RUBICON-Delphi study

Identifying priorities for future research into intra-articular corticosteroid injections for osteoarthritis: a Delphi study

Research protocol

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Host	NHS Bristol, North Somerset and South Gloucestershire CCG (BNSSG CCG)
Funder	National Institute for Health Research (NIHR) Health Technology Assessment
Study Co-ordinating Centre	Musculoskeletal Research Unit Bristol Medical School, University of Bristol Level 2, Learning and Research Building Southmead Hospital, Bristol, BS10 5NB
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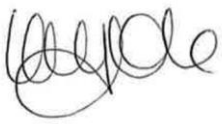
Signatures **Chief Investigator**	

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STUDY DOCUMENTS

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1	Patient invitation letter	1	01-04-2021
2	Patient information booklet	2	21-05-2021
3	Patient Round 1 questionnaire and consent form	2	21-05-2021
4	Professional invitation e-mail	1	01-04-2021
5	Professional information booklet for primary care staff	1	01-04-2021
6	Professional information booklet for secondary care clinicians, commissioners and academics	1	01-04-2021
7	Professional Round 1 questionnaire and consent form	1	01-04-2021
8	Patient cover letter for Round 2 questionnaire	1	01-04-2021
9	Patient Round 2 questionnaire	1	01-04-2021
10	Patient reminder letter for Round 2 questionnaire	1	01-04-2021
11	Professional e-mail for Round 2 questionnaire	1	01-04-2021
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PLAIN ENGLISH SUMMARY

Osteoarthritis is a condition that causes joints to become painful and stiff. Management of osteoarthritis involves reducing pain and maintaining function. Simple treatments include activity modification, staying active to maintain muscle strength and taking pain medication. Complex treatments include joint replacement (replacing the painful joint with an artificial joint), which may be required for those with pain that cannot be well controlled by other means. Before a joint replacement is considered, it is possible to use other techniques, such as injections into the affected joint, to try to reduce pain. These injections are most commonly used for knee osteoarthritis. These injections are known as 'cortisone injections' or 'steroid injections'. The injection usually contains both an anaesthetic to help with the pain and a steroid to reduce the inflammation (swelling, heat and pain) within the joint. It is known that these injections can help with pain if used infrequently and that their use is recommended by a variety of organisations, including the NHS.

We are doing a large programme of work into injections for osteoarthritis. As part of this programme, we are conducting this study to find out what future research is needed about injections for osteoarthritis and the most acceptable way of doing this. To do this, we will involve 100 people including patients, healthcare professionals, commissioners and researchers. Each participant will be sent three questionnaires over a 6-8 month period.

The first questionnaire will ask people to suggest up to five topics for research. These suggestions, along with topics identified from our larger programme of work, will be collected together, refined and used in a second questionnaire.

In the second questionnaire, people will be asked to rate how important they think each research topic identified from the first questionnaire is from 1-9 (Not important to Very important). We will look at all the responses and the research topics with the top average ratings will then be sent to all the participants again in a final questionnaire.

A summary of the average group ratings for each research topic will also be sent to people who will then be given the opportunity to keep their answers the same, or change them, based on the group feedback. Through this method, we will generate a list of questions for

future research into injections for osteoarthritis that are important to patients, healthcare professionals, researchers and commissioners.

BACKGROUND

Osteoarthritis is the most common musculoskeletal condition worldwide and it is a global public health burden [1]. It is an irreversible and progressive disease, which leads to pain, morbidity, functional decline, and loss in quality of life. It is also associated with substantial healthcare system and societal costs [2]. Due to population ageing and an increase in risk factors such as obesity, the prevalence of osteoarthritis is increasing [3]. In the UK, people with osteoarthritis are usually provided with management through primary healthcare services. Management includes core treatment (education and advice, exercise, weight loss, and use of assistive devices) and may include physical therapy (physiotherapy, insoles, or braces) and pharmacotherapy (paracetamol and non-steroidal anti-inflammatory drugs as first line treatment for pain). Some patients proceed to secondary care management in which there are more invasive treatment options, which include joint replacement.

