

BMJ Open Research priorities in foot and ankle conditions: results of a UK priority setting partnership with the James Lind Alliance

Jitendra Mangwani, Melinda Hau, Lauren Thomson 

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Trauma and Orthopaedics, University Hospitals of Leicester NHS Trust, Leicester, UK

Correspondence to

Lauren Thomson;
thomson1801@outlook.com

ABSTRACT

Objective To ascertain the priorities of research in surgical interventions and aftercare in foot and ankle conditions in adults, from inclusive viewpoints of patients, carers, allied professionals and clinicians, as a collaboration with James Lind Alliance (JLA) Priority Setting Partnership. Setting A UK-based national study organised through British Orthopaedic Foot and Ankle Society (BOFAS).

Design A cross-section of both medical and allied professionals, with patient involvement, submitted their 'top priorities' pertaining to foot and ankle pathology, using both paper and web-based formats, which were synthesised into the primary priorities. Following this, workshop-based reviews were used to determine the top 10 priorities.

Participants Adult patients, carers, allied professionals and clinicians who have experienced or managed foot and ankle conditions in the UK.

Methods A transparent and well-established process developed by JLA was carried out by a steering group of 16 members. A broad survey was designed and disseminated to the public via clinics, BOFAS meetings and website, JLA platforms and electronic media to establish potential research priority questions. Surveys were analysed and initial questions were categorised and cross-referenced with the literature. Those questions that were out of scope and sufficiently answered by research were excluded. The unanswered questions were ranked by the public via a second survey. The top 10 questions were finalised via an extensive workshop.

Results 472 questions from 198 responders were received from the primary survey. 71% (140) from healthcare professionals, 24% (48) from patients and carers and 5% (10) from other responders. 142 questions were out of scope, leaving 330 questions. These were summarised into 60 indicative questions. Reviewing against current literature, 56 questions were left. From the secondary survey, there were 291 respondents: 79% (230) healthcare professionals and 12% (61) patients and carers. After the secondary survey, the top 16 questions were brought to the final workshop to finalise the top 10 research questions. The top 10 questions were: What are the best outcome measures (ways of assessing the effect of the treatment) after foot and ankle surgery? What treatment is the best for Achilles tendon pain? What is the best treatment (including surgery) for tibialis posterior

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This Priority Setting Partnership (PSP) directly involved patients and many different clinicians throughout and is both inclusive and representative of the common demographic of foot and ankle surgery in the UK.
- ⇒ Methodology strictly adhered to the well-established protocols developed by the James Lind Alliance (JLA).
- ⇒ The scope of the priority setting process was broad, reporting on a wide variety of surgical conditions affecting the adult foot and ankle.
- ⇒ Conditions affecting diabetic foot and the paediatric foot were considered out of scope.
- ⇒ Research gaps identified regarding rehabilitation and patient-reported outcome measures were an unexpected focus from the patients' viewpoint, which were not considered by the clinician group, indicating the value of the JLA PSP process.

dysfunction (tendon on the inner side of the ankle), leading to a successful long-term outcome? Should physiotherapy be provided following foot and ankle surgery and is there an optimal amount needed to restore function after foot and ankle surgery? At what stage should a patient with ankle instability (ie, an ankle that keeps giving way) be considered for surgical treatment? How effective are steroid injections in improving pain from arthritis in the foot and ankle? What is the best surgery for bone and cartilage defects in the talus? What is better, ankle fusion or ankle replacements? What is the success of surgical lengthening of the calf muscle in improving forefoot pain? What is the best time to start weight bearing after ankle fusion/replacement surgery?

Conclusion Top 10 themes included outcomes following interventions, for example, range of movement, reduction in pain, rehabilitation, which included physiotherapy to optimise post intervention outcomes, rehabilitation and condition-specific treatments. These questions will aid to guide national research into foot and ankle surgery. It will also help national funding bodies to prioritise areas of research interest to improve patient care.

INTRODUCTION

The subspeciality of foot and ankle under the headline of Trauma and Orthopaedics has a large array of differing diagnoses and management options; both non-surgical and surgical.

