 Reporting Guideline Checklist for IDEAL Stage 1: Idea

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| Section/Topic | Item No | Checklist Item | Reported on Page No |
| Title and Abstract |
| Title and Abstract | 1a | Identify the technique or device in the title, including IDEAL Stage 1 or ‘first in human’ 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, providing a clear explanation of the rationale for the new technique, including unmet clinical need |  |
| 2b | Details of pre-clinical development of the technique, including assessment of risks of failure and analysis of efforts to avoid harm\* |  |
| Methods |
| Design | 3 | Description of study design (e.g. case report or very small case series) |  |
| Participants | 4a | Transparent account of patient selection, with explicit detail about inclusion and exclusion criteria |  |
| 4b | Informed consent process described, including explanation of risks and acknowledgement of level of experience with technique/device. If informed consent is not obtained due to unplanned technique or modification, describe the discussion with the patient after the innovation occurred |  |
|  | 4c | Setting, location, and timeframe of when and where the novel technique was performed, including hospital characteristics and appropriate details regarding the operator/team (e.g. experience) |  |
| Intervention | 5a | Clear and detailed description of the new technique/device, including necessary pre- and post-procedure care  |  |
|  | 5b | Patient safety monitoring methods and safeguards |  |
| Outcomes | 6 | Description of outcome measure(s) selected and how they were assessed, including patient reported outcome measures, if 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 |  |
| Results |
| Baseline Data | 7 | Baseline demographic and clinical characteristics for each patient. Include 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) |  |
| Intervention | 8 | Technical feasibility of technique, including visual aids (e.g. photographs, videos, etc) when available |  |
| Outcomes | 9 | Appropriate clinical outcomes, including patient-reported outcome measures, when applicable |  |
| Harms | 10 | Transparent account of all harms or unintended effects reported for each patient |  |
| Discussion |
| Stage End-Points | 11 | Author’s overall appraisal of the new technique, including discussion of risks and harms reported and suggestions to avoid them in future cases based on initial experience |  |
| Conclusions | 12 | Conclusions and relevance, including plans to progress to future IDEAL stages, or plans to discontinue further research |  |
| Other information |  |
| Protocol | 13 | 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 | 14 | Reference to ethical approvals obtained, and independent oversight, if applicable |  |
| Funding | 15 | Sources of funding and support, role of funders, and other conflicts of interest |  |
| Regulatory Approvals | 16 | Regulatory approvals being sought or obtained (e.g. CE Marking, FDA approval, etc) including the date of approval, if applicable |  |

\* If the technique was an unplanned or spontaneous innovation or forced by circumstances, this should be explicitly stated, and the circumstances described briefly. All relevant checklist items should be completed.

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