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Can we develop consensus on long-term follow-up and surveillance of primary shoulder arthroplasty? A study protocol using a real-time Delphi technique among expert clinicians in the UK

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ABSTRACT

Background Shoulder arthroplasty incidence is projected to continue its exponential growth and the resultant burden of monitoring patients with shoulder arthroplasty implants creates significant pressure on orthopaedic services. Surveillance offers the opportunity to study implant longevity, detect failing implants and potentially perform revision at lower morbidity and cost. There is a paucity of evidence to support recommendations on long-term follow-up in shoulder arthroplasty. Prospective studies comparing long-term follow-up and structure are impractical from time, resource and cost perspectives. A real-time Delphi technique represents a mechanism by which experts involved in long-term follow-up of primary shoulder arthroplasty can formulate recommendations via a transparent, reproducible and efficient process. We outline the protocol for a real-time Delphi study seeking consensus on long-term follow-up and surveillance of primary shoulder arthroplasty .

Methods A real-time Delphi technique will be used. A planning committee will design the Delphi statements. A steering committee will supervise and monitor the real-time Delphi process. Participants will be asked to rate their agreement with statements using a 5-point Likert scale. The Delphi statements will be derived from review of published literature, and the strength of evidence available for each statement will be provided. We will offer participation to all surgeons and extended-scope practitioners who are current members of the British Elbow & Shoulder Society (BESS) and have clinical practice involving shoulder arthroplasty follow-up. The questionnaire will be active for 4 weeks and requires a minimum of 20 participants. Consensus agreement is defined as 70% of participants selecting at least a 4-point on a 5-point Likert scale.

Discussion We anticipate the outlined study will achieve consensus on long-term follow-up and surveillance of primary shoulder arthroplasty. We intend to use the expert consensus recommendations achieved, in addition to the limited applicable published evidence available, to produce BESS-affiliated guidelines on long-term follow-up and surveillance of primary shoulder arthroplasty.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study offers an opportunity to obtain consensus expert opinion on long-term follow-up of primary shoulder arthroplasty.
⇒ A real-time Delphi study is highly efficient as it involves a single questionnaire.
⇒ The study aims to address a 'hole in research around shoulder arthroplasty surveillance'.
⇒ The study only relates to elective primary shoulder arthroplasty in a 'typical' patient who does not have a specific risk factor for premature implant failure.
⇒ Although clinicians currently using a wide spectrum of follow-up protocols will be offered the opportunity to participate, we cannot ensure all clinicians will accept our invitation.

Ethics
Ethical approval is not required for the real-time Delphi study.

We expect the results of this initiative will be published in a peer-reviewed, high-impact journal.

BACKGROUND

Shoulder arthroplasty incidence is projected to continue its exponential growth in the USA, far outpacing that of total hip and knee arthroplasty.[1] Significant increases have also been observed in the UK, as evidenced in the National Joint Registry Annual Reports.[2] The resultant increasing burden of monitoring patients with shoulder arthroplasty implants creates significant pressure on orthopaedic services.

Surveillance offers the opportunity to study implant longevity, detect failing implants and potentially perform revision at lower

morbidity and cost. It is also a mechanism to collect outcome data and educate patients. Finite outpatient capacity has resulted in the abandonment of long-term follow-up or adoption of alternative models of shoulder arthroplasty surveillance, including the use of extended-scope practitioners and remote monitoring, without evidence to support a change in practice. A scoping review has identified a paucity of applicable evidence to support robust recommendations on optimum long-term follow-up or structure in shoulder arthroplasty.[3]

Prospective studies comparing long-term follow-up and structure could be undertaken to compare the efficacy of different monitoring techniques for the detection of failing implants. However, analysis of a single shoulder unit prospective database of 1002 primary shoulder arthroplasty and 4019 resultant long-term follow-up appointments found that only 0.5% of the appointments identified a failing implant requiring revision.[4] Therefore, a comparative prospective study would require a very large sample size and a long duration of follow-up, rendering it impractical from time, resource and cost perspectives.

A consensus-based approach using a Delphi technique represents a mechanism by which experts involved in long-term follow-up and surveillance of primary shoulder arthroplasty can formulate expert recommendations via a transparent and reproducible process. A real-time Delphi technique allows utilisation of a single questionnaire that experts can review and comment on across a set time period with continuous aggregated results available. This highly efficient technique allows participants to interact with others' responses and revise their own.

We anticipate that the consensus recommendations achieved, and the limited applicable literature available, will be used to produce guidelines on long-term follow-up and surveillance of primary shoulder arthroplasty.

Aims

The aim of the study is to obtain a consensus view from experts in the management of shoulder arthroplasty as to the optimum long-term follow-up surveillance protocol in primary shoulder arthroplasty.

