Study Title: A qualitative study to identify factors influencing the implementation of evidenced-based recommendations from studies funded by the Health Technology Assessment program about surgical practice

Chief Investigator:	Kelly Ann Schmidtke
Co-Investigators:	Amy Grove, Laura Kudrna, Felicity Evison, and Richard Lilford
Funder:	NIHR – ARC West Midlands

This protocol written in light of the following administrative requirements.

1. Requirements for University Sponsorship from the University of Warwick.[1]

2. Requirements for the Biomedical and Social Science Research Ethics Committee's (BSREC) approval.[2]

3. Requirements for the Health Research Authority's (HTA) approval via an IRAS form.[3]

4. The Standards for Reporting Qualitative Research (SRQR) checklist to ensure that this study will meet standards for publication in a high impact journal, see Appendix A.[4]

TABLE OF CONTENTS

1. SYNOPSIS

Study Title	A qualitative study to identify factors influencing the implementation of evidenced-based recommendations from studies funded by the Health Technology Assessment (HTA) program about surgical practice	
Internal ref. no. / short title	Factors that influence implementation of HTA recommendations	
Study Design	Qualitative case study method	
Study Participants	Purposefully recruited stakeholders, starting with the authors, then surgeons those authors recommend, and lastly other practitioners / administrators those surgeons recommend.	
Planned Sample Size	36 - 48 participants	
Planned Study Period	02-March-2021 – 28-Feb-2022	
Objectives	Primary	Use semi-structured interviews and thematic analyses to identify factors that influence implementation of evidence-based recommendations in select cases.
Trial Investigators	Primary-investigator	Kelly Ann Schmidtke, University of Warwick, Assistant Professor, Kelly.A.Schmidtke@warwick.ac.uk; 07758 933026, https://orcid.org/0000-0001-5993-0358 University of Warwick, Medical School Building, CV4 7AL.
	Co-investigator	Felicity Evison, University Hospitals Birmingham, Principal Research Informatician, felicity.evison@uhb.nhs.uk; 01213712447
	Co-investigator	Richard Lilford, University of Birmingham, Professor, r.j.lilford@bham.ac.uk; 07824474289, https://orcid.org/0000-0002-0634-984X
	Co-investigator	Amy Grove, University of Warwick, Associate Professor, A.L.Grove@warwick.ac.uk; 024 76574046
	Co-investigator	Laura Kudrna, University of Birmingham, Research Fellow, L.Kudrna@bham.ac.uk; 024 7652 3352, https://orcid.org/0000-0002-8163-7112
Sponsor Contact	Jane Prewett, University of Warwick, Research & Impact Services, University House, Kirby Corner Road, Coventry, CV4 8UW, wmssponsorship@warwick.ac.uk; 024 765 22746	

Table 1. Synopsis

2. ABBREVIATIONS

AIM	Ankle Injury Management (AIM) trial
ARC	Applied Research Centre
BSREC	Biomedical Science Research Ethics Committee
CARMS	Clinical Audit Registration and Management System
CFIR	Consolidated Framework for Implementation Research
CLASS	Comparison of LAser, Surgery and foam Sclerotherapy trial
FOOD	Feed Or Ordinary Diet trial
GDPR	General Data Protection Regulation
HES	Hospital Episode Statistics
HTA	Health Technology Assessment
KAT	Knee Arthroplasty Trial
NESSTAC	North of England and Scotland Study of Tonsillectomy and Adenotonsillectomy in Children trial
NHS	National Health Service
NIHR	National Institute for Health Research
REACTIV	This appears to be the name of the trial, not an acronym
REFLUX	Randomised Evaluation oF Laproscopic sUrgery for refluX trial

Table 2. Abbreviations

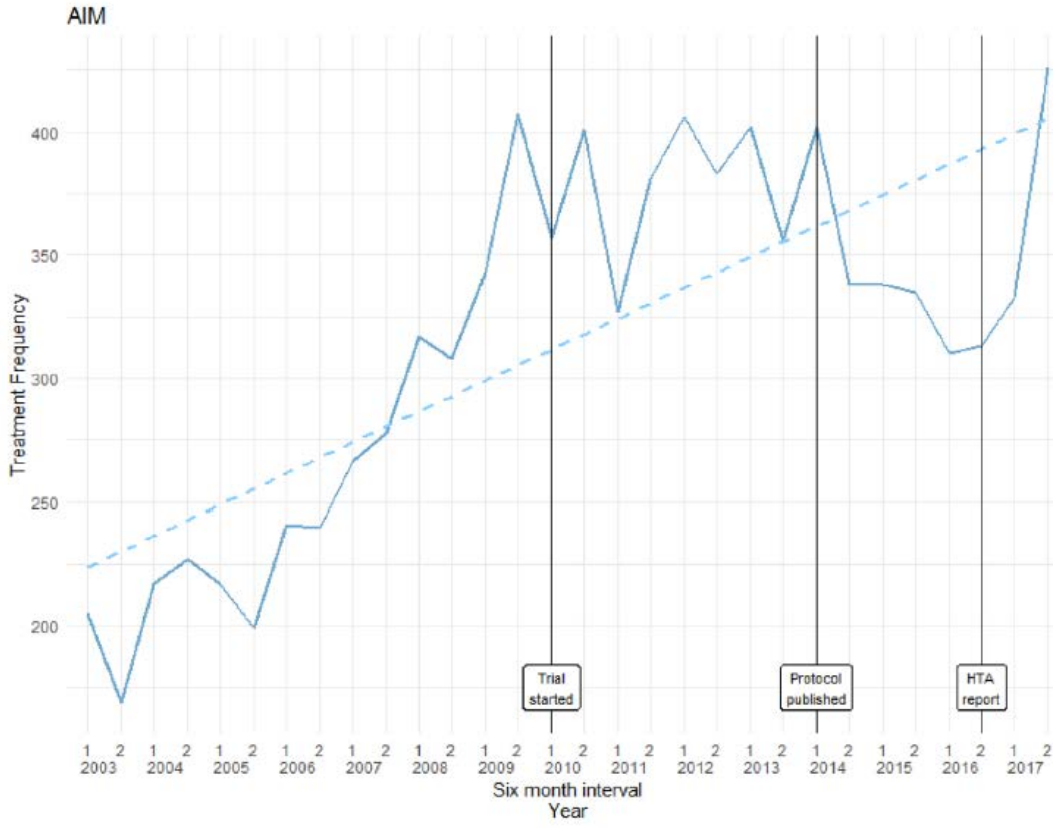
3. DETAILED BACKGROUND AND RATIONALE

Healthcare costs account for a major portion of government budgets and occupy a great deal of policy attention. In 2018/2019, the National Institute for Health Research (NIHR) awarded £317 million of funding to 334 research projects.[5] Approximately one third of these projects were delivered through the Heath Technology Assessment (HTA) program. While demonstrating a return on this investment is challenging, ensuring that NIHR funded research can improve the health and wellbeing of patients is essential.

Literature describing 'evidence-based practice' and 'evidence implementation' is vast. We identified >200,000 articles in scoping searches on Medline in May 2020. Two articles explored the impact of selected HTA case studies using the payback model with stakeholder interviews.[6,7] While both articles reliably evidence the impact of evidence-based recommendations on knowledge production, research targeting/capacity building, and information policy/product development, they struggled to evidence changes in surgical practice.

To examine impact on surgical practice, a quantitative audit study has already been published assessing whether three HTA study recommendations have changed surgical practice.[8] To do so the researchers retrieved the number of times indicated surgical procedure were performed from the Hospital Episode Statistics (HES) database and then plotted those data in six-month intervals from 2003, which is when the HES database commenced. For example, the AIM trial compared two treatments for ankle fractures and found no advantage of surgery. Figure 1 below shows that despite AIM's recommendations against surgery, surgeries actually increased after the AIM study was published in 2015.

Figure 1. A copy of Figure 3 from Reeves et al.'s paper.[9]



Our research team is currently auditing six additional HTA studies of surgical interventions using the same quantitative procedures: FOOD (2006) [10], REACTIV (2006)[11], NESSTAC (2010)[12], REFLUX (2013) [13], KAT (2014) [14], and CLASS (2015).[15] This audit was approved by University Hospital Birmingham (CARMS-16381). While the proposed research will inform and be informed by that audit, it exceeds the remit of an NHS audit and so cannot be approved as an amendment. Here we are seeking approval to conduct qualitative interviews alone.

Following-up each audit with qualitative interviews is important to identify additional factors that influence whether HTA study recommendations are implemented, beyond those studies' publication. The potential factors considered will include those described by the comprehensive and theoretically informed Consolidated Framework for Implementation Research (CFIR), including characteristics of the (1) intervention, (2) outer setting, (3) inner setting, (4) individuals involved, and (5) implementation process.[16,17] Talking to key stakeholders involved in each HTA study (i.e. authors) and its implicated surgical area (i.e. surgeons and related practitioners/administrators), will help us narrowing in on the most influential CFIR factors quickly. Then, to aid future implementation, the research team will examine the links provided between each CFIR constructs and one or more of the 73 discrete implementation strategies best suited to influence it.[18] Thus, identifying these constructs will immediately inform future interventions to increase the uptake of evidence.

3.1. Summary of main ethical issues

No major safety issues arise. We will not be interviewing any service users. However, we will interview people employed by the NHS.

The main concerning issues are described here.

Issues about participant rights will be addressed by asking for their informed consent before their interview takes place. Participants will retain the right to withdraw from the study up to two weeks after their interview takes place.

Issues around general data protection will be addressed by identifying and recruiting participants who are introduced to us by our clinical collaborators. Identifiable information connected to the data we collect will only be available to researchers named on this project who are also employed by the University of Warwick and destroyed before the project ends.

Only research services approved by the University of Warwick in the conduct of this research. A list of approved services is provided at this website: https://warwick.ac.uk/services/ris/research_integrity/researchethicscommittees/biomed/idc_approved_research_services_23.5.19.xlsx.[19]

4. RESEARCH QUESTION AND OBJECTIVE

What factors influence the implementation of evidenced-based surgical recommendations made in studies funded by the NIHR's HTA program?

Objective: To identify factors that influence implementation of evidence-based recommendations in select HTA cases through stakeholder interviews and thematic analyses.

5. STUDY DESIGN

The study design is qualitative and uses a case study approach. The data will be collected using semi-structured interviews.[20] A 'subtle realism' epistemic position will guide the interpretations of our findings.[21] Subtle realism assumes the following four positions:

1) researchers are part of the reality they study;
2) there is a 'true' reality outside researchers' perceptions/claims about reality;
3) while truth outside the self cannot be validated, this should not preclude a quest for accurate knowledge; and
4) the aim of research is to represent reality, not reproduce it.

6. PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT

The need for this research has been discussed with public contributors. Public contributors will help interpret the results and disseminate the findings with the support of the Patient and Public Involvement and Engagement Lead for the NIHR-ARC West Midlands.[22] This research may lead to a NIHR bid, for which public contributors will take on a larger role in the study design and management.

7. RESEARCHER CHARACTERISISTICS AND REFLEXITVITY

The primary investigator, Schmidtke, has a PhD in experimental psychology and no training in surgical practice. She has no "known" relationships with the participants she will interview, and if any are discovered this will be noted in the final report.

Schmidtke will be advised by Lilford, who is currently director of the NIHR-ARC West Midlands. In addition, Schmidtke will be advised by Grove, who is an expert in qualitative methods and who has published several high impact studies around evidence implementation in surgical practice.

8. SAMPLING STRATEGY

8.1. Cases

The cases were selected by reviewing 655 HTA studies published between 2006 and 2015 (inclusive) and identifying those that met the following criteria: (1) were about surgical practice (2) were not limited to a pilot trial, and (3) reached a conclusion about particular surgical procedures. Nine studies were identified as having met all three criteria. Three of these studies have already been reviewed in a previous audit, including DRAFFT,[23]AIM,[24] and ProFHER.[25,26] The six new studies are described in Table 3.

Topic	HTA study	Patient characteristics	Main Recommendation	Author list (highlights indicate the same person authored multiple HTA studies)
Feeding Tubes	FOOD trial (2006)[27]	Patients admitted to hospital with a recent stroke	Use nasogastric tube feeding rather than percutaneous endoscopic gastronomy tube feeding for patient admitted after a stroke.	M Dennis, S Lewis, G Cranswick, J Forbes, FOOD Trial Collaboration
Tonsillectomies	NESSTAC trial (2010)[28]	Patients 15 years old or less who experienced 4+ sore throats within each of the proceeding two years or 6+ in in the last year	Do not use tonsillectomies to treat children with recurrent sore throats (instead use continued medical management).	Catherine Lock, Janet Wilson, Nick Steen, Martin Eccles, Katie Brittain, Sean Carrie, Ray Clarke, Haytham Kubba, Chris Raine, Andrew Zarod, John Bond
Laparoscopic surgery	REFLUX trial (2013)[29]	Patients with severe gastro-oesophageal reflux disease	Use laparoscopic surgery to treat patients with gastro-oesophageal reflux disease (instead of continued medical management).	A M Grant, C Boachie, S C Cotton, R Faria, L Bojke, D M Epstein, C R Ramsay, B Corbacho, M Sculpher, Z H Krukowski, R C Heading, M K Campbell, REFLUX trial group
Knee replacement surgery	KAT trial (2014)[30]	Patients undergoing primary knee replacement surgery.	Resurface the patella during knee replacement surgeries (instead of not resurfacing).	David W Murray, Graeme S MacLennan, Suzanne Breeman, Helen A Dakin, Linda Johnston, Marion K Campbell, Alastair M Gray, Nick Fiddian, Ray Fitzpatrick, Richard W Morris, Adrian M Grant.
Varicose Vein surgery	REACTIV trial (2006)[31]	Patients referred by general practice with diagnosis of varicose veins	Use surgery for varicose veins to treat patients with varicose veins (instead of sclerotherapy).	Jonathan A Michaels, WB Campbell, JE Brazie, JB MacIntyre, SJ Palfreyman, Julie Ratcliffe, and, Kathryn Rigby
	CLASS trial (2015)[32]	Patients with symptomatic primary varicose veins	Use endovenous laser ablation to treat patients with varicose veins (instead of surgery or sclerotherapy).	Julie Brittenden, Seonaidh C Cotton, Andrew Elders, Emma Tassie, Graham Scotland, Craig R Ramsay, John Norrie, Jennifer Burr, Jill Francis, Samantha Wileman, Bruce Campbell, Paul Bachoo, Ian Chetter, Michael Gough, Jonothan Earnshaw, Tim Lees, Julian Scott, Sara A Baker, Graeme MacLennan, Maria Prior, Denise Bolsover, and Marion K Campbell.

Table 3. Selected HTA trials and their main recommendations.

8.2. Participants

A small number of key stakeholders will be purposefully selected for each HTA study using snowball methods.[33] Our interviews will start with authors of the selected HTA studies. Then to build a more nuanced picture of the factors those authors identify, we will interview expert surgeons identified by those authors, and lastly practitioners/administrators who those surgeons identify.

8.3. Inclusion Criteria

Eligible participants will:

- be willing and able to give informed consent;
- be aged 18 years or older;
- understand verbal and written English; and
- be living in England, Scotland, or Northern Ireland.

9. STUDY ACTIVITIES

9.1. Identifying and Recruiting

Schmidtke will work with clinical collaborators to identify and recruit participants.

Identifying/Recruiting

We will identify participants using snowball methods, see Figure 2. We will start by asking our clinical collaborators to email co-authors of each HTA study inviting them to participate. Where possible, we will start by contacting each trial's chief investigator and then continuing until at least two co-authors have taken part from each study. Then, each author participant will help us identify and invite one surgeon to take part who is an expert in the same surgical area as their study but who not involved in their study's conduct. Lastly, each non-author participant will be asked to identify and invite up to two additional participant. The final category will contain a larger number of participants, because this category will likely contain the most heterogeneous population. We cannot further specify who these participants may be in advance, beyond saying that we will focus on health care provider perspective and that no patients will be interviewed.

Figure 2. Snowball recruitment method.

The minimum number of participants will be 36 (12 authors + 12 non-authors + 12 service providers/administrators), and the maximum number will be 48 (+ 12 additional service providers / administrators). Recruitment will continue until at least the minimum of participants take part, or no further participants can be identified. Some of the potential author participants are authors of more than one HTA study, see highlighted text in Table 3. If these authors participate and discuss more than one study in their interview, then they may be counted one time for each study they discuss.

9.2. Informed Consent

Potential participants will be sent the information sheet and consent form as attachments to the invitation to take part (see Appendix B and C). Before the interview commences, participants will provide their informed consent by emailing Schmidtke's university email account their signed consent form or via an audio recording.

Participants may take as long as they wish to decide whether they would like to take part; however, they will not be able to take part if a sufficient number of participants have already been recruited or if the study ends before their consent is received. No arrangements will be made for potential participants who might not adequately understand verbal explanations or written information in the English language. This is not believed necessary, as all potential participants will be adults living in the England, Scotland, or Northern Ireland who have published research or worked around NHS surgical practice. At the beginning of the interview participants will be ask to re-affirm their consent to participate. Beyond this, it is not practically possible for the research team to monitor if participants retain capacity to consent.

9.3. Discontinuation/Withdrawal of Participants from Study

At the beginning of the interview the participants will be reminded of their right to withdraw during the interview, and up to two weeks after the interview takes place. If a participant withdraws, an additional participant may be recruited.

9.4. Interview

The interviews will be conducted by Schmidtke over her Microsoft Teams university account. Participants will be made aware that the interview will be recorded and professionally transcribed by an external transcription professional.

Schmidtke will send participants directions to join the meeting via her university email. Participants may select to join the meeting via computer by clicking a provided hyperlink or via phone by dialling a provided conference number. Participants who join via a computer will be encouraged to turn on their video, but will not be required to do so. Each interview may take 30 minutes to complete, during which participants will be asked questions according to an interview topic guide (see Appendix D). The topic guide will be used flexible rather than tightly scripted around CFIR's 5 domains or 39 construct. We accept that this means some domains/constructs may be overlooked, because we believe it will allow us to explore more relevant domains/constructs in greater depth.

9.5. Definition of End of Study

The end of study is the date one month after the last participants' transcripts have been anonymised. Data analysis will continue thereafter.

10. ANALYSIS

10.1. The Number of Participants

The minimum number of participants is 36. Overall, this number is greater than that recommended by Guest et al. to reach data saturation for broad themes for homogenous groups (recommending 12)[34] and Creswell for more heterogeneous groups (recommending 30).[35] We acknowledge that the minimum number of participants for each HTA study, i.e. 6, is less than that recommended by Guest. However we judge that we will be able to see clear signal regarding barriers after six purposefully selected interviewees. The maximum number of planned

interviews is 48 (8 for each study), which will allow us to follow and reach data saturation for promising leads. An amendment will be submitted to increase the number of participants if we wish to conduct further interviews.

10.2. Data Analysis

The data will be analysed by Schmidtke using a University of Warwick issued laptop computer in a private location. The anonymised data may be considered by additional investigators named on this protocol to agree on codes and themes via group consensus.

Descriptive data extraction

Data describing our participants demographics will be extracted into a table, like the below table.

Anon Participant ID	HTA study (or studies) discussed in interview	Participant category	Job title	Years working in this area
A48	[study acronym]	[author, non-author, other service provider/administrator]		[Number]

Table 4. Descriptive data extraction table

Thematic Analyses

The thematic analysis will follow Fereday and Muir-Cochrane's inductive and deductive approach for coding and theme development. [36] While the approach is presented here as six steps, the actual analysis will be undertaken in an iterative and reflexive manner. The data collection and analysis stages will be undertaken concurrently, and previous stages of the process may be reviewed before undertaking further analysis to ensure that the ultimate themes reflect the original quotes as comprehensively as possible.

Step 1: Developing the code manual – A coding manual will be developed based on the Consolidated Framework for Implementation Research (CFIR) framework.[37,38] CFIR is composed of five major domains and each major domain is composed of multiple constructs: intervention characteristics (8 constructs), outer setting (4 constructs), inner setting (14 constructs), characteristics of the people involved (5 constructs), and the process of implementation (8 constructs). The initial coding manual will contain one code for each constructs for a total of 39 codes. The code manual will contain each code name (i.e. construct), its definition, and a description explaining when the code should be applied. A template guide for this manual is provided in Appendix E.

Step 2: Testing the reliability of codes – Two interview transcripts will be independently coded by Schmidtke and Grove using the latest version of NVivo. Schmidtke and Grove will meet to discuss their initial codes, resolve discrepancies, and clarify the coding manual to enhance its reliability before Schmidtke independently codes the remaining transcripts.

Step 3: Summarizing data and identifying initial themes – No codes will be applied during step 3, rather this step is to increase familiarity with the raw data. Here each transcript will be reviewed and summarized by outlining the key points made by participants in response to each question asked. The interview video file will be consulted to ensure the accuracy of each transcript.

Step 4: Applying pre-determined codes and additional coding – The anonymous transcripts will be uploaded to NVivo. Then codes will be applied to the transcripts as nodes using Crabtree and Miller's template technique.[39] New codes may be developed and assigned to meaningful

segments of the data not already captured by the CFIR concepts. New codes will be added to an additional section of the code manual, along with the date they are added.

