Understanding Stage of Innovation of Invasive Procedures and Devices

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Aim: New and modified surgical procedures and devices are often introduced into clinical practice without adequate evidence of their safety and efficacy. To promote systematic evaluation of surgical innovations, the IDEAL and IDEAL-D frameworks outline recommendations for study design and governance for procedures and devices according to their stage of innovation. However, determining stage of innovation can be difficult, hindering use of such frameworks. There is a need for a detailed understanding of what stage of innovation means, and how it can be determined. The aim of this study is to understand the concept of stage of innovation as reported in the literature.

Method: A systematic review is being conducted. Searches of Ovid Medline and Embase databases have been performed. Articles were screened by title and, then by full text. s and foreign language articles were excluded. Data will be extracted verbatim regarding approaches to evaluating surgical innovations and determining stage of innovation. A thematic analysis will be conducted, and findings summarised in a narrative report.

Results: The search returned 2,946 articles, of which 46 were included. Preliminary findings have identified two approaches for evaluating procedures, and one for devices. Following thematic analysis, the narrative report will explore approaches to evaluating surgical innovations and determining stage of innovation, including barriers to implementation and proposed solutions.

Conclusions: A report of progress will be presented at the Surgical Innovation Summit. An improved understanding of stage of innovation will facilitate better evaluation of surgical innovations.