Primary aims

- To develop consensus on the requirement for long-term follow-up of primary shoulder arthroplasty of differing types (anatomical total shoulder arthroplasty (aTSA), reverse total shoulder arthroplasty (rTSA) and hemiarthroplasty (HA)).
- To develop consensus on the requirement for long-term follow-up of primary shoulder arthroplasty of differing Orthopaedic Data Evaluation Panel (ODEP) rating.

Secondary aims

If consensus agreement is obtained that long-term follow-up of primary shoulder arthroplasty is required:

- To agree on the time points a patient should receive follow-up subsequent to a satisfactory 1-year postoperative review.
- To achieve consensus agreement on what components of a surveillance appointment are essential: clinical examination, radiographic assessment or completion of a patient-reported outcome measure (PROM).
- To develop consensus on acceptable modalities of surveillance, including utilisation of extended-scope practitioners and remote consultation.

If consensus agreement is obtained that long-term follow-up of primary shoulder arthroplasty is not required:

- To develop consensus on the requirement for open access for primary shoulder arthroplasty patients to their treating institution beyond surveillance discharge.

Limits of scope

This study will not consider less than 1-year postoperative follow-up and surveillance of primary shoulder arthroplasty as we consider this short-term and Delphi consensus recommendations have been published pertaining to short-term radiographic follow-up of shoulder arthroplasty.[5] Furthermore, it will not consider follow-up of revision shoulder arthroplasty or primary shoulder arthroplasty performed for trauma, infection or malignancy due to increased complexity and variability in these cases, which may warrant more frequent surveillance.

Implant longevity and therefore requirement for long-term follow-up may be influenced by patient factors including age, comorbidities and usage. Such factors are numerous and predominantly of uncertain impact on shoulder arthroplasty failure. It is not appropriate to include all patient factors within Delphi statements, and so pragmatically we have determined that all included statements will relate to a 'typical' patient who does not have a specific risk factor for premature implant failure. Consequently, any resultant recommendations formed from this consensus study will only be applicable to a 'typical' patient.

Development of study aims and real-time Delphi questionnaire

The consensus study aims represent an attempt to address the current 'paucity of evidence related to long-term follow-up and monitoring of shoulder arthroplasty'.[3] A scoping review has identified a 'need for high quality data to inform the development of evidence-based care pathways',[3] and while a published consensus study recommends radiographic assessment of shoulder arthroplasty 12 months following surgery,[5] there are currently no consensus recommendations on primary shoulder arthroplasty follow-up beyond 1 year postimplantation.

A national survey of UK specialists was performed and subsequently discussed at the 'Improving Outcomes of the Shoulder and Elbow Meeting 2021' in partnership with Orthopaedic Research UK and the British Elbow & Shoulder Society (BESS). The survey was designed to determine current arthroplasty surveillance practice in

the UK and subsequently highlighted significant variation in primary shoulder arthroplasty follow-up format and schedules, ranging from annual surveillance of all arthroplasties to only patient-initiated review if adverse symptoms arose. No recommendations related to our study objectives could be achieved. Consequently, our real-time Delphi questionnaire will aim to address this lack of consensus.

The aim to achieve consensus on ODEP rating impact on long-term implant surveillance requirement has been prompted by the UK SAFE (poSt Arthroplasty Follow-up rEcommendations) recommendation that 'for ODEP 10A* minimum implants, it is safe to disinvest in routine follow-up from one to ten years post-non-complex hip and knee arthroplasty, provided there is rapid access to orthopaedic review' with 'clinical and radiological evaluation at 10-years post-arthroplasty'.[6] However, shoulder arthroplasty implant systems have yet to be awarded a 10A* rating, and currently only four manufacturer systems (DePuy Synthes, Lima Corporate, Stryker, Zimmer Biomet) have components that have attained a 10A rating and one manufacturer system (Mathys) has components that have attained a 7A* rating. Consequently, we will determine if consensus can be reached on long-term follow-up of primary shoulder arthroplasty implants of particular ODEP ratings.

Following the precedent of the UK SAFE recommendations, all included statements will relate to a 'non-complex' elective primary shoulder arthroplasty that underwent satisfactory clinical and radiological assessment 1 year postoperatively, with anatomical arthroplasty performed in arthritic shoulders with intact rotator cuff and a reverse prosthesis used in rotator cuff-deficient shoulders or rotator cuff-competent arthritic shoulders when deemed preferable by the treating surgeon. 'Non-complex' defines an arthroplasty in which 'off the shelf' implants were used and there were no intraoperative complications that may impact implant longevity.

In view of the UK SAFE recommendations, we will also gather consensus opinion on whether a 10-year postarthroplasty review is required for each arthroplasty type, and if so whether any intervening monitoring is required.