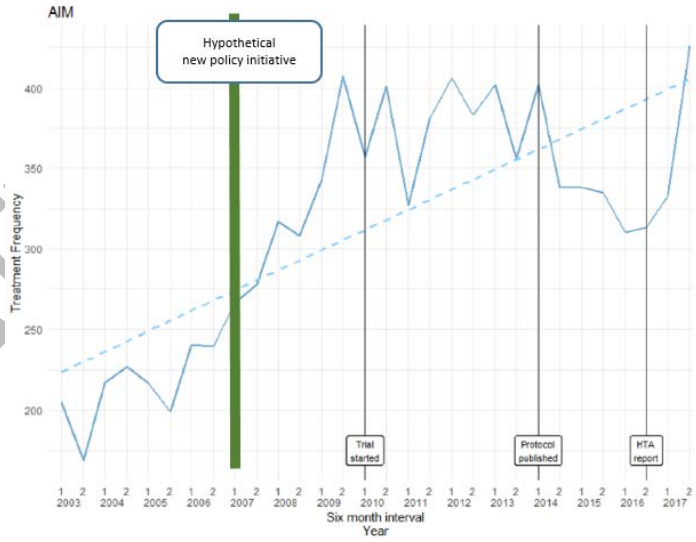
Step 5: Connecting the codes and identifying themes – The sort functions in NVivo will be used to display quotes under each nodes, such that they can be further divided or aggregated, or arranged hierarchically. The interview video file may be consulted to appreciate participant tone. This process should reveal areas of consensus and conflict in responses to each question. Later in this stage, Schmidtke will hold a data analysis sessions with the full research team to discuss the coding process, and any disagreements will be reconciled via group consensus to generate agreed themes. A preliminary name for reach theme will be developed.

Step 6: Corroborating and legitimating coded themes – The previous steps will be scrutinized to ensure that clustered themes represent the initial data analysis. By the end of this process, the codes will be clustered into final themes that exclusively and exhaustively capture participant responses and the participant video files will be deleted. The research team will agree each theme's ultimate name along with a succinct phrase describing it via group consensus.

Additional data extractions

Some participants may mention factors that entail specific dates. For example, a recommended surgical intervention may not have been implemented because a new medication became available, or perhaps a new policy initiative rendered a different treatment more attractive. Where we can uncover precise times for these events, they may inform additional analyses in our audit study and may be inserted into our audit figures to help explain increases or decreases across time, e.g. see Figure 3.

Figure 3. A revised copy of Figure 3 from Reeves et al.'s paper to include a new factor.[40]



Some participants may recall the dates these events occurred, but often our research team will need to search for the dates using common search engines like "Google." Information about each factor that entails a specific date will be recorded in a table like the below.

Anon Participant ID	HTA study (or studies) discussed in interview	Participant category	Description of Factor	Date factor occurred given by participant	Date factor occurred confirmed by independent search

A48	[study acronym]	[author, non-author, other service provider/administrator]	[Number]	[n/a, or date]	[n/a or date and source]

Table 5. Additional data extraction table

11. DATA MANAGEMENT

11.1. Custodian of the data generated

Schmidtke will have control and act as custodian of the data generated.

11.2. Storage and use of personal data during the study

The following personal data will be used during the study. Identifiable personal data will be deleted from our records when the study ends, and any direct quotations will be anonymised in reports.

- Use of personal emails and phone numbers
- Publication of direct quotations from respondents
- Use of audio/visual recording devices
- Storage of personal data on university computers

11.3. Access to Data

The data will be stored in password protected files on the University's servers.

Only named investigators from the University of Warwick will have access to identifiable information, e.g. non-anonymised files. The anonymised data may be passed between named investigators using password protected files for analysis purposes.

Direct access to will be granted to authorised representatives from the University of Warwick for monitoring and/or audit of the study to ensure compliance with regulations during the study and after the study ends.

11.4. Data Recording and Record Keeping

A data flow mapping showing the data gathered and transferred during the study is provided in Appendix F.

The signed consent forms will be stored in a separate password protected file from the study data we collect on the University of Warwick's server. If the participant gives their informed consent over Microsoft Teams, than that recording will be stored in a separate password protected file from the interview file on the University of Warwick's server.

The interview data will be collected during the interview by video recording the Microsoft Teams meeting. Initially, each video file will be given file name with the date/time of the interview, e.g. 9-Sept-10AM. The video file will be stored on the University server in a password protected file for at least two weeks, during which the participant will retain the right to withdraw by emailing the research team. After these two weeks, the date/time will be removed from the video file and replaced with an anonymous code, e.g. A48.

Next, the video file will be sent to and transcribed by an external transcription company selected from the University of Warwick preferred supplier list. While the information is transcribed, any identifiable information will be redacted. After the anonymized transcripts are returned, the video file may be consulted to check for transcription accuracy and speaker tone.

The anonymized transcripts will be stored in password protected files on the University of Warwick's server an analysed using NVIVO software. Quotes extracted from the transcripts to the analysis files will be linked via the anonymous IDs, e.g. A48. After we have completed step 6 of the analysis, the video files will be deleted.

11.5. How will you store data generated by the study?

The password protected files containing only anonymous information will be stored on the University of Warwick servers for up to 10 years after the publication of our findings.

Authorised representatives from the University of Warwick for monitoring and/or audit of the study to ensure compliance with regulations.

12. ETHICAL AND REGULATORY CONSIDERATIONS

12.1. Review of Scientific Quality

The study protocol has been reviewed by two members of the NIHR-ARC West Midlands grant who are not named as investigators on this proposal. Evidence of peer review is provided in Appendix G.

12.2. Guidelines compliance

Schmidtke will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice, the Data Protection Act, General Data Protection Regulation, and the Declaration of Helsinki. Good Clinical Practice certificates are in Appendix H. The primary investigator's CV is provided in Appendix I.

12.3. Approvals

The University of Warwick will act as the sponsor. Ethical approval will be obtained from the Health Research Authority and the University of Warwick's BSREC committee before recruitment commences. Both approvals are required by the University of Warwick.[41]

Schmidtke will submit and obtain approval for amendments to the original approved documents. Amendments to this study will be recorded in Appendix J.

13. INSURANCE AND FINANCE

13.1. Insurance

The University has in force a Public and Products Liability policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage subject to the terms, conditions and exceptions of the policy.[42]

13.2. Intellectual Property

This research is not likely to the development of a new product/processes or the generation of intellectual property.

13.3. Funding

This project is supported by the National Institute for Health Research (NIHR) Applied Research Centre (ARC) West Midlands. The views expressed are those of the author(s) and not necessarily those of the NIHR, ARC, or the Department of Health and Social Care. The funders

will have no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Funding for this study will specifically involve transcripts being produced (approx. 1,900 GBP), and an upgrade to Schmidtke's Microsoft Teams account to allow participants to dial in to attend their interview (approx.100 GBP).

14. PUBLICATION POLICY

The investigators named on this protocol will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the NIHR using the text provided in the above "funding" section. Authorship will be determined in accordance with the International Committee of Medical Journal Editors guidelines and other contributors will be acknowledged.

15. APPENDIX A: STANDARDS REPORTING QUALITATIVE RESEARCH CHECKLIST

Standards for Reporting Qualitative Research (SRQR)*

http://www.equator-network.org/reporting-guidelines/srqr/

	Page/line no(s).
Title and abstract	
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	
Purpose or research question - Purpose of the study and specific objectives or questions	
Methods	
Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	
Context - Setting/site and salient contextual factors; rationale**	
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	
Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	
Limitations - Trustworthiness and limitations of findings	

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

16. APPENDIX B: INFORMATION SHEET

Please see the next page

Participant Information Leaflet

Study Title: A qualitative study to identify factors influencing the implementation of evidenced-based recommendations from studies funded by the Health Technology Assessment program about surgical practice

Investigators: Kelly Ann Schmidtke, Amy Grove, Laura Kudrna, Felicity Evison, and Richard Lilford,

Introduction

You are invited to take part in a research study. You have been identified as potential participant by one of the research team's clinical collaborators or a previous participant. Before you decide whether you want to take part, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Who is organising and funding the study?

This project is supported by the National Institute for Health Research (NIHR) Applied Research Centre (ARC) West Midlands. The funder has no role in the design of the study and will have no role in its collection, analysis, interpretation of data and in writing the manuscript. That responsibility lies with the investigators stated above.

What is the study about?

The current research is being conducted to identify factors that may influence whether the recommendations made by an HTA trial are taken up in surgical practice. In a related audit study (approval reference: CARMS-16381), we are using quantitative information from the Hospital Episode Statistics database to trace whether the publication of evidence-based recommendations about surgical practice change surgical practice. Specifically, we are looking at the surgical recommendations made in six HTA trials: FOOD, NESSTAC REACTIV, CLASS, KAT, and REFLUX. This interview will help us identify additional factors, beyond the publication of those studies, which influence the implementation of evidenced based findings.

Am I eligible to take part?

Eligible participants will:

- be willing and able to give informed consent;
- be aged 18 years or older;
- understand verbal and written English; and
- live in England, Scotland, or Northern Ireland.

What would taking part involve?

You will take part in one interview, which may last 30 minutes. During the interview you will be asked to describe factors that may have influenced whether the recommendations made in stated HTA report(s) influenced surgical practice, e.g. characteristics of the intervention, organization, or individuals involved in implementation. The interview will take place over Microsoft Teams, which you can join online or by dialling in. If you join online, you may can choose whether or not to show your video. The interview will be recorded. After the interview is over, you will be asked to introduce the research team to additional participants who may inform our study.

Do I have to take part?

No. Participation in this study is completely voluntary and choosing not to take part will not affect you in any way. You can also choose to withdraw your participation at any time, without giving a reason by contacting one of the research team within two weeks of your interview. Further details about withdrawing from the study are provided later on in this document.

What are the possible benefits of taking part in this study?

There are no anticipated personal benefits from taking part in this study. You will be contributing to understanding the impact of research. It is an opportunity to help us identify factors that may have influence implementation of research recommendations.

What are the possible disadvantages, side effects or risks, of taking part in this study?

There are minimal risks involved with your participation. We will require some of your time. You can choose what information you want to disclose, and all information will be anonymised.

Expenses and payments

There is no financial compensation for participating.

Will my taking part be kept confidential?

Yes. However, if you are an author being interviewed about a particular study, then you should be aware that your anonymity is necessarily more limited. Noting this limitation, all information about you will be kept very safe and private in our files. Your name will not be used in any reports. Your quotes may be used in our reports, followed by your participant category and the number of years you have researched/practice in your surgical area. Any links between your data and your identifiable information (e.g. your email address) will be completely removed from our files no later than two weeks after your interview takes place.

