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Developing and implementing guidelines for infection after joint replacement

Submission date
07/04/2022

Recruitment status
No longer recruiting

Registration date
29/04/2022

Overall study status
Completed

Last Edited
11/09/2024

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
People with damaged or diseased joints may have a joint replacement to reduce pain and disability. About one in a hundred joint replacements become infected. Infection can cause severe pain, disability and death. Treatment usually requires two operations with antibiotics between surgeries. Some surgeons treat joint infection with one operation. Between 2014 and 2020 researchers conducted the INFORM Programme to find out why some patients are prone to getting joint infections, how this affects patients, NHS resources, and to evaluate treatments. They reviewed existing evidence, analysed data from international studies, talked to patients and surgeons about their experiences of infection and preferences for treatment, and developed an international network of orthopaedic infection experts. They conducted a randomised controlled trial, where 140 patients with hip infection from 12 UK and three Swedish hospitals received either one or two operations to find out which gave the best outcomes. A patient forum supported the research. It was found that the risk of hip infection was greater in obese people, men, and people with pre-existing health conditions. Patients and surgeons described the devastating effects of infection and treatment on people's lives. Important patient concerns were recovery time and ability to engage in valued activities. The research reviewed showed that treating the infection with one or two operations cleared the infection equally. It was also found that a type of operation called DAIR (debridement, antibiotics and implant retention) performed within 3 weeks of infection can clear infection in over 60% of cases, without the need for the replacement hip to be removed. The trial was also successful and the findings are in the process of being published. The researchers will now put these important findings from the programme into practice to improve patient outcomes and ensure that the NHS delivers the best possible care. Currently there are no national guidelines for the treatment of hip infection because of a lack of good underpinning evidence. Using the evidence from the INFORM programme, the researchers can now develop best practice guidelines. They will do this in two studies:
1. They will work with surgeons, patients and commissioners to develop best practice guidance for the management of infection after hip replacement, based on the INFORM programme evidence.
2. They will then work with 12 UK orthopaedic centres to put these guidelines into practice when treating patients with a hip infection.

Who can participate?
Healthcare professionals and managers involved in the management of prosthetic hip infection at one of the 12 participating centres

What does the study involve?
Healthcare professionals and managers from 12 orthopaedic centres will form a "Learning Collaborative", sharing their experiences of implementing the guidelines, what changes have been made, challenges encountered and how these might have been overcome. They will report on their experiences during two stakeholder meetings and will also take part in an interview with a researcher to talk about their experiences of using the guidelines. Learning points from each of these activities will be used to inform the design of a "toolkit" to enable other orthopaedic centres in future to use the guidelines more easily.

What are the possible benefits and risks of participating?
It is hoped that membership of the Learning Collaborative will provide a network of expertise and could support best practices in the treatment and management of prosthetic hip infection. Participants will also be instrumental in helping to design a support toolkit to enable other centres to better use the Guideline in the future. A possible disadvantage is the time it takes to attend the expert meetings, which may take up to 90 minutes, and the interview may take up to 45 minutes.

Where is the study run from?
North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
October 2021 to September 2023

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Andrew Moore
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
309417

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 52175, IRAS 309417

Study information

Scientific Title
INFection and ORthopaedic Management: Evidence into Practice

Acronym
INFORM EP

Study objectives
This is a mixed-methods implementation study and as such does not have a hypothesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/02/2022, University of Bristol Faculty of Health Sciences Research Ethics Committee (Address: not provided; Tel: not provided; research-ethics@bristol.ac.uk), ref: 10069

Study design
Both; Design type: Treatment, Diagnosis, Prevention, Process of Care, Other, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Elective orthopaedic surgery

Interventions

The researchers will use evidence from the INFORM Programme (RP-PG-1210-12005) to develop draft guidelines for the management and treatment of prosthetic hip infection. They will then implement the guidelines into practice. This development work comprises two workstreams that will take place consecutively.

Workstream 1: Using evidence from INFORM to develop best practice guidelines
The initial draft guideline will be developed by the study team members, which include orthopaedic surgeons, evidence synthesis experts, a musculoskeletal health expert, a social scientist, and a physiotherapist and implementation and knowledge mobilisation expert. The first draft guideline will then be further developed and refined through stakeholder work that includes a consensus panel and virtual stakeholder meeting.

Phase 1: The researchers will invite 20 experts to participate in a consensus panel including those with experience and roles within the treatment and management of prosthetic joint infection, representatives from professional orthopaedic societies, and primary care representatives including GPs, and frontline care practitioners involved in the identification and management of prosthetic joint infection. Orthopaedic consultants and representatives of professional organisations will be identified through networks established during the previous INFORM programme, and through which the researchers can identify and secure buy-in from stakeholders with whom they have established and trusted relationships. GPs and frontline care practitioners will be identified through our links with the Bristol and North Somerset and South Gloucestershire Clinical Commissioning Group and professional memberships.

