Paediatric Lower Limb Surgery
Priority Setting Partnership

PROTOCOL 25.09.2017

1. Purpose of the PSP and background

The purpose of this protocol is to set out the aims, objectives and commitments of the Paediatric Lower Limb Surgery (PLLS) Priority Setting Partnership (PSP) and the basic roles and responsibilities of the partners therein. The Protocol will be reviewed by the Steering Group and updated on at least a quarterly basis.

The James Lind Alliance (JLA) is a non-profit making initiative, established in 2004. It brings patients, carers and clinicians together in Priority Setting Partnerships (PSPs). These partnerships identify and prioritise uncertainties, or 'unanswered questions', about the effects of treatments that they agree are the most important. The aim of this is to help ensure that those who fund health research are aware of what really matters to both patients and clinicians. The National Institute for Health Research (NIHR – www.nihr.ac.uk) funds the infrastructure of the JLA to oversee the processes for priority setting partnerships, based at the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), University of Southampton.

Contrary to adult orthopaedics, the orthopaedic surgical practice in children is not based on good quality evidence. Treatment is often empirical rather than based on good quality research. The conditions treated are often responsible for long term impairment and disability. The results of treatment in children are influenced by growth and development. Therefore, the treatment outcome is often unclear in the short-term, whilst long-term studies are lacking.
Both the professional society (British Society of Children's Orthopaedic Surgery – BSCOS) and the relevant Parent/Patient Charity (STEPS - http://www.steps-charity.org.uk/) have recognised the need for research in this field of paediatric orthopaedics and understand the importance of setting priorities for research as the first step in this direction. To this effect, BSCOS, the British Orthopaedic Association (BOA) and the Oxford Biomedical Research Centre have jointly agreed to fund this partnership and support the setting of priorities for research in this field.

2. Aims and objectives of the (health problem) PSP

The aim of the PLLS PSP is to identify the unanswered questions about ***elective (planned) lower limb (hips to toes) surgery in children with orthopaedic problems*** from both the patient and clinical perspectives and then prioritise those that patients and clinicians agree are the most important. Orthopaedic problems of the lower limbs caused by conditions affecting other parts of the body (e.g. brain or spine) will be included in this PSP.

There is considerable common ground in paediatric orthopaedic conditions that affect the lower limb(s): deformity, joint stiffness, pain and impaired mobility are the usual problems associated with these conditions. Examples include -but are not limited to- developmental hip dysplasia, clubfoot, congenital limb deficiencies, neuromuscular conditions and bone dysplasias. Rare conditions that may affect the lower limbs would be all included. Although the aetiology of these conditions varies considerably, the clinical problems and the resulting motor disability are similar and this is what matters from the patient/family perspective. Clinical problems where the choice between orthopaedic surgery and non-surgical treatment is difficult represent a challenge for patients and families and should also be considered. The clinical subject of this work should be clearly identifiable.

From the clinical perspective, stakeholders would include paediatric orthopaedic surgeons represented by the national organisation BSCOS; paediatric physiotherapists through their national representatives; allied health professionals / nurse specialists represented by their national body. The main Patient organisation relevant to this partnership is STEPS, a Charity supporting children and families affected by lower limb conditions. Additional input from other patient/parent/carer organisations relevant to specific lower limb conditions in childhood will be sought. These organisations will be identified, listed and contacted. All members of the Steering Group will approach potential stakeholders to input to this PSP and promote the survey.

Trauma to the lower limb is excluded from this PSP and could be the subject of a future PSP. Upper limb and spinal orthopaedic or traumatic conditions cause a different type of disability and should not be included in the scope of this PSP

The objectives of the PLLS PSP are to:

- work with patients, carers and clinicians to identify uncertainties about the effects of lower limb orthopaedic surgery in children. The age frame considered is between 0-16 years. Appropriate safeguarding and consent consideration will be given to this age group by the SG.
- to agree by consensus a prioritised list of those uncertainties, for research
- to publicise the results of the PSP and process
- to take the results to research commissioning bodies to be considered for funding.

3. The Steering Group

The PLLS PSP will be led and managed by the following:

Patient representative/s:
Representing STEPS Charity:

Loredana Guetg-Wyatt (loredana@steps-charity.org.uk)

Emma Morley (emma.morley@steps-charity.org.uk)

Representing Patients, Parents and Action CP:

Helen Gregory-Osborne (helen.gregoryosborne@btinternet.com)

Catherine-Ann Geaves (catherineann@lifesbackup.com)

Bert Martin (bert.martin@hotmail.co.uk)

Clinical representative/s:
Representing Paediatric Orthopaedic Surgeons:

Daniel Perry (danperry@doctors.org.uk)

Andreas Roposch (a.roposch@ucl.ac.uk)

Nicolas Nicolaou (Nicolas.Nicolaou@sch.nhs.uk)

Stephen Cooke (stephen.cooke@uhcw.nhs.uk)

Representing Allied Health Professionals:

Elizabeth Wright (Elizabeth.Wright@uhs.nhs.uk)

Craig Walsh (Craig.Walsh@ouh.nhs.uk)

Representing Physiotherapists?:

Catherine Barry (Catherine.barry@ouh.nhs.uk)

Christine Douglas (Christine.Douglas@rnoh.nhs.uk)

The Partnership and the priority setting process will be supported and guided by:

- The James Lind Alliance (JLA)
    - Patricia Ellis

The Steering Group includes representation of patient/carer groups and clinicians.