What will happen to the data collected about me?

Your interview data will be recorded via Microsoft Teams. Your interview will be transcribed by a professional transcription company approved by the University of Warwick during which any personally identifying information will be removed. Only researchers named on this project will have access to the raw data. The anonymous data will be stored in a password protected file on the University of Warwick's servers for a period of at least 10 years from the date of any publication which is based upon it. The anonymised transcripts may be discussed with named members of the research team for analysis purposes

As a publicly-funded organisation, the University of Warwick has to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, such as this, we will use your data in the ways needed to conduct and analyse the research study.

We will be using information from your interview in order to undertake this study and will act as the data controller for this study. We are committed to protecting the rights of individuals in line with data protection legislation. The University of Warwick will keep the video files only as long as it is necessary to transcribe quotes into our data files. No identifiable information will extracted into our analysis files.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. You may withdraw from the study up to two weeks after your interview is completed. The University of Warwick has in place policies and procedures to keep your data safe. This data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project. For further information, please refer to the University of Warwick Research Privacy Notice which is available here: https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice or by contacting the Information and Data Compliance Team at GDPR@warwick.ac.uk.

What will happen if I don't want to carry on being part of the study?

You can withdraw simply by telling the research team that you wish to withdraw during the interview or up to two weeks after the interview takes place. After this time, your data will be anonymised and so it will not be possible to redact from our files. To safeguard your rights, we will use the minimum personally-identifiable information possible and keep the data secure in line with the University's Information and Data Compliance policies.

What will happen to the results of the study?

The results of the study may be published in an academic journal, an online blog (https://arcwm.wordpress.com/), or presented at an academic conference.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the Health Research Authority and the Biomedical Science Research Ethics Committee at the University of Warwick. The University of Warwick is the study sponsor.

Who should I contact if I want further information?

To obtain further information about the study, please contact Dr Kelly Ann Schmidtke at Kelly.A.Schmidtke@warwick.ac.uk.

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance

Jane Prewett
Research & Impact Services
University House
University of Warwick
Coventry
CV4 8UW
Email: researchgovernance@warwick.ac.uk
Tel: 024 76 522746

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter: DPO@warwick.ac.uk.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Thank you for taking the time to read this Participant Information Leaflet

17. APPENDIX C: CONSENT FORM

Please see the next page

Consent Form

Study Title: A qualitative study to identify factors influencing the implementation of evidenced-based recommendations from studies funded by the Health Technology Assessment program about surgical practice

Investigators: Kelly Ann Schmidtke, Amy Grove, Laura Kudrna, Felicity Evison, and Richard Lilford,

Instructions:

You may provide your informed consent using one of the following three options before your interview commences.

1. Printing this form, initialling each item, signing the document, and then emailing the signed document back to Kelly.A.Schmidtke@warwick.ac.uk.

2. Downloading this form, electronically initialling each consent item, electronically signing the document, and then emailing the signed document back to Kelly.A.Schmidtke@warwick.ac.uk.

3. Indicating your consent verbally. If you choose this option, the researcher will read you each consent item and ask for your verbal responses. Your consent will be recorded and stored in a separate file from your interview data.

	Consent Item	Please initial all boxes physical or electronically
1	I confirm that I have read and understand the information sheet (version 1.0, *x, dd/mm/yy*) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	Initials here
2	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.	Initials here
3	I understand that data collected during the study may be looked at by individuals from The University of Warwick, from regulatory authorities, where it is relevant to my taking part in this study. I give permission for these individuals to have access to my data.	Initials here
4	I give my consent for my interview to be video recorded.	Initials here
5	I give my consent for my interview to be transcribed and stored as anonymised electronic files for at least 10 years after the publication of any research findings.	Initials here
6	I give my consent for the use of my anonymised verbatim quotations.	Initials here
7	I am happy for my anonymous data to be used in future research.	Initials here
8	I am happy to help your team identify and introduce the research team to an additional participant likely to inform this study.	
9	I agree to take part in the above study.	Initials here

Name of Participant	Date	Physical or Electronic Signature
Kelly Ann Schmidtke Name of Person taking consent	Date	Electronic Signature

18. APPENDIX D: INTERVIEW GUIDE

INTRODUCTION – CONSENT AND RIGHTS TO WITHDRAW

Researcher: Thank you for agreeing to take part in this interview. The interview will start off with a few closed answered questions, but quickly become more flexible and guided by you feel is most important. Before we get started, can you please confirm that you have read the information sheet and provided your informed consent to participate in the study titled: A qualitative study to identify factors influencing the implementation of evidenced-based recommendations from studies funded by the Health Technology Assessment program about surgical practice

> Participant [if yes, interview continues, if no, the interview ends and the participant may be asked to provide their informed consent or not take part verbally - the third option on the consent form]

Researcher: Thank you. Now, I want to remind you that you have the right to withdraw at any time during the interview and up to two weeks after this interview is complete. Do you have any questions before interview starts?

> Participant: [either asks questions to which the researcher responds or does not have any questions].

OPENING QUESTIONS

Researcher: Wonderful, now to help characterise you in my report, could you describe your job title and how many years you have worked in this area?

> Participant: [says job title and years in practice]

Researcher: Thank you, my records indicate that you can to talk to us about one of the main recommendations made in the [HTA trial(s)], specifically that [describe recommendation]. Yes or No: Do you think that this recommendation has been taken up in NHS practice?

> Participant: [yes/no]

Researcher: To assess whether this recommendation has been taken up in NHS practice, our research team has used the Hospital Episode Statistics database to trace the number of times the recommended procedure was used from 2003 through 2020. Generally our results seem to indicate that [indicate what the HES finding seem to be saying, and if possible show a graph created].

MAIN QUESTION – ABOUT POTENTIALLY INFLUENTIAL FACTORS

Researcher: Now the main purpose of this interview is to gather your insights as to why this recommendation [has or has not] been taken up. For example, there might be something about the intervention that influenced whether it was taken up, or maybe there is something about the individuals using it or the micro- or macro organizations they work in. And now is when the interview should become much more flexible and guided by you. I will try to ask follow up questions as you explain why you believe the intervention [has or has not] been taken up.

> Participant: [given time to describe events]

Researcher Probe questions to ensure all CFIR Domains are addressed, these should be used flexibly acknowledging that many of the domains may be naturally addressed by participants without prompts:

- Process: Please, describe any initiatives created to disseminate this recommendation. Who were they lead by, were there any local champions, was there any outside monitoring or feedback.
- Intervention Characteristics: Tell me about any factors related to the intervention or the study that influenced implementation. For example, maybe another treatment was developed as or after the study was conducted that was more effective than the study's recommended treatment?
- Characteristics of Individuals: Do you think that the surgeons themselves had an influence? For example, are surgeons aware of the recommendation? Do they agree with the recommendation? Why/why not?
- Inner setting: Please describe factors within the NHS's working structures that may have influenced use of this intervention? For example, in your opinion does the NHS support changes in practice like this? Who would lead this change or make it a priority for surgeons, and did they do so for this study? Why/Why not?
- Outer setting: Do you think that factors outside the NHS's working structure may have influenced whether this intervention was implemented? For example, can you describe how patients' preferences influenced its use, or any external policies or incentives that influenced its use?

CLOSING

Researcher: It has been really great to speak with you today. Do you have any other questions, comments or concerns you would like to express before we end this interview?

> Participant: [either offers questions to which the researcher responds or does not have any questions].

Researcher: Thank you for taking the time to speak with me today. If you have any further questions, comments, or concerns feel free to contact me at the email address provided in the information sheet.

19. APPENDIX E. DRAFT CFIR CODING MANUAL

The template CFIR codebook was retrieved from https://cfirguide.org/wp-content/uploads/2019/08/cfircodebooktemplate10-27-2014.docx on 11-NOV-2020.

CFIR Codebook

Note: This template provides inclusion and exclusion criteria for most constructs. Please post additional inclusion and exclusion criteria, guidance, or questions to the CFIR Wiki discussion tab in order to help improve the CFIR.

This template only includes CFIR definitions and coding criteria; codebooks may include other information, such as examples of coded text, rating guidelines, and related interview questions.

I. Innovation Characteristics	
A. Innovation Source	Definition: Perception of key stakeholders about whether the innovation is externally or internally developed. Inclusion Criteria: Include statements about the source of the innovation and the extent to which interviewees view the change as internal to the organization, e.g., an internally developed program, or external to the organization, e.g., a program coming from the outside. Note: May code and rate as "I" for internal or "E" for external. Exclusion Criteria: Exclude or double code statements related to who participated in the decision process to implement the innovation to Engaging, as an indication of early (or late) engagement. Participation in decision-making is an effective engagement strategy to help people feel ownership of the innovation.
B. Evidence Strength & Quality	Definition: Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the innovation will have desired outcomes. Inclusion Criteria: Include statements regarding awareness of evidence and the strength and quality of evidence, as well as the absence of evidence or a desire for different types of evidence, such as pilot results instead of evidence from the literature. Exclusion Criteria: Exclude or double code statements regarding the receipt of evidence as an engagement strategy to Engaging: Key Stakeholders.

	Exclude or double code descriptions of use of results from local or regional pilots to Trialability.
C. Relative Advantage	Definition: Stakeholders' perception of the advantage of implementing the innovation versus an alternative solution. Inclusion Criteria: Include statements that demonstrate the innovation is better (or worse) than existing programs. Exclusion Criteria: Exclude statements that demonstrate a strong need for the innovation and/or that the current situation is untenable and code to Tension for Change.
D. Adaptability	Definition: The degree to which an innovation can be adapted, tailored, refined, or reinvented to meet local needs. Inclusion Criteria: Include statements regarding the (in)ability to adapt the innovation to their context, e.g., complaints about the rigidity of the protocol. Suggestions for improvement can be captured in this code but should not be included in the rating process, unless it is clear that the participant feels the change is needed but that the program cannot be adapted. However, it may be possible to infer that a large number of suggestions for improvement demonstrates lack of compatibility, see exclusion criteria below. Exclusion Criteria: Exclude or double code statements that the innovation did or did not need to be adapted to Compatibility.
E. Trialability	Definition: The ability to test the innovation on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted. Inclusion Criteria: Include statements related to whether the site piloted the innovation in the past or has plans to in the future, and comments about whether they believe it is (im)possible to conduct a pilot. Exclusion Criteria: Exclude or double code descriptions of use of results from local or regional pilots to Evidence Strength & Quality.
F. Complexity	Definition: Perceived difficulty of the innovation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement. Inclusion Criteria: Code statements regarding the complexity of the innovation itself. Exclusion Criteria: Exclude statements regarding the complexity of implementation and code to the appropriate CFIR code, e.g., difficulties related to space are coded to Available Resources and difficulties related to engaging participants in a new program are coded to Engaging: Innovation Participants.

