The IDEAL Collaboration

Idea, Development, Exploration, Assessment, Long-term follow-up

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The IDEAL Framework, Recommendations and Proposals: Summary of key features.

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The IDEAL Collaboration grew out of an earlier initiative known as the Balliol Group who held a series of conferences at Balliol College, Oxford in 2007-2009 with a commitment to improve the quality of research in surgery. Their discussions led to the development of the IDEAL framework for describing the stages of development of surgical and interventional innovations, and a series of recommendations about how methodology and reporting of research at each of these stages could be improved. The group also made a series of proposals about how specific groups (publishers, funders, regulators, and professional organisations) can help to change the environment for this kind of research in a positive manner. The three tables below summarise the key issues described in the Lancet publications reporting the IDEAL Framework, Recommendations and Proposals in 2009 [1,2,3] and subsequently further detailed in 3 articles published in the BMJ in 2013. [4,5,6]

Table 1. Defining characteristics of IDEAL framework phases

Phase 1 IDEA	Phase 2a **D**EVELOPMENT	Phase 2b **E**XPLORATION	Phase 3 **A**SSESSMENT	Phase 4 **L**ONG TERM MONITORING
Initial report Innovation may be planned, accidental or forced Focus on explanation and description	"Tinkering" (rapid iterative modification of technique and indications) Small experience from one centre Focus on technical details and feasibility	Technique now more stable Replication by others Focus on adverse effects and potential benefits Learning curves important Definition and quality parameters developed	Gaining wide acceptance Considered as possible replacement for current treatment Comparison against current best practice	Monitoring late and rare problems, changes in use

Table 2. Key recommendations for research design at each IDEAL phase

IDEA ***Professional Innovation Database***	**D**EVELOPMENT ***Prospective Development Studies***	**E**XPLORATION ***Phase IIS Study***	**A**SSESSMENT ***Surgical RCT***	**L**ONG TERM MONITORING ***Prospective Registries***
Compulsory reporting of all new innovations Confidential entry allowed to encourage reporting of failed innovations (similar to CHRP system) Hospital or institution to be informed separately as a professional duty	Detailed description of selection criteria Detailed technical description Prospective account of ALL cases consecutively, including those NOT treated with new technique/device Clear STANDARDISED definitions of outcomes reported Description of ALL modifications, and when they were made during the series Registration of PROTOCOL before study starts Use of Statistical Process Control (SPC) methods to evaluate progress	To evaluate technique prospectively and co-operatively To develop a consensus over *definition* of the procedure, *quality* standards and *indications* To gather *data* for *power calculations* To evaluate and monitor *learning curves* To achieve consensus on the *trial question* To develop a *multi-centre randomised trial (RCT)*	RCT – question agreed in Phase IIS Use power calculations from Phase IIS Use learning curve data to decide entry points for clinicians Use Phase IIS consensus to define operation, quality control AND outcome measures Use modified RCTs or recognised alternative if RCT not feasible: Feasibility RCT Expertise-based RCT Cohort multiple RCT Step-wedge design Controlled-interrupted time series	Should monitor indications as well as outcomes SPC used for quality control (Shewart charts, CUSUM, VLAD)

Table 3. Proposals for action by stakeholders in surgical research

Stakeholder Group	***Proposals for action to improve surgical research***
JOURNAL EDITORS	•Promotion of IDEAL design and reporting standards in instructions to authors •Assistance by editors with development of registries of surgical protocols and reports •Calls for specific prospective study designs
RESEARCH FUNDERS	•Provide specific funding for well-designed early-stage surgical innovation •Demand evidence of benefit for new techniques •Link funding to adequate scientific evaluation •Support well-designed surgical databases, registries, and reporting systems
REGULATORS	•Provide rapid, flexible, and expert ethical oversight for early-stage innovation •Link provisional approval to evaluation or registration of all cases •Accept IDEAL approved study designs as evidence of appropriate evaluation •Raise burden of proof for full licensing of new devices to demonstrate efficacy level
PROFESSIONAL SOCIETIES	•Ensure guidelines explicitly support IDEAL model of technical development and evaluation •Require members to use appropriate registers for the various stages of innovation as a condition of specialist recognition •Ensure young trainees receive education and training in the IDEAL methods

References:

1. Barkun JS, Aronson JK, Feldman LS, Maddern GJ, Strasberg SM, for the Balliol Collaboration. Evaluation and stages of surgical innovations. *Lancet* 2009; **374:** 1089–96.

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

4. McCulloch P, Cook JA, Altman DG, Heneghan C, Diener MK; IDEAL group. IDEAL framework for surgical innovation 1: the idea and development stages. BMJ. 2013 Jun 18;346:f3012.

5. Ergina PL, Barkun JS, McCulloch P, Cook JA, Altman DG; IDEAL group. IDEAL framework for surgical innovation 2: observational studies in the exploration and assessment stages. BMJ. 2013 Jun 18;346:f3011.

6. Cook JA, McCulloch P, Blazeby JM, Beard DJ, Marinac-Dabic D, Sedrakyan A; IDEAL group. IDEAL framework for surgical innovation 3: randomised controlled trials in the assessment stage and evaluations in the long term study stage. BMJ. 2013 Jun 18;346:f2820.