Mild to Moderate Hearing Loss Priority Setting Partnership

PROTOCOL February 2015

Purpose
The purpose of this protocol is to set out the aims, objectives and commitments of the Mild to Moderate Hearing Loss Priority Setting Partnership (PSP) and the basic roles and responsibilities of the partners therein.

Steering Group
The Mild to Moderate Hearing Loss PSP will be led and managed by the following:

**Patient representative/s:**
- Hearing Link
  - Linda Sharkey (UK Director, User Organisation Representative)
- NIHR Nottingham Hearing Biomedical Research Unit
  - Dr Helen Henshaw (Senior Research Fellow, PSP Coordinator)
  - Dr Melanie Ferguson (Consultant Clinical Scientist (Audiology), BRU Research Lead, Habilitation for Hearing Loss)
- Action on Hearing Loss (AoHL)
  - Gemma Twitchen (Senior Audiology Specialist)
    Deputised where required by Louise Hart (Audiology Specialist)
- UK Cochrane Centre
  - Sarah Chapman (Knowledge Broker and patient/public representative)
- Jean Straus
  - Patient/public representative
- Robin Wickes
  - Patient/public representative

**Clinical representative/s:**

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1 This is a generic protocol which should be updated to include the names and details of the Steering Group members. The document may be modified with agreement from the JLA to reflect the make-up of different PSPs and the organisations driving them.
The Partnership and the priority setting process will be supported and guided by:

- The James Lind Alliance (JLA)
  - David Crowe (JLA Advisor)

The Steering Group includes representation of patient/carer groups and clinicians.2

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.

Background to the Mild to Moderate Hearing Loss PSP

The JLA is a project which is overseen by the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC). Its aim is to provide an infrastructure and process to help patients and clinicians work together to agree which are the most important treatment uncertainties affecting their particular interest, in order to influence the prioritisation of future research in that area. The JLA defines an uncertainty as a “known unknown” – in this case relating to the effects of treatment.

All of us will be impacted, either directly or indirectly, by hearing difficulties and subsequent difficulties in communication. In 2004 the World Health Organisation (WHO) reported that over 275 million people had a significant hearing impairment,1 with adult-onset hearing loss representing the 13th most common disease burden worldwide. Currently in the UK there are an estimated 10 million people with significant hearing loss, predicted to rise to 14.5 million people over the next 20 years.2,3. The majority (92.2%) of those with hearing loss experience mild or moderate losses.3. Hearing loss is associated with difficulties with employment, depression, social isolation, reduced quality of life.4. Although there are established treatments for hearing loss that aim to improve hearing function, we still do not understand the full impact of these, nor patient preferences for available treatment options. In the majority of cases, hearing loss is incurable. As such, ‘treatment’ in this PSP will refer to the management and self-management of the difficulties arising from mild-moderate hearing loss.

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1 In some cases, it has been suggested that researchers are represented at this level, to advise on the shaping of research questions. However, researchers cannot participate in the prioritisation exercise. This is to ensure that the final prioritised research questions are those agreed by patients, carers and clinicians only, in line with the JLA’s mission.

James Lind Alliance: Mild to Moderate Hearing Loss Priority Setting Partnership Protocol_V4_25.02.15
The provision of hearing aids is the most common management option for people with mild to moderate hearing loss. Yet, the uptake of hearing aids is low, with just 20% of people with hearing loss in the UK owning them [2]. Of those who do own them, between 15%-30% do not wear their hearing aids regularly [2,5]. On average it takes over 10 years for people with hearing loss to seek help [4]. Untreated hearing loss has a substantial social impact for not only the person with hearing loss, but also those with whom they communicate [6-7]. Early intervention and appropriate management of hearing difficulties can help reduce the impact of hearing loss [4].

Disability-adjusted life years (DALYs) are a measure of disease burden in terms of the number of years lost to disability or ill health. Despite hearing loss being one of six priority areas of the National Institute for Health Research (NIHR) agenda, just £47 per DALY is spent on hearing research, which is significantly less than the amount spent on other priority areas such as cardiovascular disease (£99/DALY), sight loss (£100/DALY), and diabetes (£399/DALY) [8]. Given the proportionally limited funding available it is of paramount importance that research is informed and guided by patient need. This will help ensure that research is protected from avoidable waste in terms of inadequate focus and outcomes [9].

Patients and clinicians can play an active role in research [10], but to contribute effectively, they need to have sufficient knowledge about how reliable information about the effects of treatments is generated [11]. The first step in this process is to establish and reliably understand uncertainties surrounding treatment effects. The James Lind Initiative (JLI) was established in 2003 in response to a call by the Medical Research Council, to promote public engagement in research. The JLI established the James Lind Alliance (JLA) Priority Setting Partnerships (PSPs) provide a formal structure within which patients and clinicians can identify treatment uncertainties and agree priorities for research [12]. In 2006, the UK Database of Uncertainties about the Effects of Treatments (UK DUETs), part of the National Institute for Clinical Excellence (NICE), was launched. This database was designed to capture, publish and publicise treatment uncertainties, therefore making them widely available to government, research commissioners and research funders, to inform policy and practice.

The Mild to Moderate Hearing Loss PSP was initiated by the NIHR Nottingham Hearing Biomedical Research Unit, in collaboration with Hearing Link (the user organisation), in May 2014. The PSP aims to identify unanswered questions (uncertainties) about the cause, diagnosis, treatment (management or self-management) and outcomes for mild to moderate hearing loss, and for patients and clinicians to prioritise these unanswered questions for research.