The Steering Group will agree the resources, including time and expertise that they will be able to contribute to each stage of the process. The JLA will advise on this.

4. The wider Partners

Organisations and individuals will be invited to be involved with the PSP as partners. Partners are groups or individuals who will commit to supporting the PSP by disseminating the PSP survey and helping the PSP to gather questions and uncertainties of practical clinical importance relating to the treatment and management of the health problem in question. Partners represent the following groups:

- people who have had conditions that have required elective (planned) lower limb orthopaedic surgery
- carers of people who have had elective (planned) lower limb orthopaedic surgery
- medical doctors, nurses and professionals allied to medicine with clinical experience of paediatric orthopaedic surgery to the lower limbs

Children and young people under the age of 16 years will be encouraged to voice their views separately to those of their parents. During the survey period, parents will be asked to encourage their children to fill in a separate survey form. By inviting children to participate via their parents (or legal guardians) we will ensure that issues of consent and safeguarding do not arise.

It is important that all organisations, which can reach and advocate for these groups should be invited to become involved in the PSP. The JLA Adviser will take responsibility for ensuring the various stakeholder groups are able to contribute equally to the process.

Exclusion criteria
Some organisations may be judged by the JLA or the Steering Group to have conflicts of interest. These may be perceived to adversely affect those organisations' views, causing unacceptable bias. As this is likely to affect the ultimate findings of the PSP, those organisations will not be invited to participate. It is possible, however, that interested parties may participate in a purely observational capacity when the Steering Group considers it may be helpful.

5. The methods the PSP will use

This section describes a schedule of proposed stages through which the PSP aims to fulfil its objectives. The process is iterative and dependent on the active participation and contribution of different groups. The methods adopted in any stage will be agreed through consultation between the Steering Group members, guided by the PSP's aims and objectives. More details can be found in the Guidebook section of the JLA website at www.jla.nihr.ac.uk where examples of the work of other JLA PSPs can also be seen.

Step 1: Identification and invitation of potential partners

Potential partner organisations will be identified through a process of peer knowledge and consultation, through the Steering Group members' networks. Potential partners will be contacted and informed of the establishment and aims of the PLLS PSP. As a first step in this direction, TT will circulate an initial list of potential stakeholders as developed in the first SG meeting. The members of the SG will expand the list with further potential partners. Further to that, the SG members will contact potential stakeholders to raise interest and identify any deadlines for publicity specific to their organisations.

Step 2: Awareness raising [1]

Awareness will be raised through communication with all potential partners, using a communication package and will have several key objectives:

- to welcome and introduce potential members of the PLLS PSP
- to present the proposed plan for the PSP
- to initiate discussion, answer questions and address concerns
- to identify those potential partner organisations which will commit to the PSP and identify individuals who will be those organisations' representatives and the PSP's principal contacts
- to establish principles upon which an open, inclusive and transparent mechanism can be based for contributing to, reporting and recording the work and progress of the PSP

Step 3: Identifying treatment uncertainties

Each partner will identify a method for soliciting from its member's questions and uncertainties of practical clinical importance relating to the treatment and management of lower limb orthopaedic conditions in childhood (please see part 2 above for details). A period of **4 months** will be given to complete this survey.

The methods may be designed according to the nature and membership of each organisation, but must be as transparent, inclusive and representative as practicable. Methods may include membership meetings, email consultation, postal or web-based questionnaires, internet message boards and focus group work.

It was agreed at the first SG meeting that "Survey Monkey" possibly linked to social media would be an optimal way of communication. However, a survey in paper form should also be available to those who prefer it. It was also agreed to personalise requests for the survey as much as possible in order to increase response rate. Consideration will be given to surveying patients in clinics. The HRA on-line decision tree confirmed that this does not require ethical approval but Trust R&D departments should be informed that this survey is undertaken. It was agreed that no launching meeting will be held.

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[1] PSPs will need to raise awareness of their proposed activity among their patient and clinician communities, in order to secure support and participation. Depending on budget this may be done by way of a face-to-face meeting, or there may be other mechanisms by which the process can be launched.