The National Institute for Health and Care Excellence (NICE) Clinical Guideline for osteoarthritis recommends the use of intra-articular corticosteroid injections as an adjunct to core treatments for the relief of moderate-to-severe, uncontrolled pain in people with osteoarthritis [4]. Since the publication of the NICE guidance, further reports on the benefits of intra-articular corticosteroid injections for osteoarthritis management have been published [5-8]. The overall evidence from these further findings suggest a short-term benefit of intra-articular corticosteroids on pain relief and mild or no evidence of adverse effects with intra-articular corticosteroid therapy. However, given that the prevalence of osteoarthritis is expected to rise over the coming years and concerns that intra-articular corticosteroid injections will be used more frequently in patients, robust evidence on the long-term benefits and risks associated with recurrent use of intra-articular corticosteroid injections for osteoarthritis is urgently warranted. There is however limited and inconsistent evidence available [9-11]. Data on the current practice and patterns of use of intra-articular injections after treatment initiation in the UK and globally is also very limited [12, 13].

The RUBICON programme has been funded in response to a commissioned call from the National Institute of Health Research (NIHR) Health Technology Assessment Panel (18/103)

to provide evidence on recurrent intra-articular corticosteroid injections in osteoarthritis. The programme comprises three work packages to generate data on the pattern of use of intra-articular injections for osteoarthritis in primary care. This Work Packages are:

- Work Package 1: Establish current practice of use of intra-articular corticosteroid injections for the treatment of joint pain due to osteoarthritis and the long-term safety and outcomes of the use of recurrent injections for osteoarthritis through analysis of pseudonymised, retrospective, routinely collected data. The data sources (CPRD and HES) do not request Research Ethics Committee approval to access/extract their pseudonymised linked data for research of this nature.

- Work Package 2 (RUBICON qualitative study): Explore views and experiences of patients and clinicians on the use of injections for osteoarthritis using qualitative interviews. Ethics approval was provided by East Midlands - Leicester Central Research Ethics Committee on 20th July 2020 [20/EM/0185] and Health Research Authority approval on 14th August 2020. The IRAS project ID is 281208.

- Work Package 3: Assess priorities and associated feasibility of future primary research about injections for osteoarthritis using a Delphi study (this research study).

AIM

The aim of this project is to use a Delphi study to gain expert consensus on the key questions for future research into intra-articular corticosteroid injections for osteoarthritis and any feasibility considerations with answering these research questions.

METHODS

STUDY DESIGN

The Delphi survey technique was originally developed by the RAND Corporation in the 1950s for technological forecasting. The aim of the methodology was to obtain the most reliable consensus of a group of experts [14]. It is a structured and iterative technique that uses a series of sequential questionnaires completed anonymously by participants with relevant expertise to reach consensus about a particular issue. The Delphi survey technique uses

open-ended questions in Round 1 to elicit information to be used in subsequent rounds. A key feature of the technique is a staged approach which provides participants with the opportunity to review group feedback and revise their own views. The Delphi technique has been used in a range of healthcare areas such as technology assessment, education and training, and developing clinical practice [15]. It has several advantages over other methods of gaining consensus [14, 16]. For example, the influence of group dynamics and peer influence are removed as the participants do not interact with one another and remain anonymous to one another.

PARTICIPANT PANELS

Participants will be sampled to ensure the inclusion of views of a diverse range of different stakeholders. Four panels will be established in this study to ensure that differing views are represented equally in the final analysis [17]. These four panels will be:

- 25 patients with experience of intra-articular corticosteroid injections for osteoarthritis
- 25 healthcare professionals involved in the treatment of patients with osteoarthritis, including GPs (n~15), primary care physiotherapists (n~5), rheumatologists and orthopaedic surgeons (n~5)
- 25 academics who have conducted research and published on treatments or care pathways for patients with osteoarthritis
- 25 commissioners with experience of musculoskeletal services

PATIENTS: ELIGIBILITY, IDENTIFICATION AND RECRUITMENT

Inclusion criteria

- Adults in the South West of England who have received one or more intra-articular corticosteroid injections for osteoarthritis, within a primary care setting, within the last three years

Exclusion criteria

- Any individual who lacks capacity to provide informed consent (including dementia & learning difficulties)
- Any individuals who cannot complete the questionnaires in English