Musculoskeletal consultations account for roughly 30% of all general practitioner contacts or 30 million patient appointments. With an ageing population, this represents an increasing burden on the NHS.¹ Of these musculoskeletal consultations, a recent study noted that 3% (3 million) of all general practice encounters pertain to the foot and ankle, with this patient cohort being predominantly aged over 70 years and women.²

Traditionally, research has been led by the priorities of the treating clinicians or researchers rather than the patients and carers' preferences. Modern practice for patient research has used this resource and expanded into patient and public involvement (PPI). The National Institute for Health Research (NIHR) has recognised the importance of PPI in study influences, prioritisation and engagement for large research trials.³

The James Lind Alliance (Cite about and guide), created in 2004, is an established not-for-profit organisation designed to bring all the relevant stakeholders together, including patients, to identify the priorities for research related to different conditions and their management.⁴

Utilising this successful method (with over 100 such partnerships processes completed to date), the aim of this Priority Setting Partnership (PSP) was to ascertain the priorities for interventions in foot and ankle conditions, inclusive of all viewpoints, patients, carers, allied professionals and clinicians, to establish and then disseminate the 'top 10' priorities for future foot and ankle research.⁵ This links to funding opportunities—that is, research priorities more likely to be funded if they have been identified through JLA process. Some examples of the JLA priority partnership funding research are the Diabetes Mellitus JLA priority, which have two of their identified priorities being funded.⁶ The Early Hip and Knee Priority has also received funding for two of their priorities, including the national MOTION (Treatment of Knee osteoarthritis with chondroitin sulfate) trial.⁷

OBJECTIVE

The primary objective of the foot and ankle PSP is to identify the top 10 research priorities within foot and ankle surgery from the perspectives of all key stakeholders.

METHODS

The methodology was undertaken as outlined by the James Lind Alliance.⁸ The duration of this PSP was from November 2019 to December 2021. The James Lind Alliance uses a combination approach to obtain data, with initial surveys being undertaken both online and in paper form, steering group meetings and also consensus

workshops. Prior to initiation of the project, advice was obtained from the James Lind Alliance advisor regarding the requirement for ethical approval. As per other JLA prioritisations, we were advised that ethical approval was not a requirement for this project. At each stage of the study, participants were fully informed as to what participation entailed and how their data would be used. This is outlined within the JLA guidebook.

Steering group and partner organisation

The steering group for the PSP combined both clinician and patient representation. The clinician group contained a broad range of professionals managing foot and ankle conditions: foot and ankle orthopaedic consultant subspecialists, specialty registrars, rheumatologists and physiotherapists. The steering group also had patients with lived experience of foot and ankle conditions, and a carer supporting a patient with a foot and ankle condition. This intended to broaden the scope of the stakeholders and obtain the most diverse range of personnel and skill set for the PSP. The PSP was overseen by a senior JLA advisor, to ensure the process adhered to JLA principles, allowing transparency, and facilitating both the steering group and consensus workshops to give each member the ability to interact and contribute to the process. Two data specialists were supervised by a senior information specialist with previous experience of JLA PSPs. They were involved in the design of the surveys, cleaning and validating the raw data for analyses and synthesis of the top-10 questions from the consensus workshop.

Definition of scope

Broadly, the scope of this foot and ankle PSP was to identify any ongoing uncertainties relating to the adult non-Diabetic population, encompassing both trauma and elective care, specifically operative and non-operative management. The information survey was submitted at the annual British Orthopaedic Foot and Ankle Society (BOFAS) meeting of foot and ankle professionals, including surgeons and wider members of the allied healthcare professional sphere.

The specific scope of our JLA was defined as:

1. Surgical treatments and injections for the treatment of foot and ankle conditions and injuries in adults (over 18 yrs).
2. Postsurgical rehabilitation or injection aftercare.

The PSP concentrated the scope on postdiagnosis care, to prevent too broad a scope, thereby excluding epidemiological questions and general healthcare management within the NHS. As diabetic foot is a complex condition encompassing a multitude of different aspects, the PSP took the decision to not include the condition within this uncertainty review. Furthermore, the 'Foot Health' PSP as already reviewed the uncertainties regarding risk reduction for development of foot and ankle conditions, preventative factors and health service provision as priorities.⁹

Themes synthesised from Question Data

- 1: *Diagnosis**
- 2. Surgical management
- 3. Non-surgical management
- 4. Post-operative care
- 5. Rehabilitation
- 6. Prognosis
- 7. Outcomes
- 8. *Prevention**
- 9. *Health services**
- 10. *Risk factors**
- 11. General treatment

The asterisk denotes those considered out of scope for this PSP.

Figure 1 Themes synthesised from question data. From the initial steering group meeting, each question could be categorised into one of the following 11 themes. PSP, Priority Setting Partnership.

