Aims
The extended wait that most patients are now experiencing for hip and knee arthroplasty has raised questions about whether reliance on waiting time as the primary driver for prioritization is ethical, and if other additional factors should be included in determining surgical priority. Our Prioritization of THose aWaiting hip and knee ArthroplastY (PATHWAY) project will explore which perioperative factors are important to consider when prioritizing those on the waiting list for hip and knee arthroplasty, and how these factors should be weighted. The final product will include a weighted benefit score that can be used to aid in surgical prioritization for those awaiting elective primary hip and knee arthroplasty.

Methods
There will be two linked work packages focusing on opinion from key stakeholders (patients and surgeons). First, an online modified Delphi process to determine a consensus set of factors that should be involved in patient prioritization. This will be performed using standard Delphi methodology consisting of multiple rounds where following initial individual rating there is feedback, discussion, and further recommendations undertaken towards eventual consensus. The second stage will then consist of a Discrete Choice Experiment (DCE) to allow for priority setting of the factors derived from the Delphi through elicitation of weighted benefit scores. The DCE consists of several choice tasks designed to elicit stakeholder preference regarding included attributes (factors).

Results
The study is co-funded by the University of Aberdeen Knowledge Exchange Commission (Ref CF10693-29) and a Chief Scientist Office (CSO) Scotland Clinical Research Fellowship which runs from 08/2021 to 08/2024 (Grant ref: CAF/21/06). Approval from the University of Aberdeen Institute of Applied Health Sciences School Ethics Review Board was granted 22/03/2022 - Reference number SERB/2021/12/2210.

Conclusion
The PATHWAY project provides the first attempt to use patient and surgeon opinions to develop a unified approach to prioritization for those awaiting hip and knee arthroplasty. Development of such a tool will provide more equitable access to arthroplasty services, as well as providing a framework for developing similar approaches in other areas of healthcare delivery.

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the UK nearly six million patients are waiting for non-urgent hospital treatment, with trauma and orthopaedics providing the largest share of these patients. While attempts are being made to improve access to surgery, the unfortunate reality is that it will likely take several years to return the waiting list to pre-COVID-19 levels. Over 8% of patients on elective trauma and orthopaedic waiting lists have currently waited over a year for treatment, with this number expected to rise exponentially as referrals continue to outstrip surgical availability.

Unfortunately, waiting for routine surgery is not a benign process, particularly for those awaiting hip and knee arthroplasty. There is robust evidence to suggest that waiting for arthroplasty surgery has a significant detrimental impact on health and wellbeing, with up to a third considered to be in a health state “worse than death”. Prolonged waiting has also been shown to limit the potential health gains from surgery in some cases. Emerging evidence has already shown some of the negative effects associated with prolonged waits for surgery associated with the COVID-19 pandemic.

Historically, the main determinant of surgical priority was the date that patients were added to the waiting list. Given the extended wait that most patients are now likely to expect, this has raised questions about whether this is ethical, and how best to determine surgical priority. Recently, the use of other options, such as patient-reported outcome measures (PROMs) for orthopaedics & Trauma (surgeons). Three rounds will be conducted over a two- to three-week period, with reminders sent out centrally to encourage participation. There will be no financial incentive or reimbursement for participant involvement.

The Delphi process involves an initial round of idea generation (to ensure all potential prioritization factors are captured). In this round, participants will provide free text information regarding variables potentially included for prioritization, comments/reasoning for their choice, and a confidence rating. Each participant will be limited to ten total responses to allow for feasible processing.

A second round will then be performed, whereby participants anonymously rate and comment on potential recommendations. This is done with nine-point Likert scales consistent with a typical Delphi process. Individuals can rate both the importance and acceptability of potential recommendations, as well as detail the rationale behind their choices.

Feedback and further recommendations are then undertaken through a further round towards eventual consensus of factors that should be included in decision-making regarding prioritization for surgery. A final consensus meeting will then be held, the primary aim of which is to determine consensus for items where none has been identified during the Delphi process.

