The IDEAL Framework - what it is and how it can help surgical research

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IDEAL Collaboration

www.ideal-collaboration.net
IDEAL: a whirlwind tour

Why IDEAL is necessary – how it arose

IDEAL Stages
• Define stages
  ✓ Key questions
  ✓ Appropriate study types

Recent developments
• How can IDEAL be useful
• What can you do?
IDEAL: Why is it necessary?
Pharma paradigm doesn’t fit surgery

- **Definition of the intervention**
  - Iterative changes
  - Acceptable variation
- **Delivery**
  - Learning curves
  - Quality control
- **Strong treatment preferences**
  - Loss of equipoise
  - Invasiveness, risk, permanence
- **Availability of treatments outside clinical trials**
IDEAL Framework and Recommendations

Describes natural stages of development in surgery

Optimal study designs and research practices

Idea, Development, Exploration, Assessment, Long-term follow-up
IDEAL: An integrated evaluation pathway for surgical innovation

Surgical Innovation and Evaluation 3

No surgical innovation without evaluation: the IDEAL recommendations

Peter McCulloch, Douglas G Altman, W Bruce Campbell, David R Flum, Paul Glasziou, John C Marshall, Jon Nicholl, for the Balliol Collaboration*

Stage 1: Idea

Key Question: “What is the new treatment concept /is it possible?”

- First-in-Human use of new surgical technique
- Planned or unplanned in an emergency - justify
Recommendations

- **Report/publish**
  - Patient characteristics – how selected
  - Detailed technical description (reproducible) – consider video
  - Pre and postoperative care
- **Universal reporting (regardless of success)**
- **Liability and confidentiality? Intellectual property?**
Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms

J.C. Parodi, MD*, J.C. Palmaz, MD†, H.D. Barone, PhD, Buenos Aires, Argentina, and San Antonio, Texas

Special Report

Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

First Human Case Description

Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD


Case report

Transplantation of the human uterus

W. Fageeh*, H. Raffa, H. Jabbad, A. Marzouki

Multiorgan Transplant Unit, King Fahad Hospital and Research Center, Jeddah, Saudi Arabia

International Journal of GYNECOLOGY & OBSTETRICS

www.elsevier.com/locate/ijgo
Stage 2a: Development

- Single surgeon/centre gains experience (usually 10-20 pts)
- Focus on technique and changes made in response to outcomes

**Key Questions:**
- “Is it safe to pursue further?”
- “Is it worth pursuing further?”
- “Is technique sufficiently stable to allow replication in other centres?”
Stage 2a: Development

- Prospective Development Study - NOT a retrospective case series
- Prior protocol

Should report/publish:
- All patients considered for inclusion
- Detailed inclusion and exclusion criteria
- All consecutive patients short-term outcomes
- Evolution of technique is focus of report
Robotic Kidney Transplantation with Regional Hypothermia: A Step-by-step Description of the Vattikuti Urology Institute–Medanta Technique (IDEAL Phase 2a)

Mani Menon\textsuperscript{a}, Akshay Sood\textsuperscript{a,*}, Mahendra Bhandari\textsuperscript{a}, Vijay Kher\textsuperscript{b}, Prasun Ghosh\textsuperscript{b}, Ronney Abaza\textsuperscript{c}, Wooju Jeong\textsuperscript{a}, Khurshid R. Ghani\textsuperscript{a}, Ramesh K. Kumar\textsuperscript{a}, Pranjal Modi\textsuperscript{d}, Rajesh Ahlawat\textsuperscript{b}

Timeline: technical modifications

- Started using aortic punch, introduced through the GelPOINT™ to make the circular arteriotomy
- Ice-slush delivery becomes more systematic: 120 ml delivered just before the graft kidney introduction, 120 ml immediately following the graft introduction, and an additional 120 ml after completing the venous anastomosis (total of 360 ml)
- Started using the V-Loc CV23 6" barbed suture to perform the detrusor layer closure: decreased the average time taken to perform the ureteroneocystostomy from 26 min to 15 min
- Started retroperitonealizing the graft kidney using peritoneal flaps instead of leaving the graft kidney intraperitoneal with simple fixation to the lateral wall

Case number

- Preparation of the vessel bed before bladder take-down
- Limited dissection of EIA only to the degree required for vascular anastomosis
- GelPOINT now placed after preparing the vascular bed and bladder
- Omission of continuous temperature monitoring

Menon et al Eur Urol 2014;65:991-1000
Stage 2b: Exploration – bridge to a pivotal trial

- Use expands to more centres
- Technique stabilized with acceptable variation
- Larger dataset is accumulated

Key Questions:
- “Are we ready for a definitive RCT?”
- “Do we agree on the right technique and outcome measures?”
- “Can we do this well-enough?”
- “Can we explore and overcome barriers to feasibility?”
Stage 2b: Exploration - bridge to a pivotal trial

Prospective Exploration Study
- Multi-centre prospective cohort study

Should report:
- Collaborative collection of a common dataset
- Evaluation of operator learning curves
- Attitudes towards the interventions—equipoise
- Confirm target population and primary endpoint for RCT
Evaluation of HIFU Ablation for Uterine Fibroids: an IDEAL Prospective Exploration Study