Initial survey design and dissemination

The survey was designed by the information specialists and reviewed by the steering committee before dissemination. The survey included demographics; age, gender, ethnicity, profession identification and if a non-medical profession whether they were a patient or carer. These categories were included to ensure a diverse range of opinions that were sought to all for a realistic generalisation of any subsequent results and to reduce the over representation of any demographic (figure 1).

The initial statement was deliberately broad so not to influence any user of the survey into narrowing their questions.

The statement: *we want new ideas for research for the treatment of foot and ankle conditions, which could help patients in the future. We want to hear from ANYONE with an interest in improving healthcare outcomes for patients being treated for foot and/or ankle conditions.*

With free-text space provided with the titles of: question 1 and question 2.

This survey was disseminated throughout foot and ankle clinics nationwide, conferences, national surgical organisations, advertised on the BOFAS webpage, through open access journals, social media platforms (Twitter) and as an online link (online supplemental appendix 1). Partner organisations were also contacted to broaden the views obtained (box 1).

Theme identification and uncertainties

The initial survey responses were collated and organised in their original submitted statement onto excel. Each question was individually appraised and if writing was illegible,

Box 1 PSP Partner Organisations

- ⇒ The Chartered Society of Physiotherapy
- ⇒ Advanced Practice Physiotherapy Network
- ⇒ MSK Association of Chartered Physios
- ⇒ Association of Chartered Physiotherapists in Sports and Exercise Medicine
- ⇒ Association of Trauma and Orthopaedic Chartered Physios
- ⇒ Association of Chartered Physios with an interest in Orthopaedic Medicine Injection Therapy
- ⇒ Physio First
- ⇒ Association of Foot and Ankle Physiotherapists and AHP's
- ⇒ College of Podiatry
- ⇒ Royal College of Nursing
- ⇒ British Association of Sports and Exercise Medicine
- ⇒ British Nursing Association
- ⇒ British Association of Prosthetists and Orthotists
- ⇒ Picker: Patient Centred Care Improvement
- ⇒ East Midlands Clinical Research Network
- ⇒ The CHAIN Network
- ⇒ NIHR PIVN group
- ⇒ Centre for Evidence Based Dermatology
- ⇒ British Orthopaedic Foot & Ankle Society
- ⇒ British Orthopaedic Association
- ⇒ Patients Association
- ⇒ PATIENT.INFO
- ⇒ NOMaG (National Orthotic Managers Group).

further review by both data specialists was undertaken independently to prevent bias, if still unclear the question was not included. At this stage, no re-editing of the questions was undertaken. The steering group convened after an initial 256 questions (142 participants) were collated to review for demographic bias, and the appropriateness of the themes, ensuring that the categorisation was inclusive of the question nature. The in-scope, uncertainties exist and out of scope was then fully defined.

From the initial steering group review, 11 themes were adopted, with four of these themes considered out of scope (figure 2).

Any uncertainties were reviewed separately by the data analysts (LT and MH) for their thematic content, if concordance between each reviewer, the question was then categorised. After the two independent reviews, if no conclusion was reached, the third reviewer (JM) reviewed for categorisation, any remaining uncertainties were taken forward to the steering group, to prevent exclusion.

Interim prioritisation and the literature review

The initial survey generated a large pool of questions, which were brought to the steering committee. Questions within the same theme with similar overall purpose were then combined to create a singular core question. Each question submitted and included was reviewed for individual merit, meaning not every question was a combination, some were unchanged from their original form. Each new question was then peer-reviewed for clarity and legibility of the English language. Once each question was synthesised into the final format for review, a literature