Identification and recruitment

Patients will be identified and recruited through two avenues:

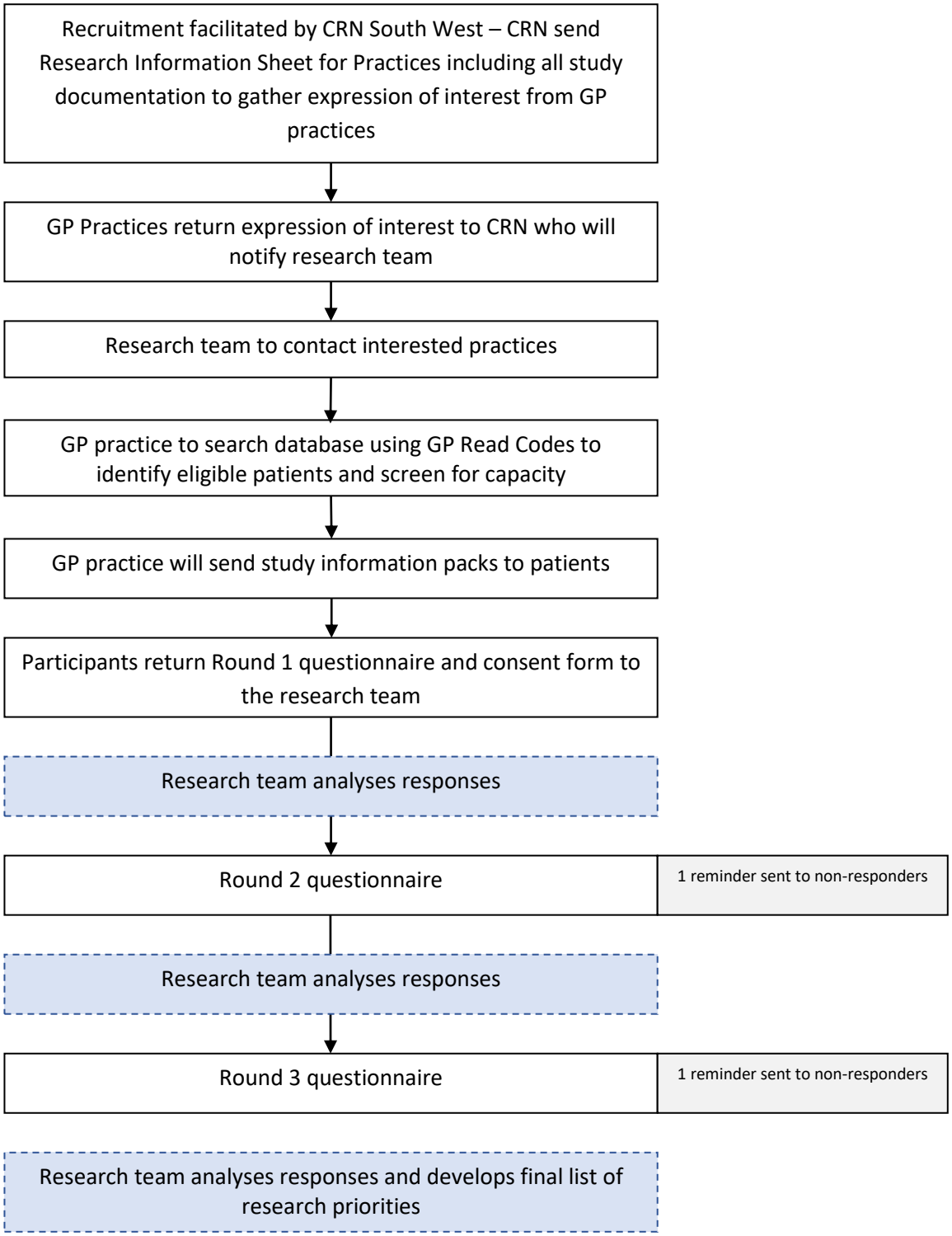
1.) Primary care

Patients will be identified through the NIHR West of England Clinical Research Network (CRN), facilitated by the Bristol North Somerset & South Gloucestershire Clinical Commissioning Group (BNSSG CCG) Research & Evidence Team. The NIHR West of England CRN will be responsible for engaging research active primary care practices in the study and will pass on details of the study via a Research Information Sheet for Practices seeking expressions of interest for the study. Primary care practices interested in taking part will then contact the research team.

