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Adoption of a novel surgical innovation into clinical practice: protocol for a qualitative systematic review examining surgeon views

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ABSTRACT

Introduction Efficient adoption of clinically effective novel surgical innovations has great potential benefits for patients. Factors affecting the adoption of surgical innovation are not well understood and proposed models of adoption do not accurately correlate with historical evidence. This protocol is for a systematic review that aims to identify the qualitative evidence relating to surgeon views regarding the adoption of novel surgical innovation into clinical practice.

Methods and analysis A systematic review following Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidance will be performed. Two independent reviewers will search the following databases: MEDLINE, Embase, Science Direct, Scopus, Web of Science and the Cochrane Library of Systematic Reviews. Inclusion criteria are studies which report on the views of surgeons who adopt a novel surgical innovation into clinical practice. Each article will be screened for inclusion and assessed according to a Critical Appraisal Skills Programme tool. Data will be synthesised and analysed according to thematic analysis. Given the anticipated yield of a small heterogeneous body of evidence meeting the eligibility criteria for the review, a narrative-based summary is planned.

Ethics and dissemination This review does not require formal ethical approval as it does not involve direct patient contact or patient-identifiable data. The results of this review will be published in a peer-reviewed journal and presented at relevant conferences. The results will also inform an empirical qualitative study exploring surgeon and other stakeholder views regarding the introduction of novel surgical technology and procedures into clinical practice.

PROSPERO registration number CRD42017076715.

Strengths and limitations of this study

- This is a protocol for a systematic review of current literature exploring surgeons' views of an adoption of innovation in surgery.
- It will use robust methodology to synthesise the research in this area.
- The scope will be to inform policy and practice and improve patient care by understanding and thus potentially reducing the gap between evidence and clinical practice.
- The first limitation might be the paucity of research available in this area.
- The second limitation is that the synthesis relies on the data presented in each of the included reports which may not reflect the full analysis of the original data.

INTRODUCTION AND RATIONALE

Innovations in surgical care have substantially improved patients' quality and length of life.[1] Innovation in surgery has led to new instruments, equipment, operative procedures and science which all contribute to reduced morbidity and mortality.[2 3] Examples include laparoscopic or robotic procedures, changes in theatre practice and novel surgical implants.

The introduction and adoption of surgical innovations should be based on evidence-based principles rather than trial and error. The stages of surgical innovation are described using the IDEAL (Innovation, Development, Exploration, Assessment, Long term) framework which has been designed with the complexity of surgical interventions in mind.[4–6]

There are many definitions of surgical innovation.[7] We have used the definition used by the IDEAL framework which describes an innovative procedure in surgery as 'a new or modified surgical procedure that differs from currently accepted local practice, the outcomes of which have not been described, and which may entail risk to the patient'.[8] The IDEAL framework also describes the adoption of an innovation into practice as 'the increase in the number of overall surgeons doing the procedure over time, which will occur until it is either accepted by surgeons or discarded'.[8]

There are many complex factors affecting the adoption and diffusion of innovation into clinical practice.[9 10] There are a number of models and frameworks which attempt to explain how these factors affect the spread of novel innovations in healthcare.[9–14] While many of these frameworks can be broadly applied to the field of surgery, the specific factors affecting adoption of surgical innovations into clinical practice are not as well understood. Historical data assessing the adoption rates of various laparoscopic procedures, do not correlate well with these models.[15] Other newer theories include the Unified Theory of Acceptance and Use of Technology which originate from the theory of reasoned action.[16]

It is clear that there are multiple factors affecting adoption of surgical innovations including perceived clinical effectiveness, cost, patient demand, manufacturer promotion and surgeon preference among others.[14] Surgical procedures are often introduced on an ad hoc basis by individual surgeons therefore leading to variation in the adoption of clinically effective innovations. This has a number of clinical consequences, most notably development of a gap between between scientific evidence and clinical practice.

Studies suggest that about 30%–40% of patients do not receive care according to present scientific evidence, and about 20%–25% of care provided is not needed or is potentially harmful.[17 18] Ensuring that patients receive care according to the best scientific evidence will reduce patient morbidity and mortality, and will also lead to improved cost efficiency for the National Health Service (NHS). For example, the change in clinical practice following the Distal Radius Acute Fracture Fixation Trial (DRAFFT) trial is estimated to save NHS £1.6m per year in implant costs alone. The more expensive plate technology had been in use for over 10 years by the time DRAFFT was published, at a huge cost to NHS.[19]

Understanding surgeons' perceptions of the challenges experienced introducing a novel surgical innovation can give new insights into what factors are taken into account when deciding whether or not to adopt an innovation in surgery. This will provide deeper insights into the adoption, implementation and diffusion of surgical innovations in hospitals in general.

Objectives

The aim of this systematic review is to explore the evidence regarding surgeon views of adoption of novel surgical innovations. This review will synthesise published qualitative evidence regarding the factors that affect surgeon decision making to adopt a novel surgical intervention.