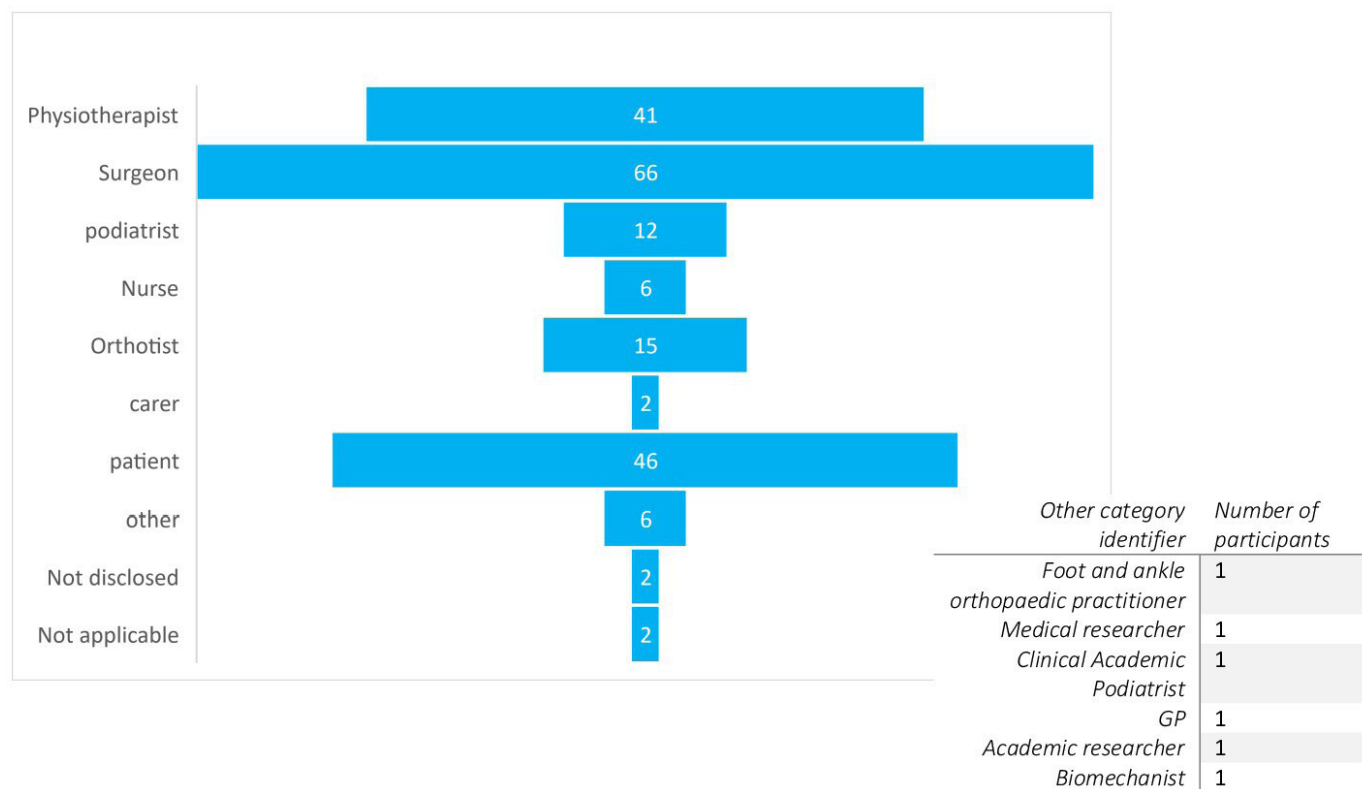


Figure 2 Participation occupation. This categorises the occupational and patient overall numbers obtained from our Priority Setting Partnership. GP, General Practitioner.

search was performed online to review NICE guidance, NICE research recommendations and the Cochrane database (DG). This was to identify if any of the current questions had previously been researched and there was a good-quality randomised control trial, systematic review and or meta-analysis performed. Each subgroup was divided between the healthcare professionals and weighted on the availability of evidence (figure 3).

The steering group reviewed the final 75 questions to be submitted for interim prioritisation. Questions felt to be duplicates were combined into one final question. The scope of each question and a final readability was undertaken. After this process, 56 questions for interim prioritisation were forwarded (online supplemental appendix 2).

A	No systematic review available
B	Systematic review available, but authors did not find any RCTs in the literature to include
C	Systematic review available, some RCTs found, but no formal meta-analysis performed (This is usually due to poor quality of RCTs or disparities of design/outcome measures)
D	Systematic review with meta-analysis available, uncertainty persists

Figure 3 Evidence categorisation. Once the questions had been created, the steering group undertook a literature search on each question for review of previous studies. Each letter denotes the evidence available. RCT, Randomised Control Trial.

Respondents were asked to review the long list of 56 questions and choose up to 10 questions that they most warranted research to address (figure 4).

Each participant ranked their top 10 priorities, these created a core group of 19 questions, as this was considered over the upper limit for questions for final prioritisation, the steering group noted any similar themes, and with group consensus decided to combine two questions from this cohort as this would not fundamentally alter the raw data but provide a workstream for this question thread.

