



## Reporting Guidelines Checklist for IDEAL Stage 4: Long-Term Study

Section/Topic	Item No	Checklist Item	Reported on Page No
<b>Title and Abstract</b>			
Title and Abstract	1a	Identify the study design and the IDEAL stage in the title or abstract	
	1b	Provide a structured summary of background, methods, results, and conclusions	
<b>Introduction</b>			
Background and objectives	2a	Review of existing scientific literature, including reference to earlier IDEAL stage reports in previous publications, if applicable	
	2b	Specific objectives stated, which may include recognizing late or uncommon safety outcomes, identifying changes in the use of procedure/device, risk adjustment, quality assurance, and effectiveness	
<b>Methods</b>			
Design	3	Describe the study design (e.g. registry, analysis of real-world data, etc)	

Data Source	4a	Describe the dataset, including who designed and funds it and who curates and manages it, addressing possible conflicts of interest. Describe whether the dataset was purposely designed for research or collected as a routine database	
	4b	Structured data fields described or referenced and each item defined, included as an appendix or supplement when necessary	
Participants	5	Detailed account of inclusion and exclusion criteria for subjects	
Intervention	6	Describe or reference the intervention/device being monitored, and comparator if applicable	
Outcomes	7	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 used	
Statistical methods	8a	Statistical methods used to describe and assess patient characteristics and outcomes, including methods of additional analysis (e.g. pre-specified subgroup analysis), and methods to minimize confounding, where appropriate	
	8b	Explanation of how missing data will be addressed	
<b>Results</b>			
Baseline data	9a	Patient demographic and clinical characteristics, and hospital/centre/operator characteristics	
	9b	Indicate extent of missing data for each variable of interest, if appropriate	

Outcomes	10	Report of main pre-specified outcome measures, including outcome variations among pre-specified subgroups and adjustments for confounders, when applicable	
<b>Discussion</b>			
Limitations	11	Discuss limitations, addressing sources of potential bias, known confounders, missing data, and secular trends, including a discussion of the implications of using data that was not originally collected to answer the specific research question, where appropriate	
Conclusion	12	Conclusions and relevance, including a discussion of the overall interpretation of results, the external validity, and any implications for policy and practice	
<b>Other information</b>			
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	Appropriate ethical approvals obtained and informed consent process described. If consent for future use of data was not obtained, please explain	
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	

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