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<td>Complete List of Authors:</td>
<td>Rangan, Amar; The James Cook University Hospital, Trauma and Orthopaedics Upadhyaya, Sheela Upadhyaya, Sheela Regan, Sandra; Oxford University Hospitals NHS Trust, Biomedical Research Centre Regan, Sandra; Oxford University Hospitals NHS Trust, Biomedical Research Centre Toye, Francine; Oxford University Hospitals NHS Trust, Nuffield Orthopaedic Centre Physiotherapy Research Unit Toye, Francine; Oxford University Hospitals NHS Trust, Nuffield Orthopaedic Centre Physiotherapy Research Unit Rees, Jonathan; University of Oxford, Rees, Jonathan; University of Oxford,</td>
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Abstract

Objective: To run a United Kingdom based James Lind Alliance Priority Setting Partnership for 'Surgery for Common Shoulder Problems'.

Setting: This was a nationally funded and conducted process. It was organised from a musculoskeletal research centre and Biomedical Research Unit in Oxford.

Participants: Were United Kingdom shoulder patients, carers and clinicians involved in treating patients with shoulder pain and shoulder problems that might require surgery.

Interventions: These were national electronic and paper surveys capturing treatment uncertainties that are important to shoulder patients, carers and clinicians.

Outcome measures: The outcomes relevant to this study were the survey results and rankings.

Results: The process took 18 months to complete with 371 participants contributing 404 in scope questions. The James Lind process then produced a final 10 research priorities and uncertainties that relate to the scope of 'Surgery for Common Shoulder Problems'.

Conclusions: The final top 10 UK research priorities (Table 1) have been produced and are now being disseminated to partner organisations and funders to guide funding of shoulder research for the next 5-10 years on topics that are important to both patients, their carers and clinicians.
Article Summary
Strengths and Limitations

- The study adheres to the structured process and principals of the James Lind Alliance.
- The process and study is patient centric.
- The process and study has produced the top 10 research treatment uncertainties in relation to surgery for common shoulder problems.
- While the process and study recommends the research priorities that are important, there is no guarantee of research funding.
- This is the first nationally funded PSP in orthopaedics and this funding model is now being adopted by other specialty societies.

Introduction and Background

The James Lind Alliance (JLA) is now hosted by the UK National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC). Its aim is to provide the approved process that enables patients and clinicians to work together to agree the most important treatment uncertainties in a particular field of interest. It then publishes and disseminates these priority areas to partners and funding organisations in order to influence the prioritisation of future research.

Shoulder Pain is the 3rd most common musculoskeletal complaint suffered by patients in primary care with 2.4% adult prevalence for GP consultations each year in the UK [1-3]. As such referrals to secondary care are increasing and with employment implications cost estimates of £100 million have been suggested. Some shoulder operations have increased 700% in 8 years [4]. With most aspects of health provision, there remains a lack of high level evidence for management pathways and therefore uncertainty still exists about some aspects of shoulder surgery such as when is the best time to operate on patients with shoulder problems, which patients need surgery and which patients are best treated non-operatively.

In 2013 funding was raised to initiate and run a JLA priority setting partnership (PSP) for ‘Surgery for Common Shoulder Problems’. This PSP was set up as a national model for orthopaedics, with funding provided by the relevant national professional organisations, namely the British Elbow and Shoulder Society (BESS) and the British Orthopaedic Association (BOA). Further financial support was provided by NIHR through the NIHR Oxford Musculoskeletal Biomedical Research Unit and the NIHR Oxford Biomedical Research Centre. It was hoped that this initiative would also encourage other orthopaedic societies to follow a similar funding model in order to help shape the relevance of future orthopaedic and musculoskeletal research in the UK by engaging with and involving patients, carers and other health professionals involved in the care of these patients. This surgical shoulder PSP and its model of funding by the national professional organisations was fully supported by NETSCC and the PSP application was approved in November 2013.

The aim of the ‘Surgery for Common Shoulder Problems’ PSP was to identify the unanswered questions about surgical treatments for Common Shoulder Problems' by:
- working with patients, clinicians and allied health professionals to identify treatment uncertainties about different types of shoulder surgery including when to operate and which patients are best treated with surgery.
- agreeing by consensus a prioritised top 10 list of uncertainties.
- publicising the results of the PSP and process and taking these results to research commissioning bodies.
Method and Stages

PSPs follow a structured process that needs to be adhered to in order to obtain final approval of the results and endorsement of the top 10 research priority areas by the JLA. Firstly a JLA adviser (SA) was appointed by NETSCC to the PSP to work with the clinical and specialist lead (JR) to set up the PSP Steering Group. This group provided oversight and management of the PSP. The steering group was made up of the most relevant stakeholders and included patients; physiotherapists; GP's; shoulder surgeons; anaesthetists and pain control experts; orthopaedic nurses and an academic clinician. Finally a JLA co-ordinator and a data analyst also joined the group. With the steering group in place, the following JLA PSP stages took place between January 2014 and July 2015. Meetings were centralised in Oxford for practical resource reasons with some steering group meetings also taking place via conference calls.