Final prioritisation

The final stage of the JLA process is a priority setting workshop, in which patients, carers and clinicians come together to discuss and agree the top 10 priorities for research. Due to COVID-19 restrictions, a face-to-face workshop was not possible. However, the protocol as set in the JLA guidebook was adhered to utilising the online Zoom platform.¹⁰ A diverse range of 22 participants was included in each group (five groups) to reduce the risk of bias of question weighting. Each group contained both healthcare professionals¹¹ and patient/carers.⁸ Each participant within the workshop was allocated a group with a conveyer via an online platform. Participants took part in facilitated breakout group sessions, each with a mix of patients and clinicians, in which they discussed and ranked the 16 priorities, and the groups' rankings were combined to create a shared ranked order. Over two

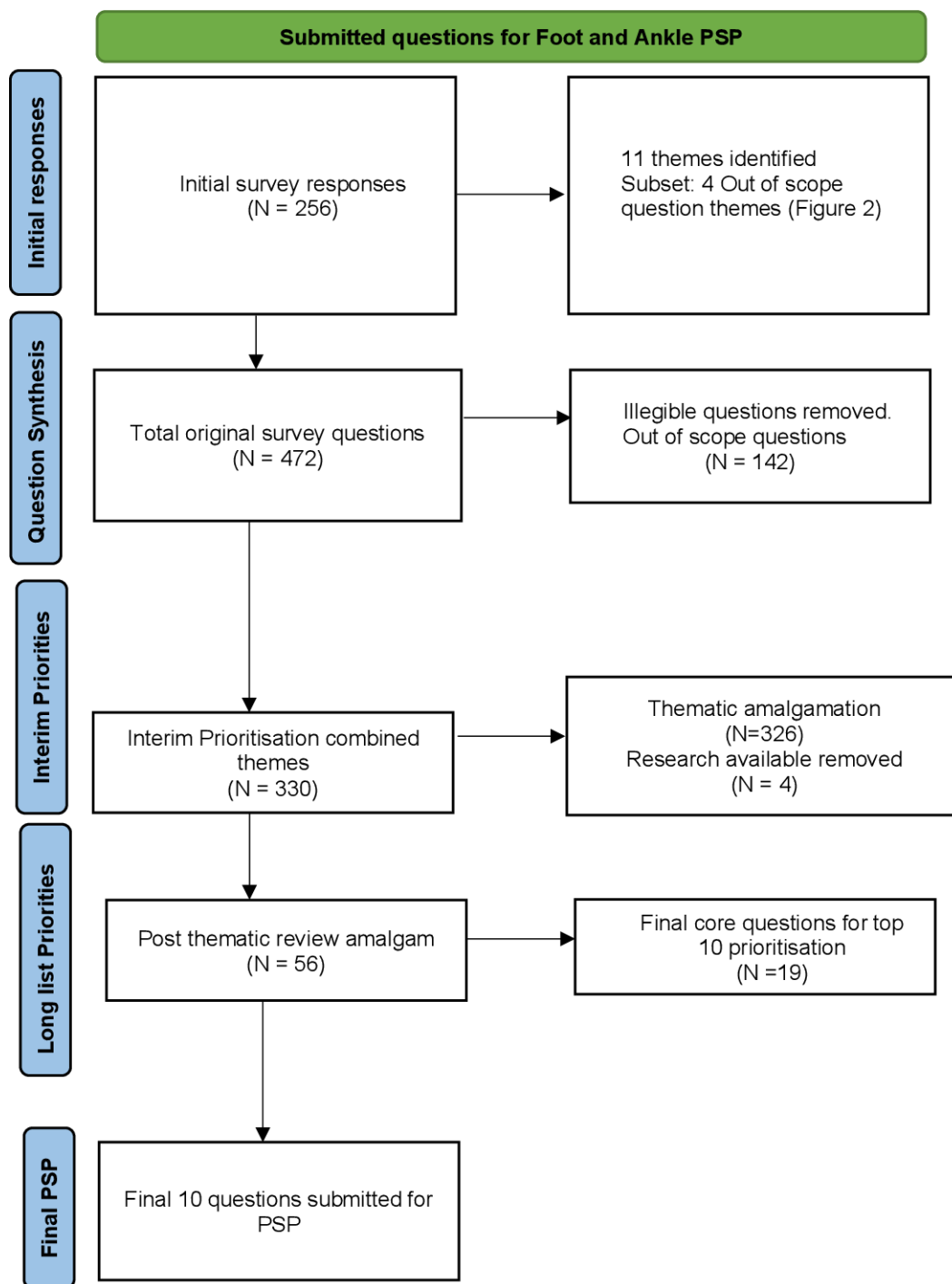


Figure 4 Submitted questions for foot and ankle PSP. This flow diagram illustrates how our ‘top 10’ questions were synthesised. PSP, Priority Setting Partnership.

rounds of discussion and ranking, a ‘top 10’ ranking was agreed.