METHODS AND DESIGN

Population

This systematic review will include qualitative studies that investigate surgeons' views on what influences their decision to adopt a novel surgical technology. Only studies relating to the adoption of novel surgical innovations in humans will be included. Interventions related to the field of dentistry will be excluded. We will use the definition of surgical innovation as described by the IDEAL framework.[4]

Study design

This qualitative systematic review will be a narrative synthesis.[20–22] Qualitative data from mixed methods studies will be screened for inclusion and included if the qualitative component is relevant. The review protocol has been registered on the International Prospective Register of Systematic Reviews (PROSPERO CRD42017076715) database.[23] This protocol has been written in line with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)-P guidelines.[24]

Search strategy

The search strategy will use a three-stage protocol (figure 1). We will first undertake an initial limited search of MEDLINE with analysis of the text words contained in the titles and abstracts to identify a list of keywords and index terms. We will run our searches using all the identified keywords and index terms customised to the different databases. We will supplement this with forward and backward citation tracking of key papers. Studies will be restricted to the English language and from database inception to July 2017, inclusive. The databases that will be searched are MEDLINE, Embase, Scopus, Web of Science and the Cochrane Library of Systematic Reviews. A sample search strategy for MEDLINE has been provided as online supplementary appendix 1. We will supplement this with a search of the grey literature for theses and reports including empirical data.

Study selection

Qualitative studies will be independently assessed by two reviewers (TLL and HNF/GWM) and reported using the PRISMA flow diagram.[25] We will only include data from full published papers, reports and theses reporting empirical data. We will not include data published in abstract form only. Foreign language papers will not be included. Two reviewers will independently screen titles and abstracts, and retrieved papers to identify included studies. Any disagreements that arise between the reviewers will be resolved through discussion and if necessary consultation with a third senior reviewer (AM or KS). Study selection will be documented and summarised in a PRISMA-compliant flow chart.

Inclusion criteria

Studies will only be included if they meet the following inclusion criteria:

- Report on the adoption of a novel innovation into clinical practice
- The innovation described meets the IDEAL framework definition of a surgical innovation[8]
- Include the views of at least one surgeon in the qualitative analysis