A study information pack sent will be sent to potential participants and will include an invitation email, an information booklet with a link to an online consensus questionnaire with an embedded consent form. The information leaflet will describe the purpose and aims of the study and will encourage professionals to contact the research team if they have any questions about the study. Those who wish to participate in the study will be asked to complete an online questionnaire with an embedded consent form, which will be administered via Online Surveys (https://www.onlinesurveys.ac.uk). The questionnaire will elicit opinions about the appropriateness of each guideline component, and participants will be asked to rank each component from 1-9 (not appropriate to very appropriate). Participants will also be provided with free text space to explain their ranking and to make suggestions for alterations or additions. This is based on the RAND/UCLA appropriateness method. Descriptive statistics will be used to summarise the results of the questionnaire and free text will be categorised according to content.

Phase 2: Virtual Stakeholder meeting - A summary report and the refined guideline will be sent to the expert panel that completed the questionnaire and they will be invited to a virtual stakeholder meeting, facilitated by the Chief Investigator and members of the research team. Participants will be presented with the material relating to the guidelines, including the summary report of findings from the questionnaires. Participants will then be asked to consider their own views before discussing them with the group. Members will be asked to re-rank each component and any suggested changes (such as the addition of new components) using the Mentimeter (interactive polling survey) app which allows participants to use their smartphones or tablets to answer the questions individually, and anonymously. Following the stakeholder meeting, the results will then be compiled into a short report and fed back to the programme's wider research team and the Programme's PPI group. The wider team and the PPI group will use the information to finalise the guideline.

Outputs
Workstream 1 will provide a co-designed guideline for the orthopaedic management of

prosthetic hip infection: The INFORM Guideline.
Workstream 2: Implementing the INFORM Guideline and developing an implementation support toolkit

Developing the INFORM Guideline is the first step to mobilising the evidence from INFORM into practice, however, evidence-based guidelines do not necessarily translate into consistent change. Recent studies show that strength of evidence underpinning guidelines, dissemination with surgeon education, collaboration and mentorship, and reinforcing feedback are most effective in achieving sustainable change. In Workstream 2 the researchers will therefore form a Learning Collaborative consisting of healthcare professionals from 12 orthopaedic centres, who will implement the INFORM Guideline over 2 waves of 6 months. Learning Collaboratives provide a way to achieve sustainable change within a specific healthcare area, by agreeing on best evidence-based practices and then rapid cycle testing of changes that align to agreed-upon principles and collaboration across centres to share learning.

Centres will be identified either through professional networks or from their involvement in Workstream 1. Surgeons from the centres will then be invited via email and sent an information pack with an online information leaflet and consent form. The information booklet explains the details of the study.

The INFORM Guideline will be implemented over two consecutive waves. In each wave, six centres will implement the guidelines over a 6-month period. During the implementation period, the Learning Collaborative will maintain communication via a closed (private) Whatsapp instant messaging Group. Whatsapp is currently used extensively by surgical teams. Within the Whatsapp Group surgeons can discuss their experience of implementing the guidelines, what changes have been made, challenges encountered and how these might have been overcome. For example, discussing any modifications of the guideline to ‘fit’ with local infrastructure and pathways. The Whatsapp platform provides a record of conversations and discussions much like an online forum. Members of the research team will frequently post on the Whatsapp Group to engage the collaborative and generate regular dynamic feedback on implementation progress, which can be rapidly incorporated into the development cycle.

Members of the INFORM PPI forum have agreed to act as a ‘sounding board’ to surgeons, so that if surgeons want patient feedback from the PPI group the Chief Investigator (Andrew Moore) and the PPI co-ordinator (Catherine Jameson) will act as a conduit taking surgeons’ questions to the group for review at the PPI meetings.

With consent from the Whatsapp Group, the researchers will keep a record of salient sections of the conversations, downloaded from the Whatsapp Group, anonymised by a research team member, and stored in a secure project folder on the secure University of Bristol network drive. PPI members can then review a hard copy of the anonymised content from the Whatsapp discussion at PPI meetings and if appropriate comment on it so that the researchers can then share feedback with the Learning Collaborative by the research team posting on the Whatsapp group.

Membership of the Whatsapp Group will be controlled via the Whatsapp Group Administrator (Andrew Moore). If group member wishes to add someone to the group who is involved in the implementation work the individual who is interested in joining the WhatsApp group will contact the administrator directly with their details and the administrator will then send them an information pack and consent form and add them to the group once they have consented. In this way membership can be monitored.