Patient and public involvement

Amanda Roberts (AR) and Steve Ingram (SI) acted as patient representatives within the steering group committee meetings to ensure clarity and to prevent over medicalisation of the questions, providing lived experience of foot and ankle conditions. They both contributed to the design of the original survey and the overall

phrasing of the submitted questions. The results of this study are available for review on the James Lind Websites.

RESULTS

Initial survey

The initial survey generated 472 questions from 198 participants, of these 106 were deemed out of scope on the primary review, and after thematic synthesis, a further

36 questions (total 142) were also considered out of scope, this gave a total question number of 330 questions. Of the 198 responders, healthcare professional predominated 70% (140), with patient and carers comprising of 25% (48) with other respondents comprising the final 5%.¹⁰ There were 91 men: 97 women and 10 non-disclosures, with White-British predominating at 76%, this being lower than the national average of 86.0%, Asian-Asian British as the second largest cohort 12%, this is above the national average of 7.5%.¹²

Interim prioritisation

After steering group review, the information specialists removed questions previously answered and amalgamated similar questions, this list was then distributed among the steering group for literature review as per the methodology. The literature search yielded four questions with systematic review and/or meta-analysis, and so these were removed from the final workshop, as the steering committee agreed there was sufficient evidence to support best practice. The steering group separated into smaller groups to review question themes en-bloc, for example, all questions pertaining to ankle replacements, or all questions relating to rehabilitation. Questions felt to be duplicated, or have a common theme were combined and a review of scope was undertaken, postanalysis, the 59 questions were discussed within the final steering group review.

The total of 291 complete responses were received, of which 59 were patients, 2 were carers (these two groups were combined) and 230 were healthcare professionals. Each time, a question was chosen, it was assigned one point. To ensure equal influence, points for each respondent category were tallied separately, generating a total for patients/carers and for healthcare professionals for each of the 59 questions.

These were submitted to the respondents (291) for a selection of at top 10, generating a core group of 19 questions. This core group of 19 questions was felt to be too large for an online forum so was pragmatically reviewed and reduced to 16 questions by the steering group for the final workshop.

Final prioritisation

The final prioritisation workshop consisted of 22 persons, 14 healthcare professional, 8 patients and carers, 5 facilitators, with 2 observers and overseen by James Lind Alliance representatives. The James Lind representatives facilitated the discussions within each breakout group, providing guidance and clarity, but without influencing the final result. The core group of 16 questions was each ranked by the group representatives, and unanimous decisions were given by each of the breakout groups.

The top 10 priorities listed are

1. What are the best outcome measures (ways of assessing the effect of the treatment) after foot and ankle surgery?

2. What treatment is the best for Achilles tendon pain?
3. What is the best treatment (including surgery) for tibialis posterior dysfunction (tendon on the inner side of the ankle), leading to a successful long-term outcome?
4. Should physiotherapy be provided following foot and ankle surgery and is there an optimal amount needed to restore function after foot and ankle surgery?
5. At what stage should a patient with ankle instability (ie, an ankle that keeps giving way) be considered for surgical treatment?
6. How effective are steroid injections in improving pain from arthritis in the foot and ankle?
7. What is the best surgery for bone and cartilage defects in the talus?
8. What is better, ankle fusion or ankle replacements?
9. What is the success of surgical lengthening of the calf muscle in improving forefoot pain?
10. What is the best time to start weight bearing after ankle fusion/replacement surgery?

This was made into an infographic for distribution (figure 5).

DISCUSSION

This PSP identified a diverse range of research themes by combining the views of healthcare professionals, patients and carers. These included measurement of outcomes, steroid injections for foot and ankle conditions, surgical interventions such as ankle replacement and fusion, cartilage defects, post-operative care and rehabilitation to improve longer term function.

The dearth of good quality orthopaedic research is being addressed by national trials and leading academic surgeons.^{13 14} The progression towards the JLA has been driven by these leaders. The disparity between the importance of a question to a clinician and that of a patient and/or carer is being addressed by the invaluable work of the PSP.^{11 15} Aligning the views of all stakeholders in the management of foot and ankle conditions. The range of themes¹² created from the initial survey indicates the diverse range of questions perceived to remain unanswered.

