

ORAL PRESENTATION

Open Access

Tailoring study design to each stage of surgical innovation: the ideal recommendations

Allison Hirst^{1*}, Jonathan A Cook², Peter McCulloch³, Douglas G Altman⁴, Carl Heneghan⁵, Markus K Diener⁶, Patrick L Ergina⁷, Jeffrey S Barkun⁸, Jane M Blazeby⁹, David J Beard¹⁰, Danica Marinac-Dabic¹¹, Art Sedrakyan¹²

From 2nd Clinical Trials Methodology Conference: Methodology Matters
Edinburgh, UK. 18-19 November 2013

The pathway of surgical innovation is complex. Inherent ethical and practical characteristics make scientific evaluation of new techniques or devices by a definitive randomized controlled trial (RCT) challenging.

The IDEAL Collaboration (<http://www.ideal-collaboration.net>) Framework for evaluating surgical innovation describes a five stage process - Idea, Development, Exploration, Assessment and Long-term study.⁽¹⁾ Early stage studies should be designed to facilitate and prepare the way for a rigorous evaluation by RCT.

IDEAL Recommendations in the early stages (Idea/Development) emphasise prospective designs, transparency and full reporting in open registries, to provide reliable data early in the innovation development process. At the Exploration stage, prospective observational studies need to address factors such as case-mix, learning and outcomes, building co-operatively and explicitly towards a definitive evaluation study, preferably an RCT, optimising the contribution of data from non-randomised prospective evaluations (Assessment stage). The Long-term stages should be characterised by registry-based surveillance for both new procedures and devices.

IDEAL proposals for high quality RCTs of surgical procedures focus on three key areas: definition of the intervention; who delivers the intervention and preferences of surgeons and patients. IDEAL Recommendations identify modifications to study design which may help address these difficult areas. We will describe examples of good practice using these suggested methods.

Everyone involved in evaluating surgical innovations is invited to join the IDEAL Collaboration community and

help further evolve methodology and reporting standards for robust trials in surgery.

Authors' details

¹Nuffield Department of Surgical Science, University of Oxford, Oxford, UK. ²Health Services Research Unit, University of Aberdeen, Aberdeen, UK. ³Nuffield Department of Surgical Science, University of Oxford, John Radcliffe Hospital, Oxford, UK. ⁴Centre for Statistics in Medicine, University of Oxford, Botnar Research Centre, Oxford, UK. ⁵Department of Public Health and Primary Care, Oxford University, Oxford, UK. ⁶Director of the Study Centre of the German Surgical Society, Department of General-, Visceral-, and Transplantation Surgery, Heidelberg University, Heidelberg, Germany. ⁷Department of Surgery, McGill University, and Oxford International Programme in Evidence-Based Health Care, University of Oxford, Montreal, Canada. ⁸Department of Surgery, McGill University, Montreal, Canada. ⁹Professor of Surgery, Centre for Surgical Research, School of Social & Community Medicine, University of Bristol, Bristol, UK. ¹⁰Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, and NIHR Oxford Musculoskeletal Biomedical Research Unit, Oxford, UK. ¹¹Division of Epidemiology, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, Food and Drug Administration, Maryland, USA. ¹²Weill Cornell Medical College of Cornell University and New York Presbyterian Hospital, New York City, NY, USA.

Published: 29 November 2013

Reference

1. McCulloch P, Altman DG, Campbell WB, Balliol Collaboration, et al: No surgical innovation without evaluation: the IDEAL recommendations. *Lancet* 2009, **374**:1105-12.

doi:10.1186/1745-6215-14-S1-O85

Cite this article as: Hirst et al.: Tailoring study design to each stage of surgical innovation: the ideal recommendations. *Trials* 2013 **14**(Suppl 1):O85.

¹Nuffield Department of Surgical Science, University of Oxford, Oxford, UK
Full list of author information is available at the end of the article