Table 1. Summary of IDEAL Framework and Recommendations 2019

	IDEAL Framework	IDEAL Recommendations
Pre-IDEAL (IDEAL Stage 0) *Pre-clinical*	**Pre-IDEAL was not described in original IDEAL framework, but its' necessity has since been recognised** **Purpose:** To evaluate the need for, definition, feasibility and safety of procedure or device **Number & Types of Patients:** None: pre-clinical **Number & Types of Surgeons:** Very few; innovators; often non-surgical **Output:** Description of aspects of addressing: • Whether there is a clinical or health economic need for the new intervention • Whether intended goal of procedure can be accomplished • Ergonomic performance, reliability and durability of devices • Safety risks, including toxicity, allergy, mutagenicity and other risks defined by regulators **Method:** Various, including simulator, cadaver, animal, modelling and cost-effectiveness studies Stage Endpoint: Any studies that could avoid predictable risks of failure or harm to the first human should have been conducted.	• All reasonably predictable risks to patients should be investigated before human studies begin • Guidelines on best scientific practice and ethics specific to the types of study should be followed where available • A minimum dataset describing technical performance of any equipment or device should be made public before first-in-human testing.
Stage 1 **Idea** *First in human*	**Purpose:** Proof of concept **Number & Types of Patients:** Single digit; highly selective. **Number & Types of Surgeons:** Very few; innovators[@] **Output:** Description of intervention and outcome **Intervention:** Evolving; procedure inception in human subjects **Methods:** Structured case reports **Outcomes Reported:** Proof of concept; technical perfomance; adverse events, subjective surgeon views of the procedure Stage Endpoint: Outcomes will determine whether to proceed to stage 2a.	• Provide full details of patient selection, technique and outcomes and patients not selected during the time frame, and why. • Use standard well-defined measures for reporting outcome and patient characteristics • Use structured reporting system eg, SCARE checklist. • Make information above available to peers regardless of outcome

Stage 2a **Development** Single centre/single intervention; case series/prospective cohort	**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:** **T**echnical and procedural success, any adverse events, short term clinical outcomes **Stage Endpoint**: Stage 2a ends when operators do not see potential for further iterative improvement	• 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
Bridge from observational to comparative evaluation.
Purpose is to gain data to decide if and how to test in a robust RCT or other appropriate pivotal design.
	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
	
	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
		• 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 **Assessment** Definitive comparative evaluation of main efficacy and safety aspects of new technique against current best treatment.	**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 **Long term monitoring**	**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