 Reporting Guideline Checklist for IDEAL Stage 2b: Exploration

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| Section/Topic | Item No | Checklist Item | Reported on Page No |
| Title and Abstract | | | |
| Title and Abstract | 1a | Identify the novel technique/device being investigated and the type of study conducted (e.g. multi-centre, prospective cohort or feasibility RCT), including the IDEAL stage in the title or abstract |  |
|  | 1b | Provide a structured summary of background, methods, results, and conclusions |  |
| Introduction | | | |
| Background and objectives | 2a | Review of existing scientific literature, including reference to IDEAL Stage 1 and 2a reports in previous publications, if applicable |  |
| 2b | Specific objectives stated, including reaching consensus on aspects necessary to conduct an RCT, or consensus that an RCT is not appropriate or feasible |  |
| Methods | | | |
| Design | 3 | Description of multi-centre study design, with prospective collection of standard data across centres |  |
| Participants | 4a | Detailed account of patient inclusion and exclusion criteria |  |
| 4b | Informed consent process described, including explanation of risks and acknowledgement of level of experience with technique/device |  |
| 4c | Setting, location, and timeframe of recruitment and follow-up, including when and where the data were collected, as well as hospital characteristics and appropriate details regarding the operator/team (e.g. prior experience with novel technique) |  |
| Intervention | 5a | Clear and detailed description of technique, or reference to it, including an assessment measure for quality of adherence to the technique for operators/teams |  |
|  | 5b | Description or reference to learning curve assessment of operators/team using pre-defined objective quality metrics |  |
|  | 5c | Patient safety monitoring methods and safeguards |  |
| Outcomes | 6 | Description of pre-specified primary and secondary outcome measures selected and how they will be assessed, including patient reported outcome measures, when appropriate, utilising those measures that are standardised and validated, when available and applicable. When these are not available, provide rationale for the outcome measure(s) used |  |
| Statistical methods | 7 | Statistical methods used to describe baseline characteristics and evaluate primary and secondary outcomes, when appropriate, including methods for additional analysis (e.g. learning curve analysis, pre-specified subgroup analysis) |  |
| Stakeholder Values | 8 | Describe or reference attempts to evaluate patient and surgeon preferences and values relevant to future RCT trial design and conduct, including any qualitative work done to ascertain views about randomization |  |
| Results | | | |
| Baseline data | 9 | Patient baseline demographic and clinical characteristics, including how many patients were assessed for treatment and a description of which patients were included, excluded, or refused, and why (to be displayed in a flow diagram format, when appropriate) |  |
| Learning Curves | 10 | Report of learning curve assessment results for operators/team based on pre-defined objective quality metrics, including statistical analysis, if feasible |  |
| Outcomes | 11 | Describe results of each pre-specified outcome measure, including patient reported outcome measures, where appropriate |  |
| Harms | 12 | Transparent account of all harms or unintended effects reported |  |
| Stakeholder Values | 13 | Report findings of attempts to evaluate patient and surgeon preferences and values relevant to future RCT trial design and conduct, including any qualitative work done to ascertain views about randomization |  |
| Discussion | | | |
| Limitations | 14 | Study limitations, addressing sources of potential bias |  |
| Stage End-Points | 15a | Pre-planned review of results and discussion of appropriateness of progressing to RCT or pilot/feasibility study |  |
| 15b | Has agreement been reached about standard technique, including accepted variants, and quality standards based on operator/team experience during this stage? |  |
| 15c | Has agreement been reached for appropriate target patient population and indications, including identification of subgroups for which the applicability of the technique is considered uncertain? |  |
|  | 15d | Has agreement been reached regarding appropriate outcome measure(s) for a trial, including an estimated power calculation of the primary outcome for a future trial? |  |
|  | 15e | Has agreement been reached regarding the appropriate comparator treatment for a trial? |  |
|  | 15f | Are operators and patients willing to accept randomisation between the proposed treatments (establishing equipoise)? |  |
|  | 15g | Ensure potential harms from learning curves are addressed by training and mentoring prior to Stage 3, where appropriate |  |
| Conclusion | 16 | Conclusions and relevance, including plans to evaluate the technique/device in a high-quality RCT against the current standard of care. If not planning to further evaluate in IDEAL Stage 3 study, please explain |  |
| Other information | | |  |
| Protocol | 17 | Please quote reference or DOI if a protocol was written in advance and made available. If a protocol was not made available, consider including as a supplement if the journal allows |  |
| Ethics | 18 | Reference to ethical approvals obtained, and independent oversight, if applicable |  |
| Funding | 19 | Sources of funding and support, role of funders, and other conflicts of interest |  |
| Regulatory Approvals | 20 | Regulatory approvals being sought or obtained (e.g. CE Marking, FDA approval, etc) including the date of approval, if applicable |  |

Bilbro NA, Hirst A, Paez A, et al. The IDEAL Reporting Guidelines: A Delphi Consensus Statement Stage specific recommendations for reporting the evaluation of surgical innovation [published online ahead of print, 2020 Jul 7]. Ann Surg. 2020;10.1097/SLA.0000000000004180. doi:10.1097/SLA.0000000000004180