G. Design Quality & Packaging	Definition: Perceived excellence in how the innovation is bundled, presented, and assembled. Inclusion Criteria: Include statements regarding the quality of the materials and packaging. Exclusion Criteria: Exclude statements regarding the presence or absence of materials and code to Available Resources. Exclude statements regarding the receipt of materials as an engagement strategy and code to Engaging.
H. Cost	Definition: Costs of the innovation and costs associated with implementing the innovation including investment, supply, and opportunity costs. Inclusion Criteria: Include statements related to the cost of the innovation and its implementation. Exclusion Criteria: Exclude statements related to physical space and time, and code to Available Resources. In a research study, exclude statements related to costs of conducting the research components (e.g., funding for research staff, participant incentives).
II. Outer Setting	
A. Needs & Resources of Those Served by the Organization	Definition: The extent to which the needs of those served by the organization (e.g., patients), as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization. Inclusion Criteria: Include statements demonstrating (lack of) awareness of the needs and resources of those served by the organization. Analysts may be able to infer the level of awareness based on statements about: 1. Perceived need for the innovation based on the needs of those served by the organization and if the innovation will meet those needs; 2. Barriers and facilitators of those served by the organization to participating in the innovation; 3. Participant feedback on the innovation, i.e., satisfaction and success in a program. In addition, include statements that capture whether or not awareness of the needs and resources of those served by the organization influenced the implementation or adaptation of the innovation. Exclusion Criteria: Exclude statements that demonstrate a strong need for the innovation and/or that the current situation is untenable and code to Tension for Change. Exclude statements related to engagement strategies and outcomes, e.g., how innovation participants became engaged with the innovation, and code to Engaging: Innovation Participants.

B. Cosmopolitanism	Definition: The degree to which an organization is networked with other external organizations. Inclusion Criteria: Include descriptions of outside group memberships and networking done outside the organization. Exclusion Criteria: Exclude statements about general networking, communication, and relationships in the organization, such as descriptions of meetings, email groups, or other methods of keeping people connected and informed, and statements related to team formation, quality, and functioning, and code to Networks & Communications.
C. Peer Pressure	Definition: Mimetic or competitive pressure to implement an innovation, typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge. Inclusion Criteria: Include statements about perceived pressure or motivation from other entities or organizations in the local geographic area or system to implement the innovation. Exclusion Criteria:
D. External Policy & Incentives	Definition: A broad construct that includes external strategies to spread innovations including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting. Inclusion Criteria: Include descriptions of external performance measures from the system. Exclusion Criteria:
III. Inner Setting	
A. Structural Characteristics	Definition: The social architecture, age, maturity, and size of an organization. Inclusion Criteria: Exclusion Criteria:
B. Networks & Communications	Definition: The nature and quality of webs of social networks, and the nature and quality of formal and informal communications within an organization.

	Inclusion Criteria: Include statements about general networking, communication, and relationships in the organization, such as descriptions of meetings, email groups, or other methods of keeping people connected and informed, and statements related to team formation, quality, and functioning. Exclusion Criteria: Exclude statements related to implementation leaders' and users' access to knowledge and information regarding using the program, i.e., training on the mechanics of the program and code to Access to Knowledge & Information. Exclude statements related to engagement strategies and outcomes, e.g., how key stakeholders became engaged with the innovation and what their role is in implementation, and code to Engaging: Key Stakeholders. Exclude descriptions of outside group memberships and networking done outside the organization and code to Cosmopolitanism.
C. Culture	Definition: Norms, values, and basic assumptions of a given organization. Inclusion Criteria: Inclusion criteria, and potential sub-codes, will depend on the framework or definition used for "culture." For example, if using the Competing Values Framework (CVF), you may include four sub-codes related to the four dimensions of the CVF and code statements regarding one or more of the four dimension in an organization. Exclusion Criteria:
D. Implementation Climate	Definition: The absorptive capacity for change, shared receptivity of involved individuals to an innovation, and the extent to which use of that innovation will be rewarded, supported, and expected within their organization. Inclusion Criteria: Include statements regarding the general level of receptivity to implementing the innovation. Exclusion Criteria: Exclude statements regarding the general level of receptivity that are captured in the sub-codes.
1. Tension for Change	Definition: The degree to which stakeholders perceive the current situation as intolerable or needing change. Inclusion Criteria: Include statements that (do not) demonstrate a strong need for the innovation and/or that the current situation is untenable, e.g., statements that the innovation is absolutely necessary or that the innovation is redundant with other programs. Note: If a participant states that the innovation is redundant with a preferred existing program, (double) code lack of Relative Advantage, see exclusion criteria below.

		Exclusion Criteria: Exclude statements regarding specific needs of individuals that demonstrate a need for the innovation, but do not necessarily represent a strong need or an untenable status quo, and code to Needs and Resources of Those Served by the Organization. Exclude statements that demonstrate the innovation is better (or worse) than existing programs and code to Relative Advantage.
2.	Compatibility	Definition: The degree of tangible fit between meaning and values attached to the innovation by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the innovation fits with existing workflows and systems. Inclusion Criteria: Include statements that demonstrate the level of compatibility the innovation has with organizational values and work processes. Include statements that the innovation did or did not need to be adapted as evidence of compatibility or lack of compatibility. Exclusion Criteria: Exclude or double code statements regarding the priority of the innovation based on compatibility with organizational values to Relative Priority, e.g., if an innovation is not prioritized because it is not compatible with organizational values.
3.	Relative Priority	Definition: Individuals' shared perception of the importance of the implementation within the organization. Inclusion Criteria: Include statements that reflect the relative priority of the innovation, e.g., statements related to change fatigue in the organization due to implementation of many other programs. Exclusion Criteria: Exclude or double code statements regarding the priority of the innovation based on compatibility with organizational values to Compatibility, e.g., if an innovation is not prioritized because it is not compatible with organizational values.
4.	Organizational Incentives & Rewards	Definition: Extrinsic incentives such as goal-sharing, awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect. Inclusion Criteria: Include statements related to whether organizational incentive systems are in place to foster (or hinder) implementation, e.g., rewards or disincentives for staff engaging in the innovation. Exclusion Criteria:

5. Goals & Feedback	Definition: The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals. Inclusion Criteria: Include statements related to the (lack of) alignment of implementation and innovation goals with larger organizational goals, as well as feedback to staff regarding those goals, e.g., regular audit and feedback showing any gaps between the current organizational status and the goal. Goals and Feedback include organizational processes and supporting structures independent of the implementation process. Evidence of the integration of evaluation components used as part of "Reflecting and Evaluating" into **on-going or sustained** organizational structures and processes may be (double) coded to Goals and Feedback. Exclusion Criteria: Exclude statements that refer to the implementation team's (lack of) assessment of the progress toward and impact of implementation, as well as the interpretation of outcomes related to implementation, and code to Reflecting & Evaluating. Reflecting and Evaluating is part of the implementation process; it likely ends when implementation activities end. It does not require goals be explicitly articulated; it can focus on descriptions of the current state with real-time judgment, though there may be an implied goal (e.g., we need to implement the innovation) when the implementation team discusses feedback in terms of adjustments needed to complete implementation.
6. Learning Climate	Definition: A climate in which: 1. Leaders express their own fallibility and need for team members' assistance and input; 2. Team members feel that they are essential, valued, and knowledgeable partners in the change process; 3. Individuals feel psychologically safe to try new methods; and 4. There is sufficient time and space for reflective thinking and evaluation. Inclusion Criteria: Include statements that support (or refute) the degree to which key components of an organization exhibit a "learning climate." Exclusion Criteria:
E. Readiness for Implementation	Definition: Tangible and immediate indicators of organizational commitment to its decision to implement an innovation. Inclusion Criteria: Include statements regarding the general level of readiness for implementation. Exclusion Criteria: Exclude statements regarding the general level of readiness for implementation that are captured in the sub-codes.
1. Leadership Engagement	Definition: Commitment, involvement, and accountability of leaders and managers with the implementation of the innovation. Inclusion Criteria: Include statements regarding the level of engagement of organizational leadership.

		Exclusion Criteria: Exclude or double code statements regarding leadership engagement to Engaging: Formally Appointed Internal Implementation Leaders or Champions *if* an organizational leader is also an implementation leader, e.g., if a director of primary care takes the lead in implementing a new treatment guideline. Note that a key characteristic of this Implementation Leader/Champion is that s/he is also an Organizational Leader.
2.	Available Resources	Definition: The level of resources organizational dedicated for implementation and on-going operations including physical space and time. Inclusion Criteria: Include statements related to the presence or absence of resources specific to the innovation that is being implemented. Exclusion Criteria: Exclude statements related to training and education and code to Access to Knowledge & Information. Exclude statements related to the quality of materials and code to Design Quality & Packaging. In a research study, exclude statements related to resources needed for conducting the research components (e.g., time to complete research tasks, such as IRB applications, consenting patients).
3.	Access to Knowledge & Information	Definition: Ease of access to digestible information and knowledge about the innovation and how to incorporate it into work tasks. Inclusion Criteria: Include statements related to implementation leaders' and users' access to knowledge and information regarding use of the program, i.e., training on the mechanics of the program. Exclusion Criteria: Exclude statements related to engagement strategies and outcomes, e.g., how key stakeholders became engaged with the innovation and what their role is in implementation, and code to Engaging: Key Stakeholders. Exclude statements about general networking, communication, and relationships in the organization, such as descriptions of meetings, email groups, or other methods of keeping people connected and informed, and statements related to team formation, quality, and functioning, and code to Networks & Communications.
IV.	**Characteristics of Individuals**	
1.	Knowledge & Beliefs	Definition: Individuals' attitudes toward and value placed on the innovation, as well as familiarity with facts, truths, and principles related to the innovation.

	about the Innovation	Inclusion Criteria: Exclusion Criteria: Exclude statements related to familiarity with evidence about the innovation and code to Evidence Strength & Quality.
2.	Self-efficacy	Definition: Individual belief in their own capabilities to execute courses of action to achieve implementation goals. Inclusion Criteria: Exclusion Criteria:
3.	Individual Stage of Change	Definition: Characterization of the phase an individual is in, as s/he progresses toward skilled, enthusiastic, and sustained use of the innovation. Inclusion Criteria: Exclusion Criteria:
4.	Individual Identification with Organization	Definition: A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization. Inclusion Criteria: Exclusion Criteria:
5.	Other Personal Attributes	Definition: A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style. Inclusion Criteria: Exclusion Criteria:
V.	**Process**	

