease) as developed countries; research collaboration is thus of mutual interest
- Emerging technologies, including telemedicine and web-based modules, might ease collaboration in surgical research

In terms of global and public health, disorders needing surgery are under-represented in funding and programme initiatives compared with infectious diseases (eg, HIV, malaria, and tuberculosis), although injuries are expected to supersede infectious diseases as causes of death in Africa in the near future.⁴

The number of global clinical trials is expanding, especially for novel drugs and biological agents, and developing countries are increasingly involved.⁵ The number of countries participating in trials more than doubled during 1995–2005, from 33 to 77 of 150 countries included.⁶ This increase was driven by lower costs (eg, in Latin America, Eastern Europe, and Asia), improved access to previously untreated patients, and improvements in health-care infrastructure in these regions. However, surgical trials have not undergone the same global expansion. Although widespread

Search strategy and selection criteria

We constructed a narrative Review on the basis of our experience in general and subspecialty surgery, including networking and collaboration across countries and continents. We searched PubMed, Medline, and Google Scholar with the search terms “surgery”, “consensus”, “multicentre studies”, “international”, “collaboration”, and “research” alone or in combination, with a main focus on the past 5 years (January, 2007, to March, 2013). We examined reference lists of articles identified by this search strategy to identify other potentially important publications, including books and book chapters on related topics. Additionally, we contacted a network of surgeons around the world, representing surgical research groups, surgical societies, and surgical specialty representatives from all continents, of whom collaborators are listed in the IRIS ad-hoc working group (appendix).