Work package two (WP2): Discrete Choice Experiment

The second stage will then consist of a DCE to allow for priority setting of the factors derived from the Delphi through elicitation of weighted benefit scores. The DCE
consists of several choice tasks designed to elicit stakeholder preference regarding included attributes (factors). Respondents are presented with several scenarios, with hypothetical patients that vary with respect to a set of factors/attributes identified from the Delphi. Making several choices enables the researcher to elicit weighted benefit scores that have previously been successfully used in healthcare priority setting to inform clinical services developments.18,19 This is, however, to the authors’ knowledge, the first application within the domain of priority setting for patients. The exact number of attributes and levels to be included will be based on the outcomes of the Delphi process.

Following determination of the attributes and levels the choice, sets will be developed using a D-efficient design (which aims to minimize the standard errors of the preference parameters, thus increasing precision).20 This task will be performed using the “idefix” package in R statistics (R Foundation for Statistical Computing, Austria).

The DCE survey with selected choice sets will then be designed and piloted to ensure that the task and questions can be sufficiently understood by the target population (patients and surgeons), as well as confirming that the number of choice tasks and alternatives can be managed by the target population.21

The final questionnaire will then be distributed to be taken in a self-administered format by participants.

Recruitment. Invited patients will include UK-based individuals with end-stage osteoarthritis of the hip or knee who are awaiting joint arthroplasty or have undergone hip and/or knee arthroplasty within the last two years. Exclusion criteria for patients will include individuals awaiting arthroplasty at other anatomical sites, and patients who are not currently on the waiting list for hip and/or knee arthroplasty or have not had a hip or knee arthroplasty within the last two years. Patients will be recruited through dissemination of relevant information and an invitation to participate delivered by Versus Arthritis, including national and local events, email distribution lists, and social media. Patients will not be recruited directly through the NHS.

Invited surgeons will include UK-based Consultant trauma and orthopaedic surgeons currently practicing hip and/or knee arthroplasty surgery (either within NHS practice or privately). Exclusion criteria for surgeons will consist of orthopaedic surgeons not routinely performing hip and/or knee arthroplasty, and those not based within the UK. Orthopaedic surgeons will be recruited primarily through dissemination of relevant information and an invitation to participate delivered by relevant orthopaedic societies.

A self-screening checklist will be performed at the start of the study using the information contained within the inclusion and exclusion criteria.

Sample size. For the Delphi study, we plan to recruit 60 to 100 participants (30 to 50 patients and surgeons, respectively). Previous work has identified that typically a panel requires more than 20 to 30 participants for engaging online discussion, and that participation rates are often 50 to 60% over the three rounds.22

Formal sample size calculation for the DCE is difficult due to a lack of necessary variables (attributes and levels), and that will primarily be informed by the results of the Delphi study. We use the framework suggested by Orme et al23 for a sample size calculation \( n = 500 \frac{c}{(ta)} \). Here \( n \) is the sample size; \( c \) is the largest number of levels for any one attribute for main effects or largest product of levels of any two attributes if considering all two-way interactions; \( t \) is the number of choice tasks; and \( a \) the number of alternatives per task. Assuming five included attributes, with a maximum of five levels, and using 12 choice sets with three alternatives would require a sample size of 69 participants; seven attributes with a maximum of five levels and a slight increase in the number of choice tasks to 16 and the alternatives to five would require a sample size of 32 participants. It is therefore anticipated that the number of individuals involved in the DCE will be similar to WP1, with a minimum of 60 to 100 participating.

Individual patients and surgeons will be able to participate in both work packages. Automated reminders will be sent to participants in the study to ensure optimum completion of all aspects of both the Delphi and DCE.

Data processing. Initial data collection will be performed using the Clinvivo platform (Clinvivo, UK) which will be used to run both the Delphi and DCE components of the study. Clinvivo uses servers operated by 1&1 IONOS. These are stored within a secure data centre in Germany that is ISO 27001:2013 certified. Data encryption is performed using a combination of SSL, public key cryptography, and an AES-256 algorithm.