Jinyun Chen, Youping Li, Zhibiao Wang, Peter McCulloch, Liang Hu, Wenzhi Chen, Guanjian Liu, Jing Li, Jinghe Lang

Committee of the Clinical Trial of HIFU versus Surgical Treatment for Fibroids

Accepted manuscript online 19 April 2017  Full publication history

- Patient preference cohort study, 20 hospitals in China
- (P) 2411 women with symptomatic fibroids
- (I) HIFU ablation
- (C) surgery - myomectomy, hysterectomy
- (O) Outcomes: major complications, LOS, QoL, re-intervention

http://evidencelive.org/speaker/claudia-ashton/
What was learnt to aid progression to RCT?

Workshop exercise
Stage 2b: Exploration

- Also includes pilot and feasibility RCTs

BMJ 2016;355:i5239 doi: 10.1136/bmj.i5239
Stage 2b: Exploration P&F RCTs

Scope of this paper
In this article we present an extension to the CONSORT statement for randomised pilot and feasibility trials conducted in advance of a future definitive RCT. In keeping with the broad scope of CONSORT, the future definitive RCT might evaluate either the efficacy or the effectiveness of an intervention. The primary aim of the randomised pilot or feasibility trial, however, is to assess feasibility of conducting the future definitive RCT.

We make no distinction in this extension between pilot and feasibility randomised trials. Although in practice we recognise that different researchers might have preferences for different terms, the lack of distinction is based on a framework developed by the authors which defines such studies. In that framework, a feasibility study for a future definitive RCT asks whether the future trial can be done, should be done, and, if so, how. Pilot studies are a subset of feasibility studies.
Stage 3: Assessment

Key Question:
“Is new technique better or worse that what we do now?”

Formal evaluation against best current therapy
• RCT preferred
Stage 4: Long-Term Study

Key Questions:
- “How does it perform in the real world?”
- “What are the rare complications?”
- “Are indications changing?”

Registries
80% of UK Bariatric surgeons participate
50,000 procedures included from 2009-2016
Is IDEAL just for surgeons?

- 2a Development studies are appropriate wherever complex interventions require refinement in live settings.

- 2b Exploration studies are appropriate wherever both the intervention and the threshold for acceptable quality of delivery require definition to allow meaningful comparisons.

**COMPLEX THERAPIES**

- Endoscopic manoeuvres
- Radiologically guided manoeuvres
- Invasive therapeutic devices (IDEAL-D)
- Physiotherapy (IDEAL-Physio)
- Psychotherapy
- Radiotherapy (IDEAL-R)
- Quality Improvement projects
- Complex public health interventions
IDEAL for Devices: IDEAL-D

IDEAL-D: a rational framework for evaluating and regulating the use of medical devices  *BMJ* 2016; 353 doi:http://dx.doi.org/10.1136/bmj.i2372

- DELPHI consensus process conclusions
  - Need a pre-clinical Stage (0) with minimum declared dataset
  - Need a flexible approach to mixes of Development (2a) and Exploration (2b) stages
  - Need Registries from an early stage, developing and changing with needs
Future:
IDEAL is a constantly evolving paradigm

International Conference, Oxford April 2016 – expert consensus update to IDEAL – recently submitted to BMJ

Main updates

- Introduction of a preclinical Pre-IDEAL stage for studies prior to ‘first in human’ use
- Registries were previously confined to IDEAL Stage 4 but their introduction at a much earlier stage is now encouraged
- Ethical guidance is applied to each IDEAL stage
- Clarity on stage endpoints more clearly defined
How can IDEAL help?

- **Research:**
  - Development (2a) and Exploration (2b) studies could help prepare the way for higher quality RCTs of complex interventions

- **Regulation:**
  - Clinical evidence requirements for regulatory approvals could be simplified by requiring (2a) Development or (2b) Exploration study results (depending on risk)

- **Purchasing & Commissioning:**
  - Evidence based purchasing decisions could be strengthened by agreeing to fund treatments with a limited evidence base only in the context of appropriate IDEAL studies
Dissemination of IDEAL

Promising follow up from NY 2017 Conference 4-5 May

- Education ACS
- Journal support for IDEAL to develop checklist for authors for each study type

What can you do?
- Use
- Inform others
- COLLABORATE

Contact:
- allison.hirst@nds.ox.ac.uk
- @IDEALCollab
- http://www.ideal-collaboration.net/
IDEAL useful references


Lancet 2009 IDEAL series


Evidence Live 2017
Workshop Plan

9.30 - 9.50 am: Introduction to IDEAL + outline of workshop (Allison Hirst)

9.50 - 10.10 am: Groups assess papers using flow diagram tool + feedback (Claudia Ashton/Claire Thompson)

10.10 - 10.30 am: Read HIFU 2b paper, review stage questions + feedback (Peter McCulloch)

10.30 - 10.50 am: Groups given an innovation idea – consider outline how to deal with each IDEAL stage – facilitated discussion (all)

10.50 - 11.00 am: Plenary Questions / reflections (Peter McCulloch)