Consensus guidelines have been produced in collaboration between the BESS, the British Orthopaedic Association and the National Health Service Getting It Right First Time in radiographic surveillance of elbow arthroplasty,[7] where it is recommended that annual surveillance is performed, including a radiograph and PROM. Consequently, we will also gather consensus opinion on whether annual surveillance is required for each arthroplasty type.

METHODS

This study has been approved by the BESS Research Committee review board. Our study methodology comprises a real-time Delphi technique using Surveylet from Calibrum.com, a commercially available real-time Delphi software solution. In contrast to a classic Delphi technique, where participants judge in discrete rounds, a real-time Delphi provides participants with access to an online questionnaire portal for a set time period. Participants can view anonymised responses from other contributors and adjust responses. Furthermore, response simultaneous calculation and feedback facilitates cognitive examination and opportunity for opinions to alter. As research suggests significant differences between two Delphi survey formats do not exist and final survey results are not affected by changes in the survey procedure,[8] the highly efficient real-time Delphi technique is preferred for our study.

Alternative methods of formulating consensus, such as a focus group, are impractical due to the costs of meeting in person. A Delphi technique also ensures participant anonymity to avoid an individual dominating discussion.

Planning committee and steering committee

A planning committee, comprising three consultant shoulder and elbow surgeons, an upper limb fellow and an upper limb consultant physiotherapist, will oversee the study design. Research methods were established in face-to-face and virtual meetings. Agreement was reached regarding participant selection, consensus thresholds, survey format and timeline, and question structure.

A steering committee, comprising a consultant shoulder and elbow surgeon and an upper limb fellow from the planning committee, will supervise and monitor the real-time Delphi process. The steering committee will not participate in the study; however, the remaining members of the planning committee will be invited to.

The planning committee will assess the questionnaire for readability and clarity and pilot the software prior to enrolment of study participants.

Structure of Delphi statements

Participants will be asked to rate their agreement with statements using a 5-point Likert scale (1 strongly disagree, 5 strongly agree) and whether the statement should be modified to improve its relevance (yes/no). If a modification is suggested by a participant, that same participant can then provide an example of how the statement should be revised. The statement revision is then voted on by other participants to determine if it should replace the original statement. The Delphi statements will be derived from our review of published literature, and the strength of evidence available for each statement will be provided. 68 statements will be included and are listed in the online supplemental material.

Selection of stakeholder groups and nominated participants

While both patients and clinicians are important stakeholders in long-term follow-up and surveillance of primary shoulder arthroplasty, we feel it is inappropriate to include patients within the study due to the complexities of differing shoulder arthroplasty modes of failure and the ODEP rating system. However, we intend to invite all clinician groups involved in long-term monitoring and

surveillance of primary shoulder arthroplasty, including surgeons and extended-scope specialist physiotherapists and nurses. Consensus recommendations from this study will be presented to a patient focus group.

We intend to invite all surgeons and extended-scope practitioners who are current members of the BESS and have opted to receive surveys related to shoulder surgery. Members will be instructed to participate only if their clinical practice involves primary shoulder arthroplasty follow-up. We anticipate participants mainly from the UK; however, the BESS does have members from a variety of other countries. BESS membership includes clinicians employed in centres throughout the UK and, as evidenced at the Improving Outcomes of the Shoulder and Elbow Meeting 2021, there is a currently significant variation in primary shoulder arthroplasty follow-up protocols across these centres. Our invitation strategy will ensure that clinicians currently using a wide spectrum of follow-up protocols are offered the opportunity to participate in the real-time Delphi. However, we cannot ensure all clinicians will accept our invitation, and this represents a limitation of this study.

All potential participants will receive an email via the BESS with an invitation to participate if they have suitable clinical practice. Participants will be asked to commit to participate in the real-time Delphi throughout the 4-week time period the questionnaire is active. We anticipate the real-time Delphi will commence on 1 February 2024.

Participants will be provided with a clear explanation of the real-time Delphi process, the use of online software and the importance of returning to the questionnaire at regular intervals due to the asynchronous nature of participant responses and the opportunity to view aggregated responses from other participants.

Invitation and reminders to Delphi panel participants

Informed consent will be obtained from all participants. Once participants have enrolled for the real-time Delphi, they will receive subsequent email correspondence via the real-time Delphi software. Participants will be contacted 1 week prior to, 1 day prior to and on the day of commencement of the questionnaire's 4-week opening. Participants will then receive further email reminders after 1, 2 and 3 weeks of the questionnaire being active.

