Identifying research priorities in clubfoot management through a Delphi process

a study protocol

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Aims

Clubfoot is the most common congenital foot deformity. Clubfoot management is lacking high-quality research to support clinical decision-making. It has been chosen as one of the elective priorities in research by the James Lind Alliance priority setting. We present the protocol of a consensus-based approach to identify research priorities for clinical trials in clubfoot management.

Methods

A modified Delphi technique will be used, which will involve an initial scoping survey, a two-round Delphi process, and a consensus meeting. The survey will be conducted among key stakeholders in the management of clubfoot, as well as patients and carers in the UK. The priorities identified during this process will each be assigned to core areas of consideration. The final list of research priorities will then be discussed and agreed in a consensus meeting of representative key stakeholders.

Conclusion

While treatment of clubfoot has become more consistent with the use of the Ponseti method, most research is retrospective from single centres, and outcomes are variable. Identifying research priorities in this group of patients through this study will shape and drive the development of multicentre prospective clinical trials deemed most important for improving clinical practice and health outcomes.

Take home message

- This protocol describes a modified Delphi process to identify key research priorities in clubfoot management.
- The results will inform multicentre clinical trials focused on improving treatment strategies and long-term patient outcomes.

Introduction

Priorities for research into clinical effectiveness among children's orthopaedic surgeons have been identified.[1] Elective topics were ranked higher than trauma and the management of clubfoot is one such elective topic. Additionally, the James Lind Alliance priority setting on lower limb surgery in children highlighted variations in practice,

geographical variation, and lack of good evidence in their top 20 priorities.[2] These concerns are the driver behind efforts to understand research priorities for children with clubfoot.

Clubfoot affects one in 1,000 children.[3] There are varying degrees of deformity affecting either one or both feet and a genetic component involved in the aetiology.[4,5] The primary goal of treatment of clubfoot is to provide long-term correction of the foot posture to optimize function and eliminate pain.[5] Ponseti treatment is the gold standard for initial correction of clubfoot,[4,6-9] which involves casting followed by an Achilles tenotomy and use of a foot abduction brace. However, there is less clarity around other aspects of care including discrepancies in assessment methods,[10,11] casting technique,[12] casting products,[13] type of instrument used for the tenotomy,[14] the type of foot abduction brace and regime, and follow-up time.[7,15]

Most studies published in the literature are based on a retrospective series from single centres.[7,9,15] Bina et al[10] highlight concerns around the certainty of evidence for non-surgical and surgical management of clubfoot, due to bias, variable inclusion of unilateral and bilateral feet, and small study populations.

Relapse is an ongoing clinical challenge. Despite a lack of consistency in reporting relapse[10,11], foot surgery is required in up to 53.3% of patients.[7,15] Steinman et al[12] reported relapse in up to 37% of children within two years of initial intervention, which may be associated with follow-up after casting, bracing adherence,[8] overactivity of tibialis anterior tendon,[16] evertor muscle activity,[17,18] and additional diagnoses.[19,20] Treatment options following relapse vary, and clinical decision-making around non-surgical intervention, together with the type and timing of intervention, is not clear.[10,21]

Recently, a set of core clinical outcomes were developed aiming to standardize assessment of children with clubfeet across centres.[6] A multicentre international study using these outcomes distinguished patients with and without relapse in terms of clinical outcomes and quality of life, with poorer outcomes in the relapse group.[22]

There are many gaps in our knowledge of clubfoot management including our understanding of the natural history, relapse, and how to improve outcomes. In this study we aim to prioritise these questions and identify equipoises to focus future research efforts.

Methods

To identify the research priorities in clubfoot management, a multistage process will be followed. A team of researchers will oversee and guide the process. The primary steering group will comprise a group of up to ten practitioners who specialize in clubfoot care.

Identification of research themes which may take priority

Identification of research questions from the literature

Systematic reviews of the research into the management and outcomes of clubfoot have identified many unanswered questions.[5,11] These questions will be collated for the next part of the study. The list of topics gathered will be separated according to core areas defined by the research team and will include prenatal and postnatal diagnoses, primary treatment, relapse, casting, and further non-surgical and surgical intervention.

Identification of key research priorities from key stakeholders

A list of suggested research topics where there is a gap in the literature, need for further research, or an equipoise in opinion around intervention, will be collated. Health professionals with expertise in clubfoot management from the UK will be invited to participate. Practitioners will be identified through professional networks and an international clubfoot conference. They will include surgeons, physiotherapists, and any other clubfoot practitioners. The initial priority list will be extended and refined according to the responses received. Similar or related research questions will be merged into a single topic.