A. Planning	Definition: The degree to which a scheme or method of behavior and tasks for implementing an innovation are developed in advance, and the quality of those schemes or methods. Inclusion Criteria: Include evidence of pre-implementation diagnostic assessments and planning, as well as refinements to the plan. Exclusion Criteria:
B. Engaging	Definition: Attracting and involving appropriate individuals in the implementation and use of the innovation through a combined strategy of social marketing, education, role modeling, training, and other similar activities. Inclusion Criteria: Include statements related to engagement strategies and outcomes, i.e., if and how staff and innovation participants became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes are coded here, the outcome of engagement efforts determines the rating, i.e., if there are repeated attempts to engage staff that are unsuccessful, or if a role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of staff - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well. Exclusion Criteria: Exclude statements related to specific sub constructs, e.g., Champions or Opinion Leaders. Exclude or double code statements related to who participated in the decision process to implement the innovation to Innovation Source, as an indicator of internal or external innovation source.
1. Opinion Leaders	Definition: Individuals in an organization that have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the innovation. Inclusion Criteria: Include statements related to engagement strategies and outcomes, e.g., how the opinion leader became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage staff determines the rating, i.e., if there are repeated attempts to engage an opinion leader that are unsuccessful, or if the opinion leader leaves the organization and this role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of the opinion leader here - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well. Exclusion Criteria:

2.	Formally Appointed Internal Implementation Leaders	Definition: Individuals from within the organization who have been formally appointed with responsibility for implementing an innovation as coordinator, project manager, team leader, or other similar role. Inclusion Criteria: Include statements related to engagement strategies and outcomes, e.g., how the formally appointed internal implementation leader became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage staff determines the rating, i.e., if there are repeated attempts to engage an implementation leader that are unsuccessful, or if the implementation leader leaves the organization and this role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of the implementation leader here - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well. Exclusion Criteria: Exclude or double code statements regarding leadership engagement to Leadership Engagement *if* an implementation leader is also an organizational leader, e.g., if a director of primary care takes the lead in implementing a new treatment guideline.
3.	Champions	Definition: "Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation]", overcoming indifference or resistance that the innovation may provoke in an organization. Inclusion Criteria: Include statements related to engagement strategies and outcomes, e.g., how the champion became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage staff determines the rating, i.e., if there are repeated attempts to engage a champion that are unsuccessful, or if the champion leaves the organization and this role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of the champion here - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well. Exclusion Criteria: Exclude or double code statements regarding leadership engagement to Leadership Engagement *if* a champion is also an organizational leader, e.g., if a director of primary care takes the lead in implementing a new treatment guideline.
4.	External Change Agents	Definition: Individuals who are affiliated with an outside entity who formally influence or facilitate innovation decisions in a desirable direction. Inclusion Criteria: Include statements related to engagement strategies and outcomes, e.g., how the external change agent (entities outside the organization that facilitate change) became engaged with the innovation and what their role is in implementation, e.g., how they supported implementation efforts. Note: Although both strategies and outcomes are coded here, the outcome of efforts to

		engage staff determines the rating, i.e., if there are repeated attempts to engage an external change agent that are unsuccessful, or if the external change agent leaves their organization and this role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of the external change agent here - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well. Exclusion Criteria: Note: It is important to clearly define what roles are external and internal to the organization. Exclude statements regarding facilitating activities, such as training in the mechanics of the program, and code to Access to Knowledge & Information *if* the change agent is considered internal to the study, e.g., a staff member at the national office. If the study considers this staff member internal to the organization, it should be coded to Access to Knowledge & Information, even though their support may overlap with what would be expected from an External Change Agent.
5.	Key Stakeholders	Definition: Individuals from within the organization that are directly impacted by the innovation, e.g., staff responsible for making referrals to a new program or using a new work process. Inclusion Criteria: Include statements related to engagement strategies and outcomes, e.g., how key stakeholders became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage staff determines the rating, i.e., if there are repeated attempts to engage key stakeholders that are unsuccessful, the construct receives a negative rating. Exclusion Criteria: Exclude statements related to implementation leaders' and users' access to knowledge and information regarding using the program, i.e., training on the mechanics of the program, and code to Access to Knowledge & Information. Exclude statements about general networking, communication, and relationships in the organization, such as descriptions of meetings, email groups, or other methods of keeping people connected and informed, and statements related to team formation, quality, and functioning, and code to Networks & Communications.
6.	Innovation Participants	Definition: Individuals served by the organization that participate in the innovation, e.g., patients in a prevention program in a hospital. Inclusion Criteria: Include statements related to engagement strategies and outcomes, e.g., how innovation participants became engaged with the innovation. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage

	participants determines the rating, i.e., if there are repeated attempts to engage participants that are unsuccessful, the construct receives a negative rating. Exclusion Criteria: Exclude statements demonstrating (lack of) awareness of the needs and resources of those served by the organization and whether or not that awareness influenced the implementation or adaptation of the innovation and code to Needs & Resources of Those Served by the Organization.
C. Executing	Definition: Carrying out or accomplishing the implementation according to plan. Inclusion Criteria: Include statements that demonstrate how implementation occurred with respect to the implementation plan. Note: Executing is coded very infrequently due to a lack of planning. However, some studies have used fidelity measures to assess executing, as an indication of the degree to which implementation was accomplished according to plan. Exclusion Criteria:
D. Reflecting & Evaluating	Definition: Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience. Inclusion Criteria: Include statements that refer to the implementation team's (lack of) assessment of the progress toward and impact of implementation, as well as the interpretation of outcomes related to implementation. Reflecting and Evaluating is part of the implementation process; it likely ends when implementation activities end. It does not require goals be explicitly articulated; it can focus on descriptions of the current state with real-time judgment, though there may be an implied goal (e.g., we need to implement the innovation) when the implementation team discusses feedback in terms of adjustments needed to complete implementation. Exclusion Criteria: Exclude statements related to the (lack of) alignment of implementation and innovation goals with larger organizational goals, as well as feedback to staff regarding those goals, e.g., regular audit and feedback showing any gaps between the current organizational status and the goal, and code to Goals & Feedback. Goals and Feedback include organizational processes and supporting structures independent of the implementation process. Evidence of the integration of evaluation components used as part of "Reflecting and Evaluating" into **on-going or sustained** organizational structures and processes may be (double) coded to Goals and Feedback. Exclude statements that capture reflecting and evaluating that participants may do during the interview, for example, related to the success of the implementation, and code to Knowledge & Beliefs about the Innovation.

VI. Additional Codes	
A. Code Name	Definition: Inclusion Criteria: Exclusion Criteria:
B. Code Name	Definition: Inclusion Criteria: Exclusion Criteria:

General Coding Rules:

When two codes are in question for a passage, consider the primary meaning of the passage to assign code; consider what the participant is truly saying. Analysts may wish to err on the side of inclusion or double coding.

General Rating Rules:

Ratings						
M	-2	-1	0	X	+1	+2

In general, ratings are determined based on two factors: 1) valence and 2) strength.

Valence: positive or negative influence on implementation

Rating component: X, 0, +, -

The valence component of a rating is determined by the influence the coded data has on the implementation process, i.e., contextual factors that facilitate or hinder implementation. Due to limited data, analysts may have to infer the influence on implementation based on simple presence or absence of a construct. For example, if a participant states that the intervention has advantages over existing programs, but does not state how this has influenced implementation, the analyst can infer that the presence of relative advantage facilitated implementation. However, whenever the data allows, the analysts should apply ratings based on the influence the construct has on implementation, not the presence or absence of a construct; presence or absence of a positive construct (e.g. relative advantage) does not always constitute a matching positive or negative influence on implementation.

In the event that comments are mixed, i.e., some comments are negative and some comments are positive, try to tip the rating to a weak positive or weak negative, based on the aggregate of the comments. However, if you feel the comments are equally positive and negative, apply a mixed (X) rating. Some users of the CFIR have denoted level of agreement among participants in their rating by adding a * to the rating if comments were mixed. For example, if the aggregate of mixed comments was positive, the rating was +1*. Some users feel it's important to record discord among participants because it indicates a negative influence on implementation.

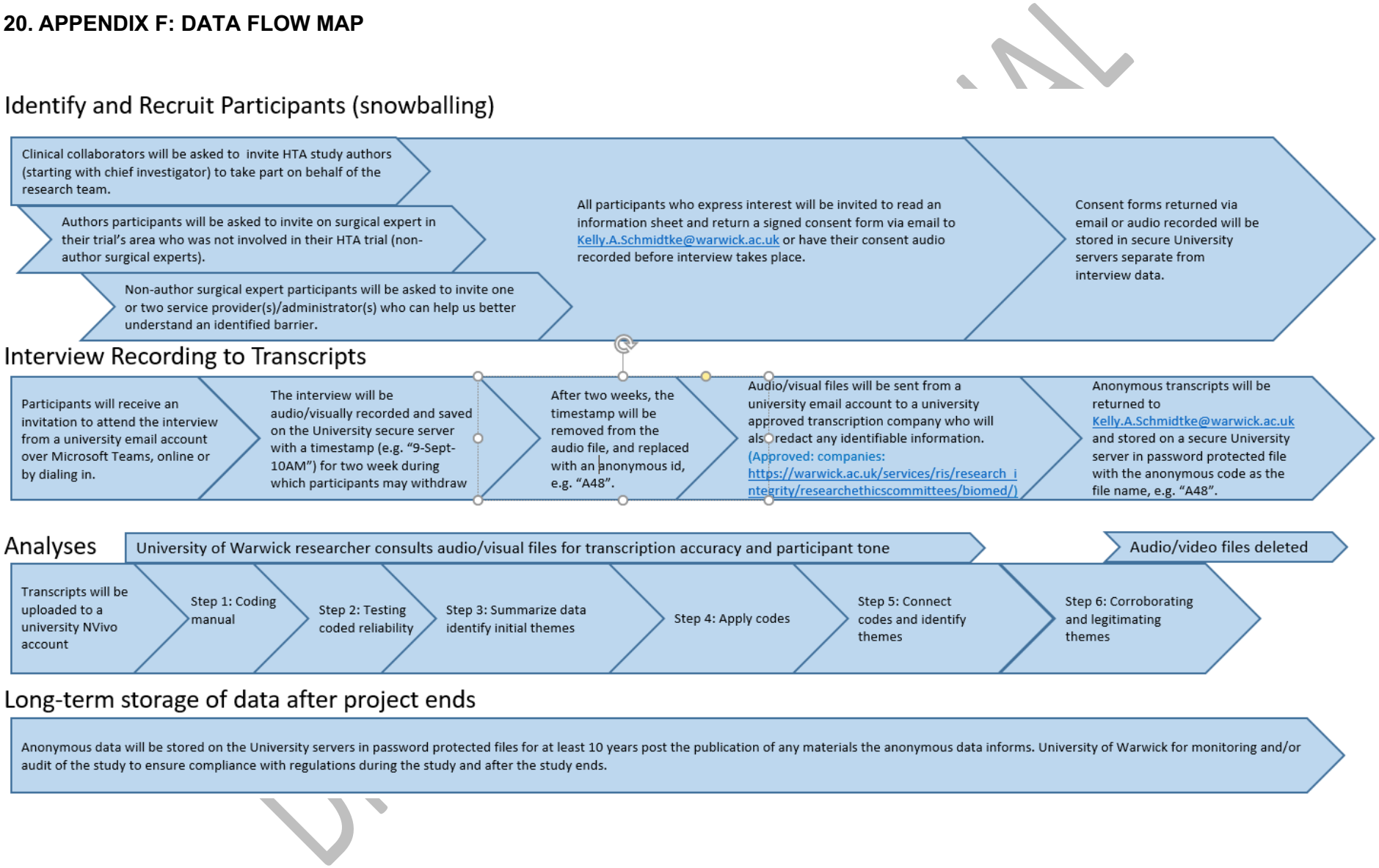
In the event that the comments are neutral, i.e., comments are related to a construct but have no bearing on the implementation, apply the neutral (0) rating.