Primary care practices will screen patient information and GP Read Codes to identify eligible patients with capacity to consent and will post out information packs about the study. The study information pack will include a letter of invitation [Patient invitation letter], information booklet [Patient information booklet], Round 1 questionnaire with embedded consent form (to minimise the chance of patients returning the questionnaire but not the consent form) [Patient Round 1 questionnaire and consent form] and pre-paid envelope. The information booklet will describe the purpose and aims of the study and provide an explanation of how to participate. The information booklet will also encourage patients to contact the research team if they would like to discuss the study or ask questions. Patients interested in taking part will be asked to return the Round 1 questionnaire with embedded consent form to the research team using the prepaid envelope provided. On receipt of these documents, the consent form will also be countersigned by a researcher. A photocopy of the consent form will be sent to the participant for their records with their Round 2 questionnaire. In the Round 1 questionnaire, patient participants will be offered the option of receiving the Round 2 and 3 questionnaires by post or by e-mail.

Patients' confidentiality will be maintained as patients who are eligible for the study will be identified and sent a study information pack, which includes a consent form and questionnaire, by a member of their own care team - usually a GP research lead, or research nurse at or working with the primary care practice. Patients interested in finding out more about the study will be able to contact the research team directly if they wish. Patients who wish to participate will be asked, in the information pack, to sign the embedded consent from and return it to the research team as part of their Round 1 questionnaire. The

research team will only have details of those who contact them for further information or who provide written consent to study participation. To ascertain response rates, details of the number of individuals invited to the study by each practice will be recorded.


Recruitment facilitated by CRN South West – CRN send Research Information Sheet for Practices including all study documentation to gather expression of interest from GP practices
GP Practices return expression of interest to CRN who will notify research team
Research team to contact interested practices
GP practice to search database using GP Read Codes to identify eligible patients and screen for capacity
GP practice will send study information packs to patients
Participants return Round 1 questionnaire and consent form to the research team
Research team analyses responses
Round 2 questionnaire
1 reminder sent to non-responders
Research team analyses responses
Round 3 questionnaire
1 reminder sent to non-responders
Research team analyses responses and develops final list of research priorities

2.) RUBICON qualitative study

As part of the wider RUBICON programme, a qualitative study is being conducted (IRAS project ID 281208). In that study, patients are recruited and interviewed. All are in the South West of England and received one or more intra-articular corticosteroid injections for osteoarthritis, within a primary care setting, within the last three years. As part of the verbal consent process, which is audiorecorded, patients are asked if they agreed to be contacted about further research conducted by the University of Bristol, relevant to joint pain. Those patients who consent to further contact will be posted paper information packs about this Delphi study. The recruitment process for the Delphi study will then follow the same procedures as described for recruiting patients from primary care.

PROFESSIONALS: ELIGIBILITY, IDENTIFICATION AND RECRUITMENT

Eligibility criteria

Healthcare professionals

Inclusion criteria

- Primary care physicians, physiotherapists, rheumatologists and orthopaedic surgeons who have experience of working with patients who have received intra-articular corticosteroid injections for osteoarthritis

Exclusion criteria

- No experience of working with patients who have received intra-articular corticosteroid injections for osteoarthritis
- Conflicts of interests that may bias their responses to the Delphi survey

Commissioners

Inclusion criteria

- Commissioners with experience of musculoskeletal services

Exclusion criteria

- No experience of commissioning musculoskeletal services
- Conflicts of interests that may bias their responses to the Delphi survey

Academics

Inclusion criteria

- Academics in the UK who have published research in the English language on treatments or care pathways for osteoarthritis

Exclusion criteria

- No relevant research experience
- Conflicts of interests that may bias their responses to the Delphi survey

Identification

Primary care clinicians

Primary care clinicians will be identified and recruited through two avenues:

1.) Primary care

The NIHR CRN West of England will be responsible for engaging research active primary care practices in the study and will pass on details of the study via a Research Information Sheet for Practices seeking expressions of interest for the study. Primary care practices interested in taking part will then contact the research team and study information packs will be provided.