**Aims and objectives of the Mild to Moderate Hearing Loss PSP**
The aim of the Mild to Moderate Hearing Loss PSP is to identify the unanswered questions about the treatment of mild to moderate hearing loss from patient and clinical perspectives and then prioritise those questions that patients and clinicians agree are the most important.

The objectives of the Mild to Moderate Hearing Loss PSP are to:

- work with patients and clinicians to identify uncertainties about the cause, diagnosis, treatment and outcomes for mild to moderate hearing loss
- 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.
Partners
Organisations and individuals will be invited to take part in the PSP, which represent the following groups:

- people who have mild to moderate hearing loss (either diagnosed or undiagnosed)
- those who communicate regularly with people who have mild to moderate hearing loss (e.g. friends and family members)
- medical doctors, audiologists and other healthcare professionals with clinical experience of mild to moderate hearing loss.

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 will take responsibility for ensuring the various stakeholder groups are able to contribute equally to the process.

Organisations wishing to participate in the PSP will be asked to affiliate to the JLA in order to demonstrate their commitment to the aims and values of the JLA. Details on the affiliation procedure can be found at www.lindalliance.org.

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.

METHODS
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 partners, guided by the PSP’s aims and objectives. More details and examples can be found at www.JLAguidebook.org.

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 and through the JLA’s existing register of affiliates. Potential partners will be contacted and informed of the establishment and aims of the Mild to Moderate Hearing Loss PSP and invited to attend and participate in an initial stakeholder meeting.

The Steering Group should draft the invitation, and an agreement should be reached as to the best organisation to distribute it.
2. Initial stakeholder meeting / awareness raising

The initial stakeholder meeting / awareness raising will have several key objectives:

- to welcome and introduce potential members of the Mild to Moderate Hearing Loss 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

The administrative process for convening this meeting will be managed by the Steering Group with input from the JLA.

3. Identifying treatment uncertainties

Each partner will identify a method for soliciting from its members questions and uncertainties of practical clinical importance relating to the treatment of mild to moderate hearing loss. A period of [6 weeks] will be given to complete this exercise.

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.

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.

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

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 [researchers at the NIHR Nottingham Hearing Biomedical Research Unit] into “collated indicative questions” which are clear, addressable by research and understandable to all. Similar or duplicate questions will be combined where appropriate.
The existing literature will be researched by [researchers at the NIHR Nottingham Hearing Biomedical Research Unit] 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.4

Uncertainties which are not adequately addressed by previous research will be collated and prepared for entry into a mild to moderate hearing loss section within the UK Database of Uncertainties about the Effects of Treatments (UK DUETs - www.library.nhs.uk/duets) by [researchers at the NIHR Nottingham Hearing Biomedical Research Unit]. This will ensure that the uncertainties have been actually checked to be uncertainties. 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 entered into UK DUETs on completion of the priority setting exercise, in order to ensure any updates or changes to the data have been incorporated beforehand.

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 mild to moderate hearing loss. This will be carried out by members of the Steering Group and the wider partnership that represents patients and clinicians.

The interim stage, to proceed from a long list of uncertainties to a shorter list (e.g. up to 20), may be carried out over email, whereby organisations consult their membership and choose and rank their top 10 most important uncertainties.

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. 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.

Findings and research
It is anticipated that the findings of the Mild to Moderate Hearing Loss PSP will be reported to funding and research agenda setting organisations such as the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), which includes the HTA Programme, and the MRC, as well as the major research funding charities. Steering Group members and partners are encouraged to develop the prioritised uncertainties into research questions, and to work to establish the research needs of

4 Steering Group members should insert information on how they intend to do this.
those unanswered questions to use when approaching potential funders, or when allocating funding for research themselves, if applicable.\(^5\)

**Publicity**
As well as alerting funders, partners and Steering Group members are encouraged to publish the findings of the Mild to Moderate Hearing Loss PSP using both internal and external communication mechanisms. The JLA may also capture and publicise the results, through descriptive reports of the process itself. 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.

\(^5\) Add further detail here about how and where the priorities will be developed and researched.
Signed by the Steering Group

The undersigned agree to follow the Mild to Moderate Hearing Loss Priority Setting Protocol.

Linda Sharkey, Hearing Link

Date: ...........................................

Dr Helen Henshaw, NIHR Nottingham Hearing Biomedical Research Unit

Date: ...........................................

Dr Melanie Ferguson, NIHR Nottingham Hearing Biomedical Research Unit

Date: ...........................................

Gemma Twitchen, Action on Hearing Loss

Date: ...........................................

Sarah Chapman, UK Cochrane Centre

Date: ...........................................
Jean Straus, Patient

Date: ............................................

Robin Wickes, Patient

Date: ............................................

Dr Helen Pryce, British Society of Audiology

Date: ............................................

Dr Vinaya Manchaiah, British Academy of Audiology

Date: ............................................

Barry Downes, British Society of Hearing Aid Audiologists

Date: ............................................
Natalie Bohm, ENT

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Date: ………………………………………..

TBD, GP

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Date: ………………………………………..

David Crowe, The James Lind Alliance

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Date: ………………………………………..
References


11. Crowe S, Fenton M, Hall M, Chalmers I. (Submitted). Researchers are not addressing the needs of patients and clinicians. Submitted to BMJ.