Parent/guardian/carer and patient involvement are of primary importance when defining research priorities. Identifying research issue of relevance to key stakeholders will be determined by including parents/guardians of children with clubfoot in the Delphi process as well as prompting them to add any new priorities to the list. Families of patients with direct experience of clubfoot treatment will be invited to participate. Participants will be recruited from several clubfoot clinics. Families for whom English is not their first language will be provided with a translation service if needed. They will be asked to comment on and augment the list of topics and questions. The information families are required to provide is not greatly different from routine questions asked during their regular clinical appointments.

Consultation with the institutional Research and Development offices has deemed that this study does not require ethical approval.

Identification of key outcomes to clinicians

Overview

The list of research questions collected from the literature, clinicians, and public involvement described in this protocol will act as the basis for a modified UK Delphi survey. The aim of the survey is to rate the priority areas for research important to families, orthopaedic surgeons, physiotherapists, and other healthcare professionals involved in the management of clubfoot. The Delphi method is a forecasting process framework comprising sequential surveys answered anonymously by a panel of participants with relevant knowledge and expertise.[23] Equal weight is given to the response of every participant to attain consensus.[9]

Participants

No agreed standard sample size has been defined for a Delphi survey.[24] It is usually determined by practicality, research area, aim of the study, and time available for analysis. There is no upper limit to number of participants. We will recruit the largest possible sample for each of the three stakeholder groups: orthopaedic surgeons, clubfoot-trained healthcare professionals, and patients and family. Participants will be recruited from partner hospitals/university institutions, from The British Society of Children's Orthopaedic Surgeons (BSCOS), the Association of Paediatric Chartered Physiotherapists (APCP), and other organizations (Clubfoot international conference, Clubfoot Special Interest Networks). For professionals, the only inclusion criterion will be expertise in clubfoot treatment.

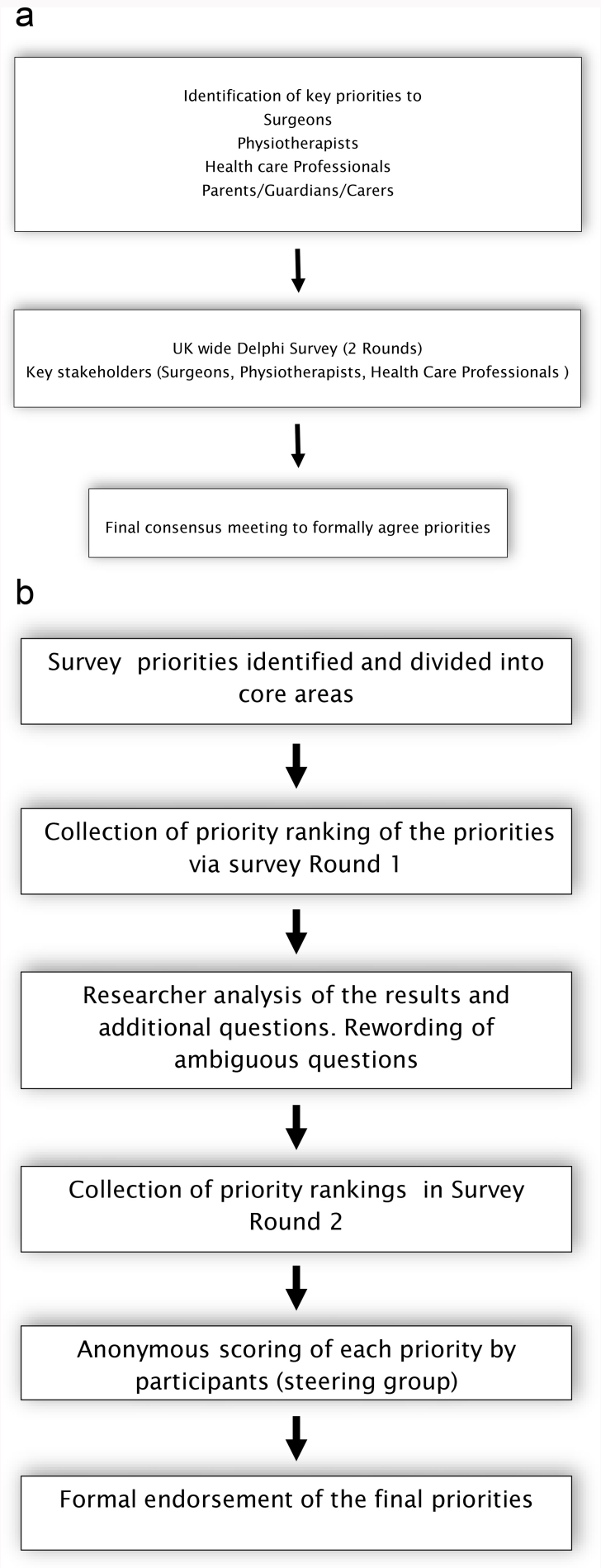

Fig. 1
a) Three-step process for Development of Research Priorities in the management of clubfoot. b) The Modified Delphi Process.