2.) RUBICON qualitative study

As part of the wider RUBICON programme, a qualitative study is being conducted (IRAS project ID 281208). The qualitative study is recruiting and interviewing primary care clinicians in the South West of England who have experience of working with patients who have received intra-articular corticosteroid injections for osteoarthritis. As part of the verbal consent process, which is audiorecorded, primary care clinicians are asked if they agreed to be contacted about further research conducted by the University of Bristol, relevant to joint pain. Those who consent to further contact will be e-mailed information packs about this study.

Commissioners

Commissioners with relevant experience will be identified by the BNSSG CCG Research & Evidence Team and sent a study information pack. The Research & Evidence team has established networks with the CCG, Public Health and Social Care commissioners, and will be able to use internal newsletters, regular meetings and seminars, as well as direct email and/or telephone calls to find commissioners with relevant experience.

Academics and secondary care clinicians

Academics and secondary care clinicians with relevant experience will be identified through the following routes:

1) The research team will conduct searches of published literature and e-mail a copy of the study information to authors of relevant research articles
2) Relevant professional organisations will be contacted e.g. British Hip Society, British Association for Surgery of the Knee, British Orthopaedic Association and organisational gatekeepers will be asked to disseminate study information to members

Recruitment

The study information pack sent to professionals will include an invitation e-mail [Professional invitation e-mail], information booklet [Professional information booklet for primary care staff/Professional information booklet for secondary care clinicians, commissioners and academics], and Round 1 questionnaire with embedded consent form and contact details form [Professional Round 1 questionnaire and consent form]. The information booklet will describe the purpose and aims of the study and provide an explanation of how to participate. The information leaflet will also encourage professionals to contact the research team if they have any questions about the study. To ensure that the professionals recruited into the study are representative of the population approached, the staff member sending the study packs will record anonymised information on profession and geographical location (when available) of all professionals who are emailed a study pack.

Professionals who wish to participate in the study will be asked to complete an online Round 1 questionnaire with embedded consent form, which will be administered via Online Surveys. On receipt of these documents, the consent form will also be countersigned by a researcher. A copy of the countersigned consent form will be e-mailed to participants for their records with their Round 2 questionnaire.

ROUND 1 QUESTIONNAIRE

The Round 1 questionnaire that is included in the study information pack will ask participants to identify up to five research questions and associated feasibility

considerations in relation to intra-articular injections of corticosteroid in osteoarthritis. The questionnaire for professionals and patients will have similar content, but the questionnaire sent to patients will be written in plain English, with input from our PPI group. Participants' contact details and any potential conflicts of interests (professionals only) will also be collected in the Round 1 questionnaire.

Round 1 questionnaire analysis

Responses will be collated, and a list of candidate research questions developed. These will be supplemented by research questions identified from other work packages (qualitative interviews, analysis of national datasets and a systematic review) within the larger RUBICON programme of work and through co-working with our PPI group. Comprehensive literature searches conducted by the research team will ensure that only research questions with a lack of evidence or treatment uncertainty are included in Round 2. Research questions with a lack of evidence or treatment uncertainty will be formulated into population, intervention, comparator, outcome (PICO) format and reviewed by our PPI group prior to being included in the Round 2 questionnaire.

ROUND 2 QUESTIONNAIRE

Participants who complete a Round 1 questionnaire will be invited to participate in Round 2. In Round 2, participants will be sent a covering letter/e-mail [Patient cover letter for Round 2 questionnaire/Professional e-mail for Round 2 questionnaire] and the Round 2 questionnaire [Patient Round 2 questionnaire/Professional Round 2 questionnaire]. The Round 2 questionnaire will contain the research questions generated in Round 1. Participants will be asked to rate the importance of each research question from 1-9 (not important to very important). Free-text boxes will be provided to comment on the associated feasibility considerations. If no response is received within two weeks, participants will be sent a single reminder letter/e-mail [Patient reminder letter for Round 2 questionnaire/ Professional reminder e-mail for Round 2 questionnaire] and another copy of the Round 2 questionnaire.