Initial registration will be performed by participants that will generate a unique identifier against which data will be stored. Basic information, such as participant email address, age, sex, ethnicity, and which stakeholder group they belong to, will be collected. Responses to questions included as part of the Delphi and DCE components will also be stored.

Pseudonymized participant information and responses will then be securely transferred to the research team running the study to allow for analysis. This data will be held on password-protected secured cloud storage within the University of Aberdeen. Data transfer will take place at the end of each Delphi round and the end of the DCE. At the end of the research project, the data will be held by
the research team for five years and then deleted securely in line with standard University of Aberdeen procedures. Data will be deleted from the Clinivivo system once it has been confirmed that it has been successfully received by the clinical research fellow.

### Analysis
For the first round of the Delphi study, direct-ed content analysis of this qualitative data will be performed, and results disseminated to individuals (including summary strength of confidence ratings, where multiple individuals have suggested similar parameters).

A nine-point Likert scale, where one is low importance and nine is high importance, will be then used for second and third rounds consistent with a typical Delphi process. The scoring system will be annotated to illustrate a score of one to three as “limited importance”, four to six “important but not critical”, and seven to nine as “critical”. After each round of the Delphi, the results will be analyzed and fed back as an online written summary to participants to review their individual grading as detailed in the WP1 section. Feedback will include individual and overall group response summaries, including point estimates of central tendency and spread. Both visual and written information will be used. After the three proposed rounds, each prioritization factor will be classified as either consensus in, consensus out, or no consensus based on the following established criteria:

- **Consensus in:** ≥ 70% scoring 7 to 9, and < 15% scoring 1 to 3.
- **Consensus out:** ≥ 70% scoring 1 to 3, and < 15% scoring 7 to 9.
- **No consensus:** Any other score combinations.

In the event of no distinctions formed between these groups, then this grading may be altered at the discretion of the study steering committee and who will be blinded to the identity of the prioritization factors.

A final online consensus meeting will then be held between a small group of up to 10 key stakeholders (including patients and surgeons) to determine agreement on the final list of core prioritization factors to be taken forwards to the DCE.

Responses from the DCE will be analyzed using multinomial logit (MNL) regression techniques. This will be used to estimate the weighted utility/benefit scores. In the MNL framework, this can be specified as:

\[
V_{njt} = \sum_{k}^{\beta_k} X_{kjt}
\]  

(1)

Where \( n, j, t, \) and \( k \) are subscripts respectively for the respondents (\( n = 1, \ldots, N \)), the patient profiles /alternatives (\( j = 1, \ldots, J \)), the choice tasks (\( t = 1, \ldots, T \)), and the attributes/factors (\( k = 1, \ldots, K \)). \( V \) is the weighted benefit score, described as a linear combination of both respondent’s preferences/weights (\( \beta_k \)) and attributes’ levels (\( X_{kjt} \)).

The negative of the ratio of any two preference parameters, \(-[\beta_1/ \beta_2] \) shows how much of one attribute an individual is willing to give up to have more of another attribute; the attribute that value is estimated in terms of the denominator in the ratio (and must be continuous). We will include waiting time as an attribute, and thus estimate how much longer an individual should wait for different levels of clinical need, as well as a total acceptable waiting time for defined clinical conditions.

For both WP1 and WP2 there are no plans to provide inter-study feedback based on group identification (patient vs surgeon) due the perceived potential to disharmonize the study process and the increased sample size required for this process that was felt to be out with the scope of this current proposal.

### Ethical approval and conduct
Consent will be implicit by completion and return of the Delphi questionnaire, with confirmation performed through a checkbox at the start of the questionnaire process. The questionnaire will also include questions that relate to a willingness to participate in future activities, in particular the final Delphi consensus meeting and the subsequent DCE.

