

How to improve surgical research: the IDEAL approach

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Abstract

Here we introduce the IDEAL Framework and Recommendations for evaluating surgical innovation from an idea of a new technique towards a pivotal trial and beyond. We explain the core concepts here and future editions of this periodical will continue the IDEAL theme. IDEAL offers a rational way to explore the effectiveness and safety of new surgical procedures and medical devices in a more robust, transparent and ethical manner than current practice.

This symposium aims to present to the readers a new rational way to design, conduct and report surgical research based on the principles of the IDEAL-Collaboration and others within shoulder and elbow surgery. We examine how to improve research methods across all stages of evaluating innovation.

Keywords: IDEAL Framework and Recommendations, Research, Surgical Innovations



Figure 1: Header of IDEAL framework | Webpage: www.ideal-collaboration.net

Introduction:

The evaluation process for developing new medicines is a well-established and regulated pathway conducted by clinical researchers globally. Several steps are involved to minimize harms whilst rigorously testing efficacy of the drug as below:

- 1) Pre-Clinical Studies: Here, a new medication is studied outside the laboratory and in vivo using an animal model.
- 2) Phase 0 Studies: Also known as microdosage studies, these provide data on any potential harms of a new medication when administered in humans as opposed to animals. In addition to ensuring that a drug is safe, these studies help determine its basic pharmacodynamics and pharmacokinetics [6].

- 3) Phase 1 Studies: These are devoted to analyze efficacy, pharmacodynamics and pharmacokinetics in non-comparative trials.

- 4) Phase 2 Studies: Small case controlled trials comparing a drug against a placebo or another medicine with known and standardized outcomes.

- 5) Phase 3 Studies: Large randomized trials, generally multicentre, comparing a new drug against a placebo or another medicine with known and standardized outcomes [16].

- 6) Phase 4 Studies: Post marketing retrospective trials. More devoted to long term safety and effectiveness [11].

Historically the same rigorous standardized process has not developed in surgical research due to both a lack of regulatory

requirements for surgical techniques but also due to several other specific challenges inherent in the nature of surgery as a complex intervention. These challenges include difficulties in defining a standard surgical intervention due to iterative changes being made by surgeons, the involvement of learning curves, attributes of individual surgeons' effects on outcomes and a lack of agreed standard outcome measures in surgery. In addition there is often a lack of equipoise with both surgeons and patients expressing preferences in treatment. However it is possible to construct high-quality RCTs in surgery to test new techniques. The IDEAL Collaboration (www.ideal-collaboration.net/) (Figure 1), an international group of surgeons and research

methodologists have developed a rational way to move towards developing pivotal surgical RCTs via a systematic system using robust study designs.

The word IDEAL present the initials of the stages of surgical development as following:

Idea, Development, Exploration, Assessment and Longterm study [7].

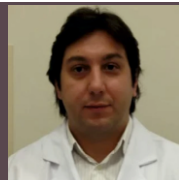
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Table 1: Defining characteristics of IDEAL framework phases

Phase 1 IDEA	Phase 2a DEVELOPMENT	Phase 2b EXPLORATION	Phase 3 ASSESSMENT	Phase 4 LONG TERM MONITORING
<ul style="list-style-type: none"> Initial report Innovation may be planned, accidental or forced Focus on explanation and description 	<ul style="list-style-type: none"> Rapid iterative modification of technique and indications Small experience from one centre Focus on technical details and feasibility 	<ul style="list-style-type: none"> Technique now established Replication by others Focus on adverse effects and potential benefits Learning curves important Definition and quality parameters developed 	<ul style="list-style-type: none"> Gaining wide acceptance Considered as possible replacement for current treatment Comparison against current best practice 	<ul style="list-style-type: none"> Monitoring late and rare problems, changes in use

Stages are broadly similar to those implemented in the pharmaceutical industry. Idea is analogous to phase 0, Development - phase 1, Exploration - phase 2, Assessment - phase 3 and Long-term-study phase 4. The only phase with no parallel in the original IDEAL is the preclinical phase, however it is comparable with surgical cadaveric studies performed to test the surgical idea before the technique reaches the live patients. The IDEAL Collaboration is currently updating the Framework and will provide further guidance on this pre-clinical stage. This has been in response to publications by researchers using IDEAL 0 [10] and it being an important stage for developing medical devices – IDEAL has now developed a separate IDEAL-D [14, 16].