Round 2 questionnaire analysis

Descriptive statistics will be used to summarise the results of Round 2. Median scores for research question will be calculated. Based on the RAND/UCLA Appropriateness Method [18], research questions with a median scores of 1-3 will be considered as unimportant (good to excellent consensus over lack of importance), research questions with a median score of 4-6 as uncertain (some consensus over importance) and those with a score of 7-9 as important (good to excellent consensus over importance). Those research questions given an importance rating of 7-9 by at ≥70% of participants will be retained and carried forward to Round 3. To ensure that research questions considered exceptionally important by only one panel (patients, healthcare professionals, commissioners or academics) are not omitted, research questions rated as 7–9 by ≥90% of members of one panel, regardless of the ratings of the other panels, will also be carried forward.

ROUND 3 QUESTIONNAIRE

Participants who responded to Round 2 will be invited to participate in Round 3. In this final Round, participants will be sent a sent a covering letter/e-mail [Patient cover letter for Round 3 questionnaire/Professional e-mail for Round 3 questionnaire] and a shortened Round 3 questionnaire [Patient Round 3 questionnaire/Professional Round 3 questionnaire] which includes only those research questions that were rated as most important by participants in Round 2. Paper questionnaires will include the individual participants' rating and the group rating for each research question retained from Round 2. For online questionnaires, individual participants' previous ratings will be included as an e-mail attachment due to the difficulty of embedding this information within the online survey [Summary of Round 2 responses]. Group responses (from all four panels combined) will be summarised as the median scores assigned to each research question. After seeing the responses, participants will be given the opportunity to re-rate the importance of each research question, and they can keep their responses the same or amend them. If no response is received within two weeks, participants will be sent a single reminder letter/e-mail [Patient reminder letter for Round 3 questionnaire/ Professional reminder e-mail for Round 3 questionnaire] and another copy of the Round 3 questionnaire.

Round 3 questionnaire analysis

Those questions given an importance rating of 7–9 by ≥70% of participants, or by ≥90% of members of one panel, will be included in the final research priority list. This list will provide recommendations on the key questions for future research and any feasibility considerations with answering these research questions.

SAMPLE SIZE

The sample size for a Delphi survey does not depend on statistical power, but on group dynamics for obtaining consensus among experts [14]. There is no set guidance available as to how many participants should be included in a Delphi survey exercise [16]. A minimum of 10 participants on a panel has been suggested [14], although some studies have included over 200 participants [16]. Because the results from the four panels will be analysed separately, it is anticipated that approximately 100 people (25 participants per panel) will be required to participate in this Delphi survey exercise to ensure the incorporation of a range of representative views and opinions. It is assumed that approximately 20% of participants will drop out between the rounds of data collection, and therefore complete data will be obtained from 80 participants.

PATIENT AND PUBLIC INVOLVEMENT

To refine the design of the RUBICON Delphi study we have collaborated with our established, dedicated patient public involvement group (The Patient Experience Partnership in Research Musculoskeletal: PEP-R) which comprises members with musculoskeletal conditions and experience of joint injections and joint replacement. The group felt that it would be appropriate for this group to meet regularly during the course of the study to discuss progress and provide input into dissemination strategies. The group will be supported by the Research Unit's experienced Patient and Public Involvement co-ordinator (Amanda Burston). PPI co-applicant, Edith Anderson, has experience of osteoarthritis and joint injections, and is a core member of the Project Management Committee and overall research team, and will attend Project Management Committee meetings with the support of our PPI group coordinator.

The lived experience offered by the PPI co-applicant and PEP-R group members will be central to guiding the presentation and development of our research outputs as well as

informing the focus and acceptability of future research studies in this area. We will continue to collaborate with PEP-R during this study, including co-working to develop study documents, generate research topics, develop the list of research topics for the Round 2 questionnaire, finalise the research priorities after Round 3, and sharing the findings.

FUNDING AND EXTERNAL REVIEW

This project is funded by a grant from the NIHR Health Technology Assessment (NIHR129011) in response to a commissioned funding call. Throughout the design and development of the project the Bristol, North Somerset & South Gloucestershire NHS Clinical Commissioning Group, and the NHS South West Clinical Research Network have also reviewed the study. As such, the scientific and statistical validity have been externally peer-reviewed by representatives from the NIHR where the proposal was scrutinised and found to be of scientific merit to justify funding. An application will be made to have this study adopted onto the NIHR Clinical Research Network Portfolio

INDEMNITY

This study will be sponsored by the University of Bristol. The University has Public Liability Insurance to cover the liability of the University to research participants. In the event that something goes wrong and a participant is harmed during the research study there are no special compensation arrangements. If a participant is harmed and this is due to someone's negligence then they may have grounds for a legal action for compensation against Bristol University or the NHS Trust or one of the other parties to the research, but they may have to pay their own legal costs.

REPORTING OF ADVERSE EVENTS (AES) AND SERIOUS ADVERSE EVENTS (SAES)

All AEs will be recorded in the study file with a note that will identify when the event occurred, the details of the AE, any potential study relation, action taken and resolution /

closure of the AE. An assessment of seriousness will be made by the researcher and serious adverse events (SAEs) will be reported in line with legislation and university guidance.

The University has a Service Level Agreement with UH Bristol to ensure that all SAE reporting is managed by UH Bristol on behalf of the University. For that reason, all SAEs must be recorded and reported to UH Bristol, in accordance with UH Bristol Research Safety Reporting Standard Operating Procedure. UH Bristol will regularly inform the University about SAEs. Expedited reporting takes place where necessary to agree corrective / preventative actions. In addition, all SAEs should be reported to the NHS Research Ethics Committee in the Annual Progress Report.

CONFIDENTIALITY

Data procedures will be in keeping with the stipulations in The General Data Protection Regulation. All data will be anonymised and made identifiable to researchers by the use of allocated study numbers. All documents will be stored securely and only accessible by study staff and authorised personnel. Original paper data collection forms will be maintained in a locked filing cabinet in the Musculoskeletal Research Unit, which is a secure unit with card controlled access. All data held on the computing network will be protected by using a combination of passwords and file permissions. Participants' personal data will be stored on an administrative Access database. The Access database will be on a University of Bristol server and will be protected by a combination of file permissions and passwords. Participants anonymised study data from questionnaires will be stored in a separate Access data.

ARRANGEMENTS FOR STORAGE OF RESEARCH DATA AFTER THE STUDY HAS ENDED

Personal data (e.g. participant contact details) will be stored for 12 months after the study has ended. In line with NIHR guidance which encourages the sharing of anonymised data sets we will be seeking consent from participants for their anonymised data to be shared with other researchers. Anonymised electronic research data (responses to questionnaires)

will be stored indefinitely in keeping with the University of Bristol Research Data Repository policy, which has processes in place for providing access to bone fide researchers. All data procedures will be in keeping with MRC guidelines, the GDPR and Data Protection Act 2018 [http://www.highlights.rsc.mrc.ac.uk/GDPR/keep.html].

DATA SHARING

Anonymised data will be stored on the Bristol Research Data Repository as restricted access and will only be made available to bona fide researchers after their host organisation has signed a Data Access Agreement.

RESEARCH GOVERNANCE

Sponsorship and insurance for this study will be provided by the University of Bristol (sponsorship reference 2019 - 6047). Ethical approval for the study has been provided by Proportionate Review Sub-Committee of the North of Scotland Research Ethics Committee (REC ref. 21/NS/0070).

DISSEMINATION

On completion of data collection and analysis, a final study report will be prepared for the funder. We will also prepare summaries of research to send to all participants. We will submit the research findings for consideration by appropriate peer reviewed journals.

Findings from the research will be presented at a variety of relevant conferences. These may include the Royal College of General Practitioners Annual Conference, the Royal Society of Medicine minor surgery and joint injection courses, the British Society of Rheumatology, the European League against Rheumatism Conference, the British Orthopaedic Association, the British Association for Surgery of the Knee and the British Hip Society. BNSSG CCG Research & Evidence Team will lead our dissemination of results to local and national CCGs. We will work with the 'Patient Experience Partnership in Research' (PEP-R) group to develop

accessible information for dissemination through other appropriate outlets, e.g. press releases, web-based resources.

GANTT CHART

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	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22
Recruitment and Round 1														
Round 2														
Round 3														
Dissemination														

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