Participation in both the Delphi and DCE will be anonymous; participants will not be able to identify others or individual responses.

There is no set duration for deliberation of participation. Individuals will be required to enrol prior to the study start, and it is anticipated there will be a one-month period from the start of the recruitment drive until the first part of the study process begins.

The chief investigator (CI) and research team involved with this project will comply with the requirements of the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. The Health Research Authority (HRA) recommended wording to fulfil transparency requirements under the GDPR for health and care research has been included in the participant information sheets (PIS).

The CI and study staff will also adhere, if appropriate, to the current version of the NHS Scotland Code of Practice on Protecting Patient Confidentiality. Access to collated participant data will be restricted to the CI and appropriate study staff.

Computers used to collate the data will have limited access measures via usernames and passwords. Published results will not contain any personal data that could allow identification of individual participants.

Ethical approval for the study has been granted by the University of Aberdeen Institute of Applied Health Sciences School Ethics Review Board on 22 March 2022 (reference number SERB/2021/12/2210).
**Results**

The study is co-funded by the University of Aberdeen Knowledge Exchange Commission (REF CF10693-29) and a Chief Scientist Office (CSO) Scotland Clinical Research Fellowship which will run from 08/2021 to 08/2024 (grant ref CAF/21/06).

The proposed start of data collection for WP1 is June 2022, and for WP2 December 2022. The results are expected to be published towards the end of 2023. International Standard Registered Clinical/soCial sStudy Number (ISRCTN) registration is currently underway. Conduct and reporting of the study will be in-line with the Standards for Reporting Qualitative Research (SRQR) guidelines.

**Discussion**

**Principal findings.** We anticipate that the PATHWAY project will provide new insights into what key stakeholders feel about factors that should influence surgical prioritization for those awaiting hip and knee arthroplasty. This will potentially allow for development of a new surgical prioritization tool that can be used to ensure equitable access to surgery.

**Comparisons to prior work.** This will be the first evidenced-based qualitative approach to determining surgical priority in hip and knee arthroplasty, including involvement of key stakeholders. Our proposed methodology of a preference-based tool is also novel and provides a clear defined framework for development of a robust priority system. Previous surgical priority tools, such as the FSSA “Clinical Guide to Surgical Prioritization During the COVID-19 Pandemic” and “Recovery Prioritization Matrix”, have been designed without strong patient involvement, and therefore are unlikely to accurately reflect their opinions. There is also a significant lack of transparency in their development.

Specialist societies, such as the British Hip Society have also attempted to provide further clarification of the surgical prioritization of orthopaedic patients with problems around the hip through the use of small Delphi study of expert members, but again the system lacks discriminative ability when considering patients with end-stage osteoarthritis of the hip awaiting total hip arthroplasties (which forms the vast majority of patients) and did not consider patient preference.

**Strengths and weaknesses.** Strengths of this study include the novel use of a combined Delphi and DCE approach to assess what should be contained within a clinical prioritization system. This includes key stakeholder representation to ensure that the developed prioritization factors are an accurate reflection of what should be included according to those who will be affected by the decisions made regarding prioritization in hip and knee arthroplasty.

Weaknesses include the potential for poor recruitment or sampling misrepresentation in those who have responded to be included in the survey. Any developed prioritization may also be subject to manipulation by users.

**Future directions.** The PATHWAY project provides a potential future framework for a transparent evidence-based approach to the development of clinical prioritization systems, within not only other aspects of trauma and orthopaedics, but other medical specialities as well.

Once constructed a planned pilot assessment of the finalized PATHWAY prioritization tool will take place in order to test its efficacy and acceptability when utilized in clinical practice.

**Take home message**

- This study sets out the protocol for a project designed to help provide a potential future framework for prioritisation of patients on the waiting list for hip and knee arthroplasty.
- This project provides a novel methodology (including involvement of key stakeholders) that, if successful, will also provide a blueprint for similar work in other orthopaedic domains.

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