Expert facilitated meetings
At the end of the first wave of implementation the researchers will conduct a virtual expert facilitated meeting with all members of the learning collaborative via an online platform (Zoom or Teams). With the consent of participants the meeting will be recorded to facilitate review of the discussion, but the recording will not be shared beyond the research team. The meeting will be facilitated by the Chief Investigator and members of the research team. During the meeting members of the learning collaborative will discuss their experiences of implementing the guideline and share learning points with other participants. A patient representative from the INFORM PPI group will also attend the virtual meeting as an expert patient and will be supported by the PPI co-ordinator. Learning points from the meeting will be recorded on a Word document and circulated to the collaborative to inform the second wave of implementation. At the end of the second wave, the researchers will conduct a second expert facilitated meeting in the same format.

Qualitative interviews
During the implementation waves the researchers will conduct semi-structured interviews with up to 36 clinicians (surgeons, microbiologists, physiotherapists, health psychologists, counsellors) and managers responsible for prosthetic hip infection service delivery, to understand the potential drivers and challenges to implementing the INFORM Guideline.

Sample identification and recruitment to interviews
Healthcare professionals (HCPs) who are part of the Learning Collaborative and therefore known to the research team, and who indicated on the initial information leaflet and consent form that they agree to be contacted about an interview will be contacted via email by the Chief Investigator and lead qualitative researcher (Andrew Moore). Other HCPs or managers will be identified by members of the Learning Collaborative within their centre and their contact details will be sent to the Chief Investigator who will send them an invitation e-mail. The invitation email will ask that the HCP/manager contact the researcher within 7 days if they are interested in taking part in an interview. Those interested in taking part will then contact the research team directly by email, or telephone for more information, and to discuss arranging an interview. A single reminder will be sent to those who do not reply within 7 days.

Consent processes
The researchers are offering verbal recorded consent in keeping with the proportionate approach recommended by the HRA for non-CTIMP and low-risk non-interventional studies and to reduce the risk of infection transmission. Following government advice on shielding and physical distancing during the COVID-19 pandemic, all interviews will be conducted virtually. Verbal consent will be affirmed at the beginning of the interview and therefore audio-recorded. Also, at present orthopaedic staff and healthcare professionals in general are under unprecedented time pressures and reducing the burden of documentation by offering verbal recorded consent is likely to reduce any potential errors in the completion and transfer of documents.

Logging of recruitment details
Recruitment will be logged on a secure database kept on a University of Bristol secure server. Individuals will be identified by their unique study ID which will be used in all subsequent study documents (interview transcripts etc). Contact details of all participants in the study will be logged on a password protected database on a secure University of Bristol server.

Data collection
Interviews will be conducted by an experienced qualitative researcher and will take place via telephone or video-calling. Topic areas will include participant experiences of implementing the

guidelines, any changes to practice, and barriers and drivers to implementation and any mitigating factors or solutions employed.

Data analysis
To analyse the data from interviews, the audio-recorded interviews will first be transcribed by a University of Bristol approved transcription company before being anonymised by the researcher. Transcripts will be analysed using rapid content analysis. Analysis of qualitative data will also be supported by the use of an implementation science conceptual framework, the Theoretical Domains Framework (TDF), used to identify and understand the facilitators and barriers to change. This framework has been successfully used to identify the determinants of adoptive behaviour in surgical practice.

Data synthesis and development of implementation support toolkit
Anonymised data from the interviews will be considered along with learning points from the expert meetings and Whatsapp Group discussion, to inform the development and refinement of an implementation support toolkit that will be iteratively developed through this co-design process.

At the end of Workstream 2, the implementation support toolkit will be refined and ready for roll-out to other orthopaedic centres across the UK, via members of professional organisations including the British Hip Society and British Orthopaedic Association.

The implementation support toolkit will be made available as an interactive electronic and downloadable resource hosted via a webpage.

Intervention Type
Other

Primary outcome(s)
Qualitative interviews intend to explore the stakeholders' experience of implementing the guidelines over a 6-month timeframe. Analysis of the qualitative data will be supported by the use of an implementation science conceptual framework, the Theoretical Domains Framework (TDF), used to identify and understand the facilitators and barriers to behaviour change.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Healthcare professionals and managers involved in the management of prosthetic hip infection
2. Has been involved in the implementation of the INFORM Guideline
3. Provides consent to participate

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
17

Key exclusion criteria
Does not provide consent to participate

Date of first enrolment
01/03/2022

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR202943

Results and Publications

Individual participant data (IPD) sharing plan
Once the study has ended, the anonymised interview data will be stored in the University of Bristol Research Data Storage Facility and will be shared via the University of Bristol Research Data Repository. Access to the data will be restricted to ensure that data is only made available to bona fide researchers after a Data Access Agreement has been signed by an institutional signatory.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	Development and implementation of the inform guidelines presented at The British Hip Society (BHS) Meeting 2024, Belfast, Northern Ireland, 28 February – 1 March 2024.	28/02/2024	11/09/2024	No	No
Other publications	Development of the INFORM guidelines	01/04/2023	11/09/2023	Yes	No
Other publications	INFORM guidelines		11/09/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes