

## **Cystic Fibrosis Priority Setting Partnership**

**PROTOCOL [5 February 2016]**

### **1. Purpose of the PSP and background**

The purpose of this protocol is to set out the aims, objectives and commitments of the Cystic Fibrosis Priority Setting Partnership (PSP) and the basic roles and responsibilities of the partners therein. It is recommended that the Protocol is 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 JLA is coordinated and overseen by the National Institute for Health Research ([NIHR](#)) Evaluation, Trials and Studies Coordinating Centre ([NETSCC](#)), based in Southampton.

The JLA PSP in Cystic Fibrosis (CF) came about through discussions between the chief investigator (Prof Alan Smyth), a person with CF (Oli Rayner) and the CF Trust. Oli Rayner has, until recently, been Cystic Fibrosis Trust Special Adviser on Research & Patient Involvement. The CF Trust has funded the PSP, through its Venture and Innovation Awards, with matched funding from the University of Nottingham and the Nottingham University Hospitals (NUH) Charity. Dr Keith Brownlee (Director of Impact at the CF Trust) has taken part in early discussions about the PSP and is a member of the steering committee. Dr Matt Hurley, established the CF Unite website (<http://cfunite.org>) - a collaborative platform which has hosted web based interactive seminars, where researchers and patients with CF can discuss research in the field of CF. The JLA PSP in CF is distinct from previous PSPs in that patient participants cannot meet together in person because of the risk of cross infection. Hence, CF Unite platform, developed by Dr Hurley, will allow online communication within the CF community as the PSP progresses.

### **2. Aims and objectives of the Cystic Fibrosis PSP**

The aim of the CF PSP is to identify the unanswered questions about CF treatment from patient and clinical perspectives and then prioritise those that patients and clinicians agree are the most important.

The objectives of the CF PSP are to:

- work with patients and clinicians to identify uncertainties about the effects of CF treatments
- 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 CF PSP will be led and managed by the following:

Patient representative/s:

- Oli Rayner (Independent Patient Representative)
- Katie Gathercole (Independent Patient Representative)
- Zoe Elliott (Parent of child with CF)
- Jess Nickless (Parent of child with CF)
- Kirsty Widdowson (Young persons advisory group leader)
- Keith Brownlee (CF Trust)

Clinical representative/s:

- Alan Smyth (Respiratory Paediatrician)
- Tracey Daniels (CF Physiotherapist)
- Edward Nash (Adult Chest Physician)
- Sarah Collins (CF Dietician)
- Beverley Govin (CF Nurse)
- Alastair Duff (CF Clinical Psychologist)
- Keith Thompson (CF Pharmacist)
- Matthew Hurley (Specialist Trainee in Paediatric Respiratory Medicine)
- Ursula People (CF Commissioner)

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

- University of Nottingham
  - Margaret McPhee (PSP Coordinator)
  - Nicola Rowbotham (Academic Clinical Fellow)
  - Sherie Smith (Cochrane Systematic Reviewer)
  - Paul Leighton (Qualitative Researcher)
- The James Lind Alliance (JLA)
  - Richard Morley

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 CF

- family and friends of people who have CF
- medical doctors, nurses and professionals allied to medicine with clinical experience of treating CF.

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 at [www.JLAGuidebook.org](http://www.JLAGuidebook.org) and examples of the work of other JLA PSPs can be seen in the 'The PSPs' section of the JLA website at [www.jla.nihr.ac.uk](http://www.jla.nihr.ac.uk)

### **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 CF PSP and may be invited to attend and participate in an initial stakeholder meeting if this is being arranged.

### **Step 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 CF 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 members questions and uncertainties of practical clinical importance relating to the treatment and management of CF. A period of **12 months** 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](http://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 **Margaret McPhee, Sherie Smith and Nicola Rowbotham** 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 **Nicola Rowbotham and Sherie Smith** 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. These “answerable questions” will be collated by the PSP team and communicated to the Cochrane CF & Genetic Disorders Group and the CF Trust at the end of the process – for onward dissemination to the CF community. They may also be the subject of a separate publication.

Uncertainties which are not adequately addressed by previous research will be collated and prepared for entry onto the James Lind Alliance website by **Sherie Smith and Margaret McPhee**. 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 onto the JLA website on completion of the priority setting exercise, in order to ensure any updates or changes to the data have been incorporated beforehand.

#### **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 CF. 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 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](http://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 an online 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.

## 6. Dissemination of findings and research

### **Findings and research**

It is anticipated that the findings of the CF 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.

### **Publicity**

As well as alerting funders, partners and Steering Group members are encouraged to publish the findings of the CF 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.

## 7. Agreement of the Steering Group

### Signed by the Steering Group

The undersigned agree to follow the CF Priority Setting Protocol.

University of Nottingham School of Medicine and Nottingham University Hospitals NHS Trust

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Date: .....

Cystic Fibrosis Trust

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Date: .....

Richard Morley, The James Lind Alliance

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Date: .....