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<th>IDEAL Framework</th>
<th>IDEAL Recommendations</th>
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<td><strong>Pre-IDEAL (IDEAL Stage 0)</strong>&lt;br&gt;Pre-clinical</td>
<td>Pre-IDEAL was not described in original IDEAL framework, but its’ necessity has since been recognised&lt;br&gt;&lt;br&gt;<strong>Purpose:</strong> To evaluate the need for, definition, feasibility and safety of procedure or device&lt;br&gt;&lt;br&gt;<strong>Number &amp; Types of Patients:</strong> None: pre-clinical&lt;br&gt;&lt;br&gt;<strong>Number &amp; Types of Surgeons:</strong> Very few; innovators; often non-surgical&lt;br&gt;&lt;br&gt;<strong>Output:</strong> Description of aspects of addressing:&lt;br&gt;- Whether there is a clinical or health economic need for the new intervention&lt;br&gt;- Whether intended goal of procedure can be accomplished&lt;br&gt;- Ergonomic performance, reliability and durability of devices&lt;br&gt;- Safety risks, including toxicity, allergy, mutagenicity and other risks defined by regulators&lt;br&gt;&lt;br&gt;<strong>Method:</strong> Various, including simulator, cadaver, animal, modelling and cost-effectiveness studies&lt;br&gt;&lt;br&gt;Stage Endpoint: Any studies that could avoid predictable risks of failure or harm to the first human should have been conducted.</td>
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<td><strong>Stage 1</strong>&lt;br&gt;<strong>Idea</strong>&lt;br&gt;First in human</td>
<td><strong>Purpose:</strong> Proof of concept&lt;br&gt;&lt;br&gt;<strong>Number &amp; Types of Patients:</strong> Single digit; highly selective.&lt;br&gt;&lt;br&gt;<strong>Number &amp; Types of Surgeons:</strong> Very few; innovators®&lt;br&gt;&lt;br&gt;<strong>Output:</strong> Description of intervention and outcome&lt;br&gt;&lt;br&gt;<strong>Intervention:</strong> Evolving; procedure inception in human subjects&lt;br&gt;&lt;br&gt;<strong>Methods:</strong> Structured case reports&lt;br&gt;&lt;br&gt;<strong>Outcomes Reported:</strong> Proof of concept; technical performance; adverse events, subjective surgeon views of the procedure&lt;br&gt;&lt;br&gt;Stage Endpoint: Outcomes will determine whether to proceed to stage 2a.</td>
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| Stage 2a Development | Purpose: Development of procedure to stable version  
Number & Types of Patients: Few; Selected  
Number & Types of Surgeons: Few; innovators and early adopters  
Output: Technical description of procedure and its development with reasons for and outcomes of changes in technique or indications  
Intervention: Evolving; procedure development  
Methods: Prospective development studies  
Outcomes: Technical and procedural success, any adverse events, short term clinical outcomes |
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<td>Stage Endpoint: Stage 2a ends when operators do not see potential for further iterative improvement</td>
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- Make protocol for study available  
- Use standard well-defined measures for reporting outcome and patient characteristics  
- Report and explain all exclusions  
- Report all cases consecutively, with annotation and explanation of when and why changes to indication or procedure took place.  
- Display main outcomes graphically to illustrate the above.

| Stage 2b Exploration | Purpose: Achieving consensus on procedure definition envelope and indications so that an RCT can be considered  
Number & Types of Patients: Many; broadening indication to include all potential beneficiaries  
Number & Types of Surgeons: Many; innovators, early adopters, early majority  
Output: Main Effect estimate based on large sample; Development and validation of measures of delivery quality; Analysis of operator learning curves using these; Analysis of impact of pre-specified technical variants and patient subgroups on outcome.  
Intervention: Stable; acceptable variants defined  
Method: Prospective multi-centre exploration cohort study (disease or treatment based); pilot/feasibility multicentre RCTs. Inclusion of qualitative studies of values and attitudes  
Outcomes: Safety; clinical outcomes (specific/graded); quality measures, learning curves, short-term outcomes; patient centred reported outcomes; feasibility outcomes; qualitative evaluation of attitudes and values of investigators and patients |
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<td>Stage Endpoints: fall in to two main groups; Demonstrate that technique can be more widely adopted; and, Demonstrate that progression to RCT is desirable and feasible</td>
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- Make protocol for study available  
- Use standard well-defined measures for reporting outcome and patient characteristics  
- Participate in collaborative multi-centre co-operative data collection, incorporating feasibility issues such as:  
  - estimating effect size,  
  - defining intervention quality standards,  
  - evaluating learning curves,  
  - exploring subgroup differences,  
  - eliciting key stakeholder values and preferences,  
  - analysis of adverse events:  
- Pre-planned consensus meeting prior to progressing to an RCT to identify feasibility and ability to recruit, intervention and comparator definitions, appropriate patient selection criteria, primary endpoint.
| Stage 3  | Purpose: Comparative effectiveness testing  
Number & Types of Patients: Many; expanded indications (well-defined)  
Number & Types of Surgeons: Many; early majority  
Output: Comparison with current standard therapy  
Intervention: Stable  
Method: RCT with or without additions/modifications; alternative designs (cluster, preference RCTs, stepped wedge, adaptive designs)  
Outcomes: Clinical outcomes (specific and graded); potentially Patient Reported outcomes, Health Economic outcomes  
Stage Endpoints: two main endpoints; Clear valid evidence on relative effectiveness of innovation; and, Identification of issues requiring long term monitoring. |  
- Register on an appropriate international register (e.g., clinicaltrials.gov)  
- Use standard well-defined measures for reporting outcome and patient characteristics  
- Incorporate information about patient and clinician values and preferences in consent information and outcome measure design  
- Reporting guidelines: CONSORT update of 2010 with extension for non-pharmacological treatments  
COMET  
TIDieR  
SPIRIT (for RCT protocol design) |  
| Stage 4  | Purpose: Surveillance  
Number & Types of Patients: All eligible  
Number & Types of Surgeons: All eligible  
Output: Description; audit; regional variation; quality assurance; risk adjusted evaluation  
Intervention: Stable  
Method: Registry; routine database; rare-case reports; linked administrative/clinical datasets, other “Real World Evidence”  
Outcomes: Rare events; long-term outcomes; quality assurance  
Registries for devices – IDEAL-D  
Registries at earlier stages of IDEAL |  
- Registries may begin from the earliest stages of human use  
- Registry datasets should be defined by the clinical community with patient input  
- Datasets should be simple, cheap and easy to collect  
- Curation of registries by clinical community is desirable  
- Funding of registries should be agreed between government and commercial interests but kept separate from curation  
- Consent for use of registry data in research should be broad and where possible automatic  
- Studies based on Real World Evidence should clearly define dataset completeness, recording methods, data collection methods, funding, and curation |  
@ Terms used under this heading refer to the classification of Everett Rogers (Diffusion of Innovations, 4th Ed, 1995)  
*Registries should be organised according to the IDEAL recommendations and should be available for enrolment at any Stage  
**Patient consent should always include outcomes from previous IDEAL Stage  
Items in purple relate to clarifications in Framework added since 2009 publication.  

**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