1. Identification and invitation of potential partners
Potential partner organisations were identified, contacted and informed of the establishment and aims of the ‘Surgery for Common Shoulder Problems’ PSP. Organisations and individuals that were invited represented people who have had hospital treatments for Common Shoulder Problems, carers of people who have had hospital treatments for Common Shoulder Problems, medical doctors, nurses and allied health professionals with clinical experience of treating patients with Common Shoulder Problems, medical doctors (General Practitioners) with clinical experience of referring patients with common shoulder problems for hospital care. These groups were invited to attend and participate in the initial stakeholder meeting, to be a partner, and to help disseminate surveys and results.

2. Initial stakeholder meeting / awareness raising
The initial stakeholder meeting had several key objectives; to welcome and introduce potential members of the PSP; to present the proposed plan for the PSP; to initiate discussion, answer questions and address concerns; to identify those potential partner organisations which would commit to the PSP and identify the contact representatives; to establish principles upon which an open, inclusive and transparent mechanism could be based for contributing to, reporting and recording the work and progress of the PSP.

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For common shoulder problems, each partner identified the method for soliciting from its members questions and uncertainties of practical clinical importance relating to different types of shoulder surgery including which patients might be best treated with or without surgery.

4. Refining questions and uncertainties
The Steering Group allocated responsibility for this stage and two members (JR and FT) ran the data management and analysis, while the steering group and JLA provided guidance, to ensure accountability and transparency. The consultation process produced “raw” unanswered questions. These raw questions were assembled and categorised by the data analysts into “collated indicative questions”, which were made clear and understandable to all. Similar or duplicate questions were combined. Uncertainties, not adequately addressed by previous research were recorded and prepared for entry into a ‘Surgery for Common Shoulder Problems’ section within the UK Database of Uncertainties about the Effects of Treatments (UK DUETs - www.library.nhs.uk/duets). This ensured that the uncertainties were not lost if they did not make the top 10.
5. Prioritisation – interim and final stages

The aim of the final stage of the PSP was to prioritise through consensus the identified uncertainties. This was carried out by the steering group and the wider partnership represented by patients and clinicians. For the interim stage, a long list of uncertainties was reduced to a shorter list by means of an online survey and steering group meeting. The final prioritisation stage to reach the 10 prioritised uncertainties, was conducted by a face-to-face meeting, using group discussions and plenary sessions. The JLA facilitated the final day process and again ensured transparency, accountability and fairness. All participants needed to declare their interests in advance of this final meeting.

Results

The initial national survey produced 652 questions from 371 patients, carers and clinicians. When each question was reviewed, 404 fell within the pre-defined scope of this PSP. There were a number of duplications highlighting the importance in some areas and allowing the combining of these duplications to produce 143 questions. With further merging of questions that were essentially asking the same question, and by taking into account which questions were asked by different demographic sources and then ensuring any remaining questions were true uncertainties, 49 questions were finally produced. These 49 questions then went out for the interim prioritisation in a further electronic web based survey in March 2015. This produced a shortlist of 25 uncertainties that underwent final prioritisation at a workshop in Oxford on June 5th 2015.

Figure 1: Flow chart of PSP process indicating the number of questions at each stage

- Survey: 652 questions submitted, 371 respondents
- Collation: 248 were removed (out of scope), 404 uncertainties taken forward
- Combining and checking: Duplications and the same uncertainties were merged or grouped together = 143
- The existing evidence base was reviewed and some answered questions removed, and further merging and combining of similar questions = 49
- Interim and final prioritisation: Long list of 49 uncertainties sent out for voting by the public. Steering group reviewed results, and agreed on shortlist of 25 research uncertainties for the final workshop on June 5th 2015
Final prioritisation resulted in the top 10 uncertainties for surgery for common shoulder problems. While a view was taken at the final prioritisation meeting that these 10 priorities are equally important and would be presented as bulleted priorities, the order in which they appear in Table 1 represents their ranked positions and scores on the final day. Ranking is important to some funders who prefer to assess the ranking order when considering funding research questions extracted from these priority areas.

Table 1: Top 10 research priority areas from the James Lind Alliance Priority Setting Partnership for surgery for common shoulder problems.