Strength: weak or strong influence on implementation

Rating component: 1, 2

The strength component of a rating is determined by a number of factors, including: level of agreement among participants, strength of language, and use of concrete examples. However, sometimes analysts may choose to apply relative ratings, versus absolute ratings, in order to differentiate between organization in the study.

20. APPENDIX F: DATA FLOW MAP



21. APPENDIX G: EVIDENCE OF PEER REVIEW

NIHR | Applied Research Collaboration West Midlands

Peer Review Comments Form

Reviewer Name	Beck Taylor

Theme Title	Methodology, Informatics and Rapid Response (Theme 6)
Study Title	A qualitative study to identify factors influencing the implementation of evidenced-based recommendations from studies funded by the Health Technology Assessment program about surgical practice
Theme Leader	Aileen Clarke

Peer Review:

The overall purpose of the peer review is primarily to improve the quality of the proposed research. Comments from the referees are fed back to the theme leader in anonymised form. Please make clear any open comments and closed comments that you wish to make and feel free to expand pages in document, as necessary.

OPEN COMMENTS

Thank you for asking me to review this protocol, which addresses an important evidence to practice gap, using qualitative methods to complement a parallel quantitative study.

Do you think all relevant areas are being covered in the research plan?
Most areas are covered comprehensively in the research plan. There are a few areas for clarification listed at the end of the review.

Are the methods proposed sufficiently robust to answer the research question?
The method is appropriate for the research question, which is clear. I have listed suggestions at the end of the review which may strengthen it further.

Do you have any specific suggestions for the overall improvement of the research protocol?

CLAHRC WM Central Office Address: Room A155, Division of Health Sciences (Population & Public Health), Warwick Medical School, University of Warwick, Coventry, CV4 7AL

NIHR | Applied Research Collaboration West Midlands

- Were all of the eligible HTA trials identified included as case studies, and were any excluded as this was not completely clear to me?
- Participants in the earlier trials may struggle more to recall events and perspectives, or may not have been practising at the time of earlier trials, which may need to guide participant eligibility criteria (e.g. 2006 FOOD trial).
- For practising NHS surgeons who are not involved in research (i.e. do not have contact details on university sites or in publications) it may be challenging to find email addresses from public sources, as these are not widely published. The researchers may already have established processes to contact these individuals, but alternative methods may be required.
- How many potential participants are there, and how will the researchers decide whom to invite to participate? This may be straightforward if pools of possible participants are small. Is overlap expected, with some participants able to provide perspectives on more than one trial? Will purposive sampling consider variations in experience of participants, and context (e.g. small/large, urban/rural, research active NHS site/not)?
- If possible, researcher triangulation including dual coding of a proportion of data gathered would strengthen credibility of findings. Will findings be shared with participants for comment/reflection?
- The proposed analysis is inductive. It may be worth considering a deductive element, informed by implementation and evidence and theory (e.g. CFIR).
- Might it be possible to sample participants and triangulate the qualitative findings with HES, i.e. by exploring varied performance between sites alongside local surgeons' perspectives of the influences on implementation?

CONFIDENTIAL COMMENTS

- Are there any additional comments that you would like to include which should remain confidential? These will not be shown to the lead author.

CLAHRC WM Central Office Address: Room A155, Division of Health Sciences (Population & Public Health), Warwick Medical School, University of Warwick, Coventry, CV4 7AL

Revision made based on this review (12-Oct-2020).

1. The protocol now more clearly describes how eligible HTA trials were identified.

2. Recall problems will be mentioned as a limitation for early HTA trials (difficult to remember trial in 2006).

2. To identify surgeons not named on the trials, we now plan to contact their department managers or secretaries whose contact information is more likely to be publically available.

3. The participant categories is defined exclusively:
- (Category 1) co-author or named contributor of the published HTA report, or
- (Category 2) not a co-author or contributor of the published HTA report, but practicing with relevant surgical expertise

As participants may be involved in/have relevant expertise in multiple HTA trials the number of participants may be less than planned, i.e. 54.

4. Schmidtke and Grove will now independently code two transcripts, and the full research team will meet to discuss codes and agree themes.

5. We now include a hybrid data analysis plan with a deductive components based on the CFIR Framework and an inductive component allowing for new codes outside CFIR to be developed.

6. Triangulation is out-of-scope for this research.

NIHR | Applied Research Collaboration West Midlands

Peer Review Comments Form

Reviewer Name	Sarah Damery

Theme Title	Methodology, Informatics and Rapid Response (Theme 6)
Study Title	A qualitative study to identify factors influencing the implementation of evidenced-based recommendations from studies funded by the Health Technology Assessment program about surgical practice
Theme Leader	Aileen Clarke

Peer Review:

The overall purpose of the peer review is primarily to improve the quality of the proposed research. Comments from the referees are fed back to the theme leader in anonymised form. Please make clear any open comments and closed comments that you wish to make and feel free to expand pages in document, as necessary.

OPEN COMMENTS

(Unattributed comments for verbatim feedback to lead author)

We do not have specific criteria for peer reviewers but ask for comments based around some broad questions:

Do you think all relevant areas are being covered in the research plan?

This is a detailed and thorough research plan which has been designed to complement an existing quantitative audit of the impact of HTA study recommendations on surgical practice. The authors recognise that publication of an HTA study is not the only factor that may affect whether or not recommendations are adopted, so the proposal to undertake some semi-structured interviews to uncover additional influences on implementation is very sound and should yield interesting results.

Are the methods proposed sufficiently robust to answer the research question?

Yes, I think so. Some elements of the research design would benefit from greater elaboration – for example the 'subtle realism' epistemic position cited under the study design section on page 8 is not familiar to me, and simply referencing this is perhaps not enough. A brief description of what this means for the interpretation of findings would be beneficial.

The authors may need to consider the impact of length of time since HTA studies were published when exploring implementation of findings. For example, a study published in 2006 following an HTA study may not have had an appreciable impact on surgical procedure rates because 14 years is a long time and surgical innovations are constantly evolving. The methodology being followed in this study may not be helpful in understanding what happened in a given surgical field so long after HTA recommendations were made: were there subsequent clinical guidelines? Were there subsequent studies which found different results to the HTA study? Was there emerging international evidence which may have changed the likelihood of adoption? This is not going to be an issue for the included studies published fairly recently, but in the case of those published some time ago, it may be difficult to disentangle the relevant chain of events/influences.

Including co-authors/contributors to the published studies makes sense and the recruitment process to be followed is clearly described (although in the case of studies with large numbers of co-authors, how will the study team select those who it may be best to approach given that the specific contribution to the work of some individuals may be minimal?) Perhaps the CI should be approached for all studies, which may or may not be the same as the main report author. This level of detail is not described in the protocol.

CLAHRC WM Central Office Address: Room A155, Division of Health Sciences (Population & Public Health), Warwick Medical School, University of Warwick, Coventry, CV4 7AL

NIHR | Applied Research Collaboration West Midlands

It is less clear how the authors will identify people trained to use the surgical procedures described in the HTA reports who were not involved in the selected trials. In the case of – for example – tonsillectomies, there must be hundreds of surgeons in England alone who are able to perform these procedures. I don't think that the procedure outlined in Section 10.1 (identifying surgical experts from hospital websites that are not explicitly named as being involved in the relevant HTA studies) will be effective in identifying an unbiased sample and in the case of common procedures may represent an extremely large amount of work. Linked to this – how will the authors determine who is a surgical expert? Will these be heads of surgical departments, or those with a specific level of seniority within their institution? In the event that there are many, many 'experts' in a given surgical field who might be approached to participate, how will the decision on who to approach be undertaken, and using what criteria?

Inclusion of people working in England, Scotland or Northern Ireland but excluding Wales seems awkward. I understand that this is to do with the need to translate study materials into Welsh but in that case surely it would be more sensible to restrict the entire study just to England.

Do you have any specific suggestions for the overall improvement of the research protocol?

The structure was good but the repeated insertion of the relevant headings from the IRAS form was off-putting. Presumably this is an aide-memoire to the authors to ensure that all elements of the ethical conduct of the study are covered in the protocol but it did not make for a smooth read – indeed at points it was not clear whether this was a study protocol or an abridged ethics form, as there were some elements that whilst essential for ethics forms, are not normally included in protocols, or at least not in such exhaustive detail e.g. Section 9, research procedures, risks and benefits. Hopefully the IRAS-related pointers will be removed from the protocol in a later iteration.

I would suggest a standalone section on PPIE rather than squeezing this in under the 'study design' heading as the current treatment of PPIE in the protocol appears somewhat tokenistic.

There are a number of typographical errors that should be ironed out (e.g. section 7 title 'reflexivity').

Section 8.1 (Cases sampling strategy) – it's not clear whether the 9 cases selected were the only studies that met the 3 criteria outlined in the table, or whether there were more to start with and a longer list of eligible studies was whittled down to form the 9 selected. A PRISMA type diagram would be really useful here, to show how the 665 HTA studies became the 9 that have been chosen.

Add Table headings.