Within the published literature, this is the first PSP specifically looking at the broad scope of foot and ankle conditions, including surgery, but this PSP does build on and complement the 'Top 10 Foot Health PSP 2019'. Foot and ankle conditions encompass a wide range of conditions, some deserving of PSP review alone—Diabetic foot and the Paediatric foot being identified as future areas of PSP research.⁹ This diversity of conditions prevented one stakeholder group from a 'disease specific', which has been a risk within other PSPs.

The scope of questions as expected was broad, and during thematic review, the steering group committee with the data analysts aimed to retain the majority of the original question from the submitter. This is the first PSP to review foot and ankle surgery using the JLA method. Having the ability to use



James Lind Alliance FOOT AND ANKLE SURGERY Priority Setting Partnership



The James Lind Alliance and the British Orthopaedic Foot and Ankle Society had worked together to identify 'Top Ten' unanswered research themes in foot and ankle surgery by involving patients, carers, and clinicians.

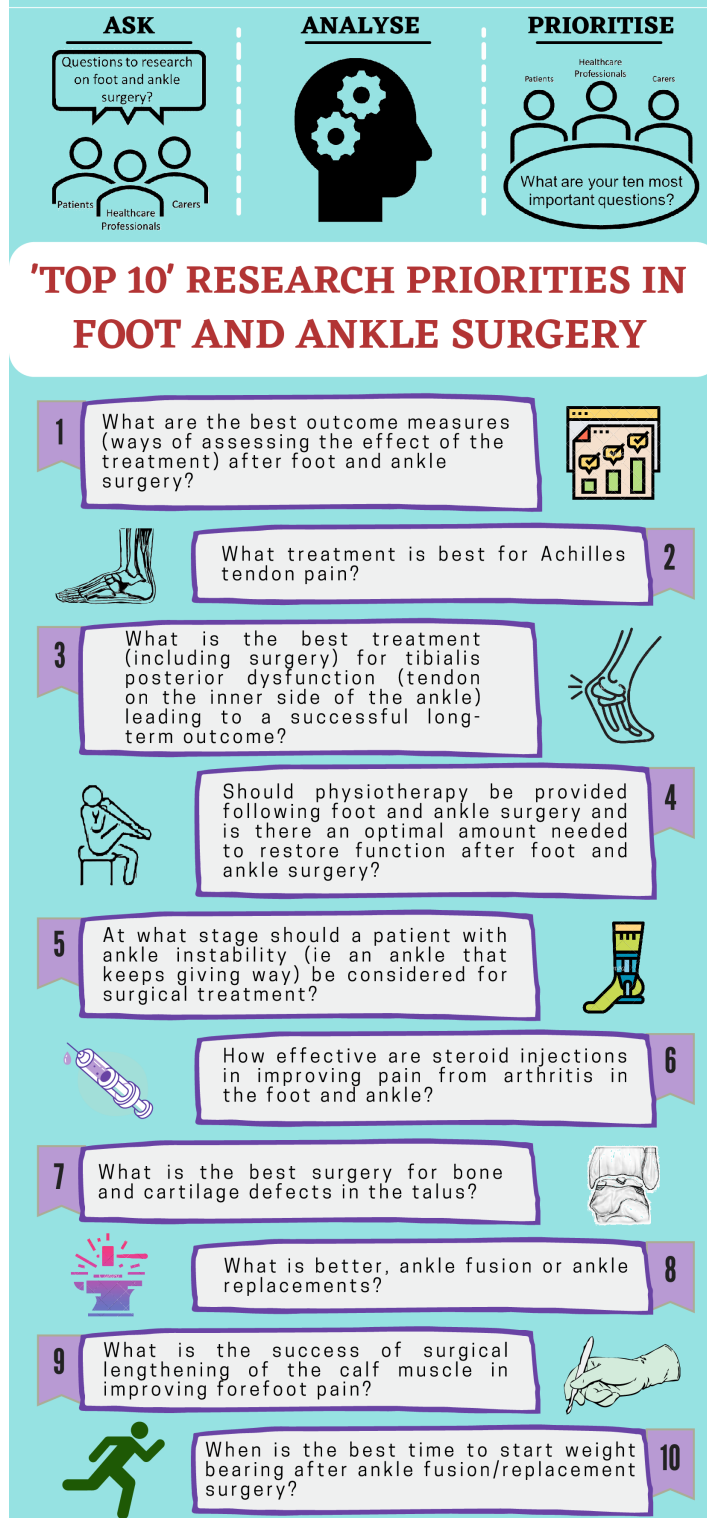


Figure 5 Infographic of top 10. This infographic was used to disseminate our top 10 questions in an accessible format for patients and clinicians.