Patient and public involvement

We intend to present the consensus recommendations from this study to a patient focus group to ensure their role as a stakeholder is respected. This group will include patients who have undergone or are scheduled to undergo primary shoulder arthroplasty. Resultant feedback will influence incorporation of consensus recommendations into evidence-based guidelines. Feedback will also be sought on the preferred method by which resultant change in follow-up practice should be disseminated to patients. Ethical approval is not required for the real-time Delphi study; however, it will be required to undertake a patient focus group.

Sample size

There is no agreement or criteria on a minimum sample size for classic, modified or real-time Delphi panels,[9] but it is accepted that more participants will increase the reliability of group judgements.[10] A minimum number of 20 participants will be set with no upper limit.

Anonymity

Participants will remain anonymous to each other but not to the steering committee as per standard Delphi technique. Participants will be offered the choice to remain anonymous or receive acknowledgement in the publication for their participation.

Defining and achieving final consensus and timeline

For the purpose of this study, consensus agreement is defined as 70% of the participants selecting at least a 4-point on a 5-point Likert scale as per previous Delphi studies related to shoulder surgery.[11 12] Statements for which less than 70% of the participants select at least a 4-point on a 5-point Likert scale will be defined as lacking consensus agreement.

DISCUSSION

A National Institute for Health and Care Excellence (NICE) evidence review for long-term follow-up and monitoring of primary hip, knee and shoulder arthroplasty identified 'a hole in research around shoulder arthroplasty surveillance' and made a research recommendation.[13] It reported insufficient evidence to guide surveillance timing, format or whether radiographs were required.

A subsequent scoping review published in 2023, in association with the BESS, confirmed the NICE findings. Only level 4 evidence was identified and the review was unable to answer whether follow-up of shoulder arthroplasty beyond 1 year identifies asymptomatic failure, whether identification of asymptomatic failure permits a revision that leads to lower patient morbidity and cost, or what format of surveillance (time scale, mechanism and delivered by whom) best identifies a failing implant.[3]

Although NICE suggests a pragmatic, multicentre, randomised controlled clinical trial (RCT) comparing a surveillance regime and no routine follow-up with a healthcare professional following the standard 6 postoperative weeks of follow-up appointment[13] could provide the high-quality data required to inform the development of evidence-based guidelines, a study of prospectively collected primary shoulder arthroplasty surveillance data raises doubts as to the practicality of such an endeavour.

Morris et al's study identified that only 0.5% of long-term follow-up appointments identified a failing primary shoulder arthroplasty that required revision: 0.1% in rTSA, 0.5% in aTSA and 1.2% in HA.[4] Consequently, an impractical study duration and sample size would be necessary to produce an RCT of sufficient power to detect a significant difference. However, it should be acknowledged that

this study was performed using data from a high-volume shoulder unit in which a minimum of 7A ODEP implants were used and arthroplasties performed for trauma, infection and malignancy were excluded.

Seeking expert consensus offers an alternative method by which to produce recommendations that could contribute to guidelines. However, focus group discussion and anonymised voting were unable to achieve consensus opinion on long-term follow-up and surveillance of primary shoulder arthroplasty at the Improving Outcomes of the Shoulder and Elbow Meeting 2021. We anticipate that the real-time Delphi methodology will increase the likelihood of consensus being achieved as participants will be able to review responses and comments of other participants and, if their opinion is altered by this review, amend their own response. The Delphi method facilitates convergence of opinion and is therefore a valuable technique for reaching consensus when empirical evidence is scarce or contentious.[14]

The Delphi technique has successfully achieved expert consensus in shoulder arthroplasty previously. A Delphi consensus process reached international consensus for radiographic assessment of asymptomatic patients after shoulder arthroplasty in the first postoperative year.[5] The process comprised a classic Delphi technique involving three discrete rounds and included 98 surgeons from Europe, North America, Chile, Brazil, Israel and Australia. Consensus was achieved that radiographic assessment of a shoulder arthroplasty should be performed within 6 weeks of implantation and then 3–6 months and 12 months following surgery.

Consequently, we anticipate that a Delphi process using this outlined protocol will be able to achieve consensus on our primary and secondary aims related to long-term follow-up and surveillance of primary shoulder arthroplasty.

Dissemination plan

We expect the results of this initiative will be published in a peer-reviewed, high-impact journal, which will lend credibility to the resulting consensus recommendations. The findings will also be disseminated to national and international audiences via presentations at relevant research meetings.

Application

We intend to use the expert consensus recommendations achieved, in addition to the limited applicable published evidence available, to produce BESS-affiliated guidelines on long-term follow-up and surveillance of primary shoulder arthroplasty. In addition, the guidelines can be incorporated into the BESS/BOA (British Orthopaedic Association) Patient Care Pathway Glenohumeral Osteoarthritis[15] or other future BESS/BOA-affiliated evidence-based care pathway documents that involve primary shoulder arthroplasty.

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Competing interests None declared.

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