Topic guide is fairly brief and a bit short on prompts perhaps. It's obviously difficult to know at this stage but it reads as fairly mechanistic. There's also not much of a sense that the study co-authors and surgical experts may need different questions rather than the same topic guide. Also perhaps tone down the 'researcher' parts of the example interview conversation in Appendix F – I'm not sure that many interviews can routinely be termed a 'spectacular' conversation when signing off with an interviewee.

The data flow map in Appendix G was very useful.

CONFIDENTIAL COMMENTS

- Are there any additional comments that you would like to include which should remain confidential? These will not be shown to the lead author.

None – this was a very good protocol that outlined a worthwhile and scientifically robust study that should yield some valuable insights.

CLAHRC WM Central Office Address: Room A155, Division of Health Sciences (Population & Public Health), Warwick Medical School, University of Warwick, Coventry, CV4 7AL

Revision made based on this review (14-Oct-2020).

1. 'Subtle realism' is now more fully explained.

2. Recall problems will be mentioned as a limitation for early HTA trials.

3. We now specify that the Chief Investigators of the selected HTA studies will be the first co-author we approach, and then at least a week later all other co-authors will be approached. This ensures that the Chief Investigator has the first opportunity to take part, without delaying further recruitment.

4. To identify surgeons not named on the trials, we now plan to contact their department managers or secretaries whose contact information is more likely to be publically available. No extra criteria will be applied to determine what surgeons will take part, as we are very concerned about under-recruitment.

5. Presently, we retained Scotland and Northern Ireland in the sample for now, as the only reason to exclude Wales was our lack of ability to translate the study material to Welsh, and this reason does not extend to Scotland or Northern Ireland.

6. "IRAS" headers have been removed.
7. PPIE is now in a unique section.
8. The protocol now more clearly describes how eligible HTA trials were identified. A PRISMA table was not included as this is believed out of scope for a protocol.
9. Table headings have been added.
10. Topic guide has been revised. I plan to discuss with a public contributor, which might lighten the tone.

UNFORMATTED REFERENCES

[1] https://warwick.ac.uk/services/ris/research_integrity/sponsorship/sponsorship_application_form_v6.0_protected.docx

[2] https://warwick.ac.uk/services/ris/research_integrity/researchethicscommittees/biomed/bsrec_application_form_v4_13.01.2020.docx

[3] https://www.myresearchproject.org.uk/help/hlphraapproval.aspx

[4] O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook, DA. Standards for Reporting Qualitative Research, Academic Medicine. 2014;89(9), 1245-1251.

[5] National Institute for Health Research. NIHR Annual Report 2018/2019. Available at: https://www.nihr.ac.uk/about-us/our-contribution-to-research/research-performance/12228_NIHR_Annual_Report_18_19.pdf Accessed on 04 May 2020.

[6] Hanney S, Buxton M, Green C, Coulson D, Raftery J. An assessment of the impact of NHS Health Technology Assessment Programme. Health Technol Assess 2007;11(53).

[7] Guthrie S, Bienkowska-Gibbs T, Manville C, Pollitt A, Kirtley A, Wooding S. The impact of the National Institute for Health Research Health Technology Assessment programme, 2003 13: a multimethod evaluation. Health Technol Assess 2015;19(67)

[8] Reeves K, Chan S, Marsh A, Gallier S, Wigley C, Khunti K, Lilford RJ. Implementation of research evidence in orthopaedics: a tale of three trials. BMJ Qual Saf. 2020 May;29(5):374-381.

[9] Reeves K, Chan S, Marsh A, Gallier S, Wigley C, Khunti K, Lilford RJ. Implementation of research evidence in orthopaedics: a tale of three trials. BMJ Qual Saf. 2020 May;29(5):374-381.

[10] Dennis M, Lewis S, Cranswick G, Forbes J. FOOD: a multicentre randomised trial evaluating feeding policies in patients admitted to hospital with a recent stroke. *Health Technol Assess* 2006;10(2)

[11] Michaels J, Campbell B, Brazier J, MacIntyre J, Palfreyman S. Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial). Health Technol Assess 2006;10(13)

[12] Lock C, Wilson J, Steen N, Eccles M, Mason H. North of England and Scotland Study of Tonsillectomy and Adeno-tonsillectomy in Children (NESSTAC) : a pragmatic randomised controlled trial with a parallel non-randomised preference study. *Health Technol Assess* 2010;14(13)

[13] Grant A, Boachie C, Cotton S, Faria R, Bojke L. Clinical and economic evaluation of laparoscopic surgery compared with medical management for gastro-oesophageal reflux disease: 5-year follow-up of multicentre randomised trial (the REFLUX trial). Health Technol Assess 2013;17(22)

[14] Murray D, MacLennan G, Breeman S, Dakin H, Johnston L, Campbell M et al. A randomised controlled trial of the clinical effectiveness and cost-effectiveness of different knee prostheses: the Knee Arthroplasty Trial (KAT). *Health Technol Assess* 2014;18(19)

[15] Brittenden J, Cotton S, Elders A, Tassie E, Scotland G, Ramsay C, et al. Clinical and cost-effectiveness of foam sclerotherapy, endovenous laser ablation and surgery for varicose veins: results from the CLASS trial. Health Technol Assess 2015;19(27)

[16] Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.

[17] Smith, L.R., Damschroder, L., Lewis, C.C. et al. The Consolidated Framework for Implementation Research: advancing implementation science through real-world applications, adaptations, and measurement. Implementation Sci 10, A11 (2015). https://doi.org/10.1186/1748-5908-10-S1-A11 Download citation

[18] Waltz, T.J., Powell, B.J., Fernández, M.E. et al. Choosing implementation strategies to address contextual barriers: diversity in recommendations and future directions. Implementation Sci 14, 42 (2019). https://doi.org/10.1186/s13012-019-0892-4

[19] https://warwick.ac.uk/services/ris/research_integrity/researchethicscommittees/biomed/idc_approved_research_services_23.5.19.xlsx

[20] Bauer, M. W., & Gaskell, G. (Eds.). (2000). *Qualitative researching with text, image and sound: A practical handbook for social research*. Sage.

[21] Hammersley, M. (1992). What's wrong with ethnography?: Methodological explorations. Psychology Press.

[22] https://warwick.ac.uk/fac/sci/med/about/centres/arc-wm/ppie/

[23] Costa ML, Achten J, Plant C, *et al*. Uk DRAFFT: a randomised controlled trial of percutaneous fixation with Kirschner wires versus volar locking-plate fixation in the treatment of adult patients with a dorsally displaced fracture of the distal radius. *Health Technol Assess* 2015;19:1–124.

[24] Keene DJ, Mistry D, Nam J, et al. The Ankle Injury Management (AIM) trial: a pragmatic, multicentre, equivalence randomised controlled trial and economic evaluation comparing close contact casting with open surgical reduction and internal fixation in the treatment of unstable ankle fractures in patients aged over 60 years. Health Technol Assess 2016;20:1–158.

[25] Handoll H, Brealey S, Rangan A, et al. The ProFHER (proximal fracture of the humerus: evaluation by randomisation) trial—a pragmatic multicentre randomised controlled trial evaluating the clinical effectiveness and cost-BMJ Qual Saf: first published as 10.1136/bmjqs-2019-010056 on 27 November 2019. Downloaded from http://qualitysafety.bmj.com/ on November 28, 2019 by guest. Protected by copyright. 8 Reeves K, et al. BMJ Qual Saf 2019;0:1–8. doi:10.1136/bmjqs-2019-010056 Original research effectiveness of surgical compared with non-surgical treatment for proximal fracture of the humerus in adults. Health Technol Assess 2015;19:1–280.

[26] Reeves K, Chan S, Marsh A, Gallier S, Wigley C, Khunti K, Lilford RJ. Implementation of research evidence in orthopaedics: a tale of three trials. BMJ Qual Saf. 2020 May;29(5):374-381.

[27] Dennis M, Lewis S, Cranswick G, Forbes J. FOOD: a multicentre randomised trial evaluating feeding policies in patients admitted to hospital with a recent stroke. *Health Technol Assess* 2006;10(2)

[28] Lock C, Wilson J, Steen N, Eccles M, Mason H. North of England and Scotland Study of Tonsillectomy and Adeno-tonsillectomy in Children (NESSTAC) : a pragmatic randomised controlled trial with a parallel non-randomised preference study. *Health Technol Assess* 2010;14(13)

[29] Grant A, Boachie C, Cotton S, Faria R, Bojke L. Clinical and economic evaluation of laparoscopic surgery compared with medical management for gastro-oesophageal reflux disease: 5-year follow-up of multicentre randomised trial (the REFLUX trial). Health Technol Assess 2013;17(22)

[30] Murray D, MacLennan G, Breeman S, Dakin H, Johnston L, Campbell M et al. A randomised controlled trial of the clinical effectiveness and cost-effectiveness of different knee prostheses: the Knee Arthroplasty Trial (KAT). *Health Technol Assess* 2014;18(19)

[31] Michaels J, Campbell B, Brazier J, MacIntyre J, Palfreyman S. Ratcliffeand J, Rigby K. Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial). Health Technol Assess 2006;10(13)

[32] Brittenden J, Cotton S, Elders A, Tassie E, Scotland G, Ramsay C, et al. Clinical and cost-effectiveness of foam sclerotherapy, endovenous laser ablation and surgery for varicose veins: results from the CLASS trial. Health Technol Assess 2015;19(27)

[33] Stake R. The art of case study research. Thousand Oaks, CA: Sage. 1995.

[34] Guest G, Bunce A, Johnson L. How Many Interviews Are Enough?: An Experiment with Data Saturation and Variability. Field Methods. 2006;18(1):59-82. doi:10.1177/1525822X05279903

[35] Cresswell, J., (2007) Qualitative Inquiry and Research Design: Choosing among five approaches. Sage, Thousand Oaks.

[36] Fereday J, Muir-Cochrane E. Demonstrating rigor using thematic analysis: a hybrid approach of inductive and deductive coding and theme development. Int J Qual Methods. 2006;5:80–92.

[37] Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.

[38] https://cfirguide.org/constructs/

[39] Crabtree, B., & Miller, W. (1999). A template approach to text analysis: Developing and using codebooks. In B. Crabtree & W. Miller (Eds.), Doing qualitative research (pp. 163-177.) Newbury Park, CA: Sage.

[40] Reeves K, Chan S, Marsh A, Gallier S, Wigley C, Khunti K, Lilford RJ. Implementation of research evidence in orthopaedics: a tale of three trials. BMJ Qual Saf. 2020 May;29(5):374-381.

[41] https://warwick.ac.uk/services/ris/research_integrity/humanparticipants_material_data

[42] https://warwick.ac.uk/services/ris/research_integrity/researchethicscommittees/nhs_rec/apply/iras_qa_.insurance._projects.nhs_involve.v3.pdf