the national BOFAS conference as a launchpad meant the survey covered a large proportion of healthcare trusts, and multiple different specialities, to enable the survey to cover multiple specialists, this in conjunction with the Chartered Society Physiotherapy, link from a steering group committee member further broadened the reach. The unknown computer literacy of candidates meant that we supplemented the survey with a paper alternative to ensure no person would be unable to submit their questions. Patients receiving non-surgical and surgical interventions were included. We did not specify, 'only patients receiving care within the NHS' in our initial recruitment; however, we did not specifically record data on whether patients were receiving treatment in the NHS or private sector.

Initial difficulties of the paper copies being illegible, partially were less of an issue with the online link provided. This also gave participants to access the survey at home or on web-linked devices within the clinical setting.

The COVID-19 pandemic affected the collation of data within this PSP. The lack of face-to-face patient contact due to the halting of inpatient clinics led to somewhat lower than expected patient/carer input. We had a large number of partner organisations (box 1) with the aim of using their member bases to increase the patient and carer proportion. However, the access to these forums was dictated by access to web-based resources. The requirement of the use of an online platform will have potentially limited access to some patient/carer groups who are not a computer literate. This may have skewed some of the questions forwarded to the group. The effect on the steering group was minimised, with meetings arranged to have minimal impact with maximal attendance. This was not unique to our PSP but a national recruitment issue.^{16–19}

As expected, and seen in other PSPs, there was a higher Healthcare Professional (HCP) to patient/carer ratio, but a more diverse range of ethnicity representation than the national average. The interim demographic responders also indicated that a larger proportion of the groups were middle aged, and Caucasian, but Asian/Asian British were 20% of the interim responders, which although only 1:5 ratio is still higher than the national demographic.¹²

Interim review following the original prioritisation, thematic analysis, uncertainty removal and question amalgamation provided a diverse range of questions for top 10 selection, covering all range of foot and ankle issues, surgical, rehabilitation, soft tissue conditions, etc. We managed to maintain a diverse cohort of respondents, male to female ratio 59.8%:37.6%, but the age was 30–49 years predominantly (more than 50% of responders). Of the HCP, the majority were foot and ankle surgeons (53.7%) and the next largest group physiotherapists (16.5%), this may reflect the questions from the final prioritisation. Patient/carers had a stronger focus on questions pertaining to rehabilitation, physiotherapy and non-surgical management of their foot and ankle conditions. This was the obverse to the HCP group, who as the largest combined group was foot and ankle/trauma consultants (57.2%) had

a stronger interest in surgery and outcome measures following procedures.

The final priorities maintained a range of questions affecting surgical and non-surgical aspects of the foot and ankle. But there is a clear lean towards conditions affecting the non-traumatic hindfoot and rehabilitation. This PSP had both narrow and broad scope questions, indicating not only the range of patient questions (tended towards broader questions) but also the alignment of uncertainties seen among the HCPs. Questions raised by the James Lind Alliance have the ability to secure future funding due to the respected JLA process and the links with the National Institute for Health and Care Research. This gives future researchers a platform for application of funding, with the necessity of their research being documented as a priority. This funding for specific priorities has been achieved by other PSPs.^{7,20}

In accordance with the JLA protocol, the long list of uncertainties raised, the raw data in the unedited format and the out of scope questions are available on the JLA website to ensure complete transparency and open access to all researchers (online supplemental appendix 3).²¹

In conclusion, we want this platform to continue to positively influence research within the foot and ankle community, leading to improved procedural knowledge, quality of care and patient-reported outcomes. We hope that this PSP provides the impetus for funding of these key questions in the future.

Twitter Lauren Thomson @theenglishmot

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Contributors Origin of study idea: JM. Guarantor of study: LT. PSP design: JM. Study management: LT, MH, JM. Acquisition of data: LT, MH. Analysis of data: LT, MH. Interpretation of data: LT, MH, JM. Drafting and revision: LT. Final revisions: LT, JM. Final approval: LT, MH, JM. Agreement of accountability: LT, MH, JM. All authors met the ICMJE criteria for authorship.

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Competing interests This work received funding from the British Orthopaedic Foot and Ankle Society. LT, JM are members of the society. JM is chair of the scientific committee.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. All raw data is obtainable from the author team. The primary questions have all been included in the original document.

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ORCID iD

Lauren Thomson <http://orcid.org/0000-0003-1682-0647>

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