Existing sources of information about treatment uncertainties for patients and clinicians will be searched. These can include question-answering services for patients and carers and for clinicians; research recommendations in systematic reviews and clinical guidelines; protocols for systematic reviews being prepared and registers of ongoing research. In particular, it was agreed that the relevant SG members will seek “frequently asked questions” list from STEPS and Action Cerebral Palsy. Further to that, the Journal of Bone and Joint Surgery will be searched for previous work identifying gaps of knowledge in paediatric orthopaedics.

The starting point for identifying sources of uncertainties and research recommendations is NHS Evidence: www.evidence.nhs.uk.

Step 4: Refining questions and uncertainties

The Steering Group will need to have agreed exactly who will be responsible for this stage – the JLA can advise on the amount of time likely to be required for its execution. The JLA will participate in this process as an observer, to ensure accountability and transparency.

The consultation process will produce “raw” unanswered questions about diagnosis and the effects of treatments. These raw questions will be assembled and categorised and refined by Tim Theologis into “collated indicative questions” which are clear, addressable by research and understandable to all. Similar or duplicate questions will be combined where appropriate.

Systematic reviews and guidelines will be identified and checked by the BSCOS Research Committee and Tim Theologis to see to what extent these refined questions have, or have not, been answered by previous research. Sometimes, uncertainties are expressed that can in fact be resolved with reference to existing research evidence - ie they are "unrecognised knowns" and not uncertainties. If a question about treatment effects can be answered with existing information but this is not known, it suggests that information is not being communicated effectively to those who need it. Accordingly, the JLA recommends strongly that PSPs keep a record of these 'answerable questions' and deal with them separately from the 'true uncertainties' considered during the research priority setting process.[2]

Uncertainties which are not adequately addressed by previous research will be collated and recorded on a template supplied by the JLA) by Tim Theologis. This will demonstrate the checking undertaken to make sure that the uncertainties have not already been answered. This is the responsibility of the Steering Group, which will need to have agreed personnel and resources to carry this accountability. The data should be submitted to the JLA for publication on its website on completion of the priority setting exercise, taking into account any changes made at the final workshop, in order to ensure that PSP results are publicly available.

Step 5: Prioritisation – interim and final stages

The aim of the final stage of the priority setting process is to prioritise through consensus the identified uncertainties relating to the treatment or management of paediatric lower limb orthopaedic surgery. This will be carried out by members of the Steering Group and the wider partnership that represents patients and clinicians.

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[2] Steering Group members should insert information on how they intend to do this.

- The interim stage, to proceed from a long list of uncertainties to a shorter list to be discussed at the final priority setting workshop (e.g. up to 30), may be carried out over email or online, whereby organisations consult their membership and choose and rank their top 10 most important uncertainties. There are examples of how other PSPs have achieved this at www.jla.nihr.ac.uk in the Key Documents of the Anaesthesia and Perioperative Care PSP section and the Childhood Disability PSP section.

- The final stage, to reach, for example, 10 prioritised uncertainties, is likely to be conducted in a face-to-face meeting, using group discussions and plenary sessions.

- The methods used for this prioritisation process will be determined by consultation with the partner organisations and with the advice of the JLA Adviser. Methods which have been identified as potentially useful in this process include: adapted Delphi techniques; expert panels or nominal group techniques; consensus development conference; electronic nominal group and online voting; interactive research agenda setting and focus groups.

The JLA will facilitate this process and ensure transparency, accountability and fairness. Participants will be expected to declare their interests in advance of this meeting.

Time Frames

Preparation for Survey and Awareness Raising completed by 1.01.18
Roll out Survey in January 2018
Close Survey by end February 2018
Work on data to be completed by 31.05.18
Interim Prioritisation to start 1.06.18
Final prioritisation meeting on 5th November 2018

6. Dissemination of findings and research

Findings and research
It is anticipated that the findings of the PLLS PSP will be reported to funding and research agenda setting organisations such as the NIHR and the major research funding charities. Steering Group members and partners are expected to develop the prioritised uncertainties into research questions, and to work to establish the research needs of those unanswered questions to use when approaching potential funders, or when allocating funding for research themselves, if applicable.[3]

Publicity
As well as alerting funders, partners and Steering Group members are encouraged to publish the findings of the PLLS PSP using both internal and external communication mechanisms. The Steering Group may capture and publicise the results through descriptive reports of the process itself in Plain English. This exercise will be distinct from the production of an academic paper, which the partners are also encouraged to do. However, production of an academic paper should not take precedence over publicising of the final results.

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[3] Add further detail here about how and where the priorities will be developed and researched.

7. Agreement of the Steering Group

Signed by the Steering Group

The undersigned agree to follow the Paediatric Lower Limb Surgery Priority Setting Protocol.

[Insert name and organisation]

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Date: ………………………………………..

[Insert name and organisation]

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Date: ………………………………………..

[Insert name], The James Lind Alliance

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Date: ………………………………………..