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Discussion

This JLA PSP was funded and set up in response to what is currently a pendulum swing for research funding bodies towards prioritising research questions by engaging patients in the selection of priority areas. This is to ensure that priority areas chosen are important to patients, carers and clinicians and not just researchers and academics. The James Lind Alliance is the process and method that has been approved in the UK for such priority setting partnerships.

At present a number of very diverse PSPs have been completed with many more underway. The processes are the same but there are different challenges and variations to the methods needed within these processes for differing PSPs. Our observations are
that duration and costs of running a PSP can vary from one to another. This can depend on a number of variables, but breadth of topic is critical in depicting duration of the process as well as whether the priority outcomes will be useful and will likely be funded. This is a balance that needs careful consideration. We would recommend to anyone wishing to run JLA PSPs to consider the topic very carefully, as duration affects cost, but selecting a narrow topic is not necessarily cost effective. We found the breadth of this shoulder surgery PSP to be probably at the limit of what is practical. Delivering it in an 18 month window has required a large amount of resource and professional time. While we received >600 questions that required processing, some PSPs receive well over 1000 questions, which would clearly impact resource requirements, duration and highlights the reasons for variability seen in different PSPs.

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Contributorship statement: All authors were involved with the study design, collection of data, analysis, writing and editing the manuscript.

Competing interests: The authors have no competing interests.

Funding: This study and process was funded by the British Elbow and Shoulder Society, the British Orthopaedic Association, the NIHR Oxford Biomedical Research Centre and the NIHR
Oxford Biomedical Research Unit.

Data sharing statement: All results are within the manuscript. The other 39 uncertainties identified during this study have already been made public by uploading them into UK DUETS (UK Database of Uncertainties about the Effects of Treatments).

References:


**Research Priorities for Shoulder Surgery: results of the 2015 James Lind Alliance patient and clinician priority setting partnership.**

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The aim of the final stage of the PSP was to prioritise through consensus the identified uncertainties. This was carried out by the steering group and the wider partnership represented by patients and clinicians. For the interim stage, a long list of uncertainties was reduced to a shorter list by means of an online survey and steering group meeting. This online survey was written in lay language and adopted the principals of a red light, amber light and green light system, with the responses allowed being ‘yes’ (important),
‘no’ (not important) and ‘unsure’. This method of interim prioritisation has been used by other PSP’s and allows the steering group to assess all the responses from all stakeholder groups. This fully informs the interim prioritisation with ‘green light’ responses to the same questions from different stakeholder groups indicating a high level of importance of that uncertainty.

The final prioritisation stage to reach the 10 prioritised uncertainties, was conducted by a face-to-face meeting, using group discussions and plenary sessions. All 25 uncertainties were discussed, considered and ranked by break out groups with equal representation of stakeholders. Each group was led by an independent JLA advisor and the groups rotated throughout the day with the process continuing until there was agreement over the top 10 uncertainties. The JLA facilitated the entire final day ensuring the JLA process was followed and ensuring transparency, accountability and fairness. All participants needed to declare their interests in advance of this final meeting.

Results

The initial national survey produced 652 questions from 371 patients, carers and clinicians. When each questions was reviewed, 404 fell within the pre-defined scope of this PSP. There were a number of duplications highlighting the importance in some areas and allowing the combining of these duplications to produce 143 questions. With further merging of questions that were essentially asking the same question, and by taking into account which questions were asked by different demographic sources and then ensuring any remaining questions were true uncertainties, 49 questions were finally produced. These 49 questions then went out for the interim prioritisation by the electronic web based survey in March 2015. This interim prioritisation produced a shortlist of 25 uncertainties that underwent final prioritisation at a workshop in Oxford on June 5th 2015. Figure 1 highlights the stages and processing of the questions.

*Figure 1: Flow chart of PSP process indicating the number of questions at each stage*

Final prioritisation resulted in the top 10 uncertainties for surgery for common shoulder problems. While a view was taken at the final prioritisation meeting that these 10 priorities are equally important and would be presented as bulleted priorities, the order in which they appear in table 1 represents their ranked positions and scores on the final day. Ranking is important to some funders who prefer to assess the ranking order when considering funding research questions extracted from these priority areas.

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### Top 10 questions compared to standard immobilisation and physiotherapy?

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### Discussion

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Contributorship statement:
A Rangan, S Regan, S Upadhyaya, F Toye and J L Rees all made substantial contributions to this work including study design, data collection, analysis and interpretation as well as writing and editing the manuscript.

All authors have read and approved the final version.

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References:
Figure 1.
254x190mm (72 x 72 DPI)
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