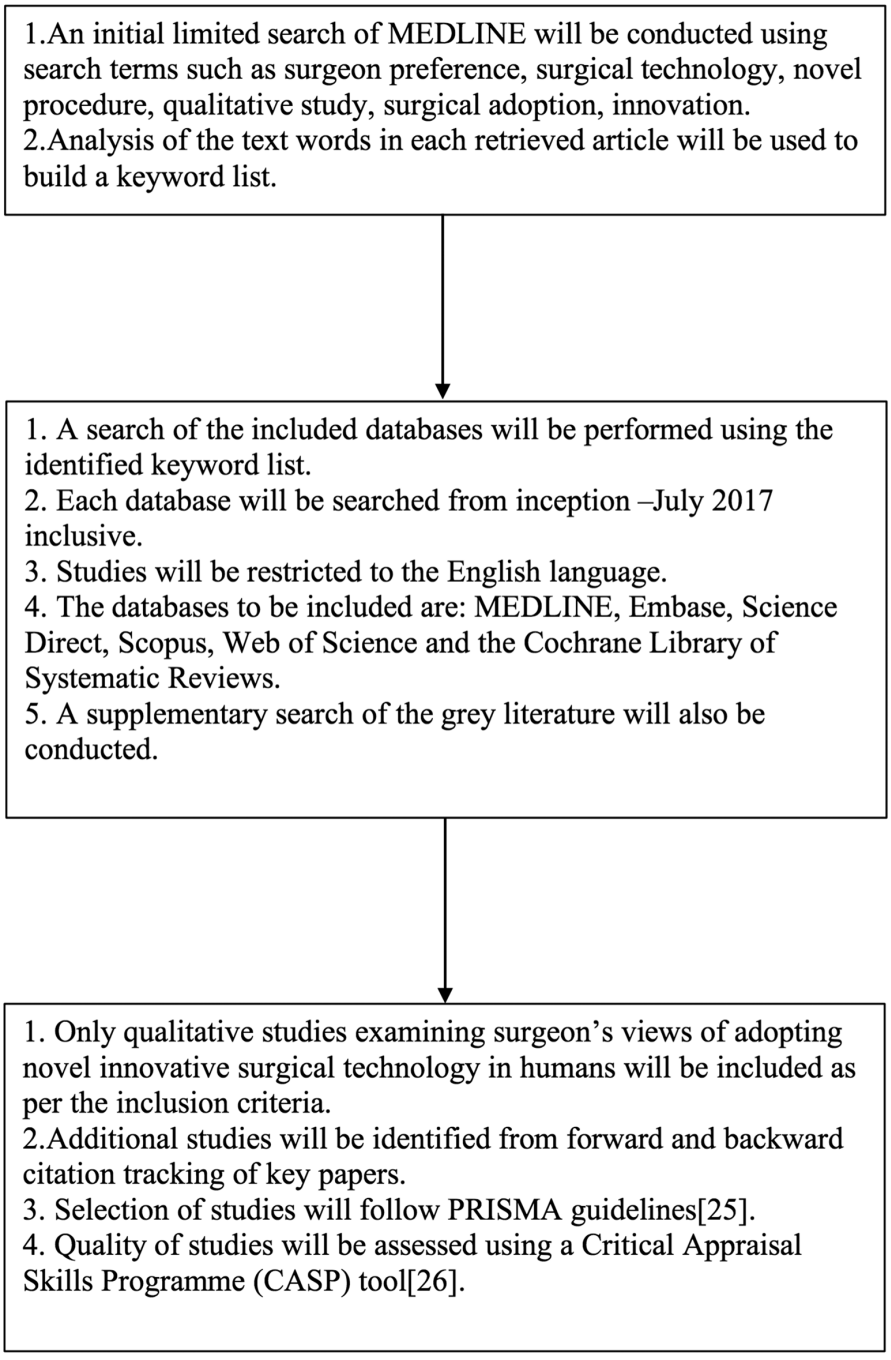

Figure 1 A schematic of the search process of the proposed systematic review.

- The innovation needed to be considered novel at the time of investigation

Quality assessment

To minimise bias two reviewers (TLL and HNF) will independently extract data from included studies. Any disagreement will be referred to a third reviewer. All included articles will be subject to critical appraisal using a Critical Appraisal Skills Programme (CASP) tool.[26] There are recognised issues assessing the quality parameters of qualitative studies, however, the 10-item CASP tool is commonly used for this purpose in qualitative systematic reviews.[27 28] Studies will be grouped into low quality (0–3 points), medium quality (4–7 points) and high quality (8–10 points). Articles will not be excluded on the basis of quality so that the review will capture both theoretical and empirical contributions from the study. The quality of each study will be specifically considered during data analysis.

Data extraction

Data extraction will be conducted by two authors (TLL and HNF) and use a purpose-designed proforma. Screening and extraction of data records will be managed in Covidence—a web-based systematic review manager.[29] Extracted material will reflect the inclusion criteria and

the designated aims of the review, derived from the article as a whole. Disagreements will be resolved by discussion with a senior member of the team (AM or KS). Information will be gathered on: author; year of publication; country of study; study type; setting; relevant background and impetus for the study; methodological approach and specified methods; surgeon characteristics and demographics including the type of novel surgical technology; main findings including pertinent themes relating to surgeon perspectives regarding the factors that affect a decision to adopt novel surgical technology and/or procedures; strengths and limitations and key relevant discussion points.

Data synthesis

Data will be analysed using thematic synthesis to generate descriptive and analytical themes.[20] Two reviewers will independently identify themes and any disagreements will be resolved by a senior member of the project team (KS). Given the anticipated yield of a small heterogeneous body of evidence meeting the eligibility criteria for the review, a narrative-based summary is planned. This study will consider both the theoretical and empirical contributions from each study, and will synthesise the full current body of literature on this important topic. Where possible, associations between the different themes will be identified and grouped into higher-order themes, which will be used to answer the review questions. If possible, these themes will be categorised according to a pre-existing framework describing the adoption or implementation of innovations in healthcare.

The descriptive or conceptual outputs will be related to the research questions and objectives. The results of this review will been guided by the Enhancing Transparency of Reporting the Synthesis of Qualitative Research framework.[30] We will also use and clearly document confidence in the review findings using the Grading of Recommendations Assessment, Development, and Evaluation and Confidence in the Evidence from Reviews of Qualitative research (GRADE-CERQual) approach .[31 32] This framework will consider the methodological limitations, relevance, coherence and adequacy of the data to address potential concerns regarding the validity, and confidence of each research finding.

DISCUSSION

Understanding the complexity of adoption of novel treatments or innovations in healthcare is a challenge, despite the recognised benefits such an understanding would have on reducing the gap between evidence and clinical practice.[18]

Surgeon preference is one of many factors which has been identified to be crucial in determining the adoption of a new surgical innovation.[33] To the best of our knowledge, this study will be the first to collate and summarise the current evidence base regarding surgeons' views and preferences about adoption of novel surgical technology into clinical practice. The findings from this study will potentially benefit patients, surgeons, hospitals, device manufacturers, commissioning bodies and policy makers by providing an evidence base that could be used to inform service design and delivery with regard to adoption of surgical innovation. The findings of this paper will also be of use to researchers in the field to set future research priorities.

The findings from the review will inform an empirical qualitative study exploring surgeon and other stakeholder views regarding the adoption of novel surgical technology and procedures into clinical practice.

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Contributors TLL designed the systematic review with inputs from HNF, GWM, NP, KS, MU and AM. TLL drafted the review protocol with inputs from HNF, GWM, NP, KS, MU and AM. All authors approved the final protocol.

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