Indeed creating a pathway for evaluation designed to address the unique characteristics of surgical procedures rather than simply applying drug clinical trials to the surgical field offers many advantages. Further research and development of IDEAL by using the Framework in practice will lead to more robust and comparable data thus providing reliable answers to the central questions within the field of surgery. Therefore the IDEAL-Collaboration developed stages for surgical development in a similar way to phases of clinical trials but respecting the characteristics that surgical trials need.

How to use IDEAL in your research

The IDEAL Collaboration has endorsed a

number of suggestions for specific study designs and reporting standards which are recommended at different stages in the Framework. These suggestions are underpinned by a series of general principles for design and reporting, which are based on the different questions to be addressed and the challenges faced at each stage in the process [5]. Study design and reporting ideas for improving evidence on surgical and interventional therapy innovation are as follows:

The IDEAL Framework, Recommendations and Proposals:

Summary of key features.

The IDEAL Collaboration grew out of an

Table 2: Defining characteristics of IDEAL framework phases

IDEA Professional Innovation Database	DEVELOPMENT Prospective Development Studies (PDS)	EXPLORATION Prospective Exploration Studies (PES)	ASSESSMENT Surgical RCT	LONG TERM MONITORING Prospective Registries
<ul style="list-style-type: none"> Compulsory reporting of all new innovations Confidential entry allowed to encourage reporting of failed innovations Hospital or institution to be informed separately as a professional duty 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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 randomized trial (RCT) 	<ul style="list-style-type: none"> RCT – question agreed in PES Use power calculations from PES 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 recognized alternative if RCT not feasible: 	<ul style="list-style-type: none"> Should monitor indications as well as outcomes SPC used for quality control (Shewart charts, CUSUM, VLAD) Possible new evaluation methods using registries

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

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 organizations) 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 [1,4,8] and subsequently further detailed in 3 articles published in the BMJ in 2013. [2,3,9]

This initial effort of the IDEAL-

Collaboration needs to be expanded to many other important points in order to achieve the best surgical designs for surgical trials.

It is known that the current status of surgical trials remain something like a babel tower with regard to initiation of a new procedure, performing it in patients and assessing its safety and efficacy.

A wide discussion involving the main surgical societies about the organization of these points must be discussed. Within the field of bone and soft tissue lesions for instance, the variability of lesions is an area that requires better standardization of terms. In order to group these conditions accordingly and provide data that can be applied clinically, it may be useful for surgical trials to be designed in such a way that data is collected on those lesions that share the same clinical characteristics. This would be made possible by studying the most common lesions within one package allowing for variations to be minimized and comparisons to be made more easily.

Within shoulder and elbow surgery we can use the example of lesions of the supraspinatus tendon.

Lesions of the supraspinatus tendon with retraction Patte[12] type one and two, not compromising the biceps and with 50% or less degeneration (thus three types of

degeneration) would most likely result in (2x3=6) the six most common types of lesions. Within the shoulder and elbow surgery community, to agree to group these lesions together, it is necessary to enter into an international agreement to be entitled, for example, the International Standards for Surgical Trials.. Local and international societies of all specialties and subspecialties would need to work together to arrive at this consensus.. While the author's preferences to certain outcomes and timing to assess must be respected, a minimum of methodological harmonization is a current necessity.

To begin this step towards better standardization it is important for this discussion to take place within all the main surgical organizations. Primary trials need to be improved within a rational harmonization and follow the stages that can make surgical trials more reliable and generalizable.

Acta for Shoulder and Elbow Surgery is a journal committed to the new patterns from the IDEAL-Collaboration, CONSORT, COMET initiative and others in order to improve the research quality within the orthopedic subspecialty of shoulder and

elbow surgery.

The practical guides for investigators evaluating new surgical interventions will be better explored in the following volumes of this journal, beginning by the stages 1, 2a

and 2b of the IDEAL Framework [13].

Important Links

Comet-Initiative is Available from:
<http://www.comet-initiative.org>

The CONSORT statement is Available from: <http://www.consort-statement.org>
Ideal-Collaboration is Available from:
<http://www.ideal-collaboration.net>

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