The goal is to involve a broad range of practitioners and families from diverse clinical and home settings and geographical locations. This includes clinicians engaged in various stages of clubfoot care, working in clinics of different sizes, with varying levels of resources, and facing different cultural challenges. Such inclusive representation will help to ensure that all barriers to optimal treatment are identified and addressed.

Participants will be contacted and invited to participate in the survey by email. Informed consent will be assumed if the participants complete the survey.

Modified Delphi survey

The survey will be divided into two rounds (Figure 1a). Participants involved in the study will have three weeks to complete each round. A reminder email will be sent at the end of week two and 24 hours before closing of each round to encourage completion of the survey and thus reduce the dropout rate.

Modified Delphi round 1

Each participant in the survey will complete the electronic data collection form, which starts by requesting participants' demographic data including name, role, institution, and contact details. Participants will then be asked to review a list of selected priorities to be graded on a five-point Likert Scale ('low priority' to 'high priority') based upon the importance of each question to their clinical practice.[1] Each participant will have the opportunity to add additional research questions they consider important.

Analysis of modified Delphi round 1

The data will be analyzed to summarize the distribution of scores, and will be separated for each stakeholder group. Additional priorities suggested by the participants will be considered, refined, and added to round 2. Priorities will be checked for duplication and ambiguity. The response rate will be recorded.

Modified Delphi round 2

Participants who respond to round 1 of the survey will be invited to participate in round 2. They will be able to see the summary of the data obtained in round 1 and will be asked to review again the list of outcomes, with the opportunity to confirm or change their previous ratings. Additional priorities added to the survey from round 1 feedback will be clearly indicated to participants. Participants who do not respond to round 1 will be excluded from round 2.

Analysis of modified Delphi round 2

The total number of participants in round 2 will be recorded. The analysis of the data will have separate results for each stakeholder group. As this is a preliminary analysis of the results, all classified outcomes will be brought forward to the consensus meeting for final considerations and scoring/weighting.

Bar charts will be produced to show the scores for each question. The fully scored and ranked list of research priorities will be presented. The mean score and range for the 'relative degree of importance' of each question posed will be calculated. The highest-scoring research questions will be selected. The final number of research priorities will be decided in the consensus meeting.

Consensus meeting

The final list of priorities obtained from the modified Delphi study will be discussed either in a face-to-face or virtual consensus meeting including a pre-selected group of UK stakeholders (Figure 1b). The meeting will include 12 participants adhering to the OMERACT guidelines for the consensus meeting structure.[25] Informed consent will be assumed if participants agree to take part in the final consensus meeting.

The meeting will be chaired by an independent researcher who is familiar with the Delphi process and did not participate in the voting procedure. Before the meeting, participants will be able to review the score of the outcomes from the modified Delphi survey and the data will then be discussed during the consensus meeting following four steps (Figure 1b): 1) presentation of the results from the Delphi survey; 2) group discussion; 3) scoring of each outcome by the participants (using an online platform, COMET Initiative);[26] and 4) formal endorsement (sign off) of the final priorities by all participants in the consensus meeting.

A report of the consensus meeting will be written and published on the BSCOS website and in the scientific literature. The findings will be disseminated to the BSCOS, the APCP at their annual meeting, and other organizations (Clubfoot international conference, Clubfoot Special Interest Networks).

Discussion

For children with clubfoot, the Ponseti method of casting followed by tenotomy and bracing is considered the gold-standard intervention.[4,6-9] However, outcomes still vary, and a considerable proportion of feet relapse as the child grows, interfering with function and comfort.[7,10,13] Knowledge deficits remain in diagnostics, variation in presentation, natural history, timing and type of interventions, as well as functional outcomes.[5,10,12,18] These factors may contribute to the varying intervention techniques and timings across different geographical locations.

Managing clubfoot is a continuous process throughout childhood due to the risk of relapse necessitating various interventions at different stages.[7,10,13,18] Identifying risk factors for recurrence, determining the most effective strategies to maintain correction, and selecting appropriate interventions at each stage are crucial for effective long-term management. High-quality research is essential to guide decision-making at these critical points.[27]

Multicentre prospective studies have been recommended to improve our understanding of this condition and optimize intervention pathways.[10] With greater knowledge, we can improve long-term outcomes.[27] Prioritising the open research questions around the management of clubfoot with input from patients, carers, and clinicians with expertise in treating children with clubfoot, and from different geographical locations will help steer future research studies. The findings from this modified Delphi process will inform clinicians, academics, and funders in designing clinical trials aimed at strengthening the evidence base and enhancing our understanding and treatment of clubfoot.

Social media

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Ethical review statement

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