

ORAL PRESENTATION

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

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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 - **I**dea, **D**evelopment, **E**xploration, **A**ssessment and **L**ong-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 (**I**dea/**D**evelopment) emphasise prospective designs, transparency and full reporting in open registries, to provide reliable data early in the innovation development process. At the **E**xploration 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 (**A**ssessment stage). The **L**ong-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.

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Published: 29 November 2013

Reference

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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.

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