

Advanced Heart Failure Priority Setting Partnership

PROTOCOL V1.5 13.03.18

1. Purpose of the PSP and background

The purpose of this protocol is to set out the aims, objectives and commitments of the Advanced Heart Failure 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 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.

Heart failure (HF) is a common condition affecting 1–2% of adults in the developed world, with a prevalence greater than 10% in older adult cohorts. Mortality rates are comparable to many cancers and HF is a common cause of unscheduled admissions. Despite high mortality, it is often difficult to predict when people with HF are reaching the end of their life, which has been shown to hinder advance care planning and proactive end of life management. There have been significant improvements in the treatment of HF especially through use of medications and cardiac devices overall, although trials of treatments for HF recruited predominantly younger patients without co-morbidity in specialist settings. The majority of people with HF are community dwelling older people with multiple co-morbidities who are under-represented in trials. These treatments may not be appropriate for these patients or might leave patients with refractory symptoms or other difficulties such as their ability to carry out activities of daily living or care for themselves. This group of patients also require frequent hospital admission which can be stressful for the patient, and their carer, and costly to the healthcare economy. National and international guidance recommend a palliative or supportive approach for patients with advanced HF, but the details of how to implement this are uncertain. There are many areas of healthcare where the right treatment approach is unclear. Traditionally, researchers search out these areas, formulate the research questions they feel are most important and apply to funders to undertake work which will provide an answer. The JLA believes that where uncertainties exist, it is most beneficial to bring together those directly involved, particularly patients with the condition, their carers and clinicians, to determine the key priorities for future research. Otherwise, questions which are most important to patients and the doctors caring for them may be overlooked.

The scope of this PSP will be the management of adults (age 18 and over) with Advanced HF. This will include physical health (symptoms, treatments), emotional wellbeing and services/support. The PSP will not cover diagnosis of HF. There is no universally agreed definition for advanced HF either within the clinical community or amongst patient and carer groups. For the purposes of this PSP, we have defined the scope as below, with appropriate wording for patients and carers and the clinicians:

Heart failure is a condition where the heart struggles to pump blood around the body. Patients can feel breathless, tired and have swollen ankles but with the right treatment these symptoms usually improve. We want to find out what research is needed to help people with 'advanced' heart failure who are living in the

community. By this we mean people who know they have heart failure, may have had it for time and find their condition has a significant impact on their life. They may need to take a lot of medication, or have needed hospital admission because of their heart failure, but are not currently in hospital. (Patient/Carer)

Heart failure is a clinical syndrome where the heart is unable to pump sufficient blood around the body leading to symptoms of breathlessness, ankle swelling and fatigue. We want to find out what research is needed for people with 'advanced' heart failure. There is no universally agreed definition of 'advanced' amongst professional groups. For example, specialist cardiologists may recognise 'advanced' as patients requiring tertiary referral for consideration of devices or transplantation whilst generalists, such as geriatricians or GPs, may consider 'advanced' heart failure in those patients with significant and progressive symptoms also in the context of frailty, multimorbidity and polypharmacy. Our agreed definition is a person with a known diagnosis of heart failure who has symptoms, such as breathlessness, which impact on what they are able to do, require them to take multiple medications and may have required admission to hospital but are not currently an inpatient. (Clinician)

Patients with advanced HF are also not commonly identified by non-disease specific primary care supportive or palliative care registers. We will use methods of identification that will as far as possible uncover this partially "hidden" population. We will access patients with advanced HF via a variety of routes including through generalists working in the community (including GPs, district nurses and community matrons), HF services (including HF nurse specialists and community cardiologists) and local and national patient organisations to establish their views on what research questions are most important to them.

The core team leading the PSP includes two academic GPs with a research interest in HF, a consultant in Palliative Medicine, an information specialist, a senior advisor to the Cochrane Collaboration and a hospice-based HF nurse specialist. The team have expertise in researching and managing patients with advanced HF.

2. Aims and objectives of the Advanced Heart Failure PSP

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

The objectives of the Advanced Heart Failure PSP are to:

- work with patients and clinicians to identify uncertainties about the effects of advanced HF 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 Advanced Heart Failure PSP will be led and managed by the following:

PSP lead Oxford (GP)	Clare Taylor
PSP co-ordinator	Sarah Morrish
PSP lead Bristol (GP)	Rachel Johnson
Information specialist	Alyson Huntley

Patient representative/s:

Patient and Pumping Marvellous charity	Daniel Smith
Patient	Richard Morley
Patient	Annette Tremlin
Patient (remote member)	John Burden
Carer (+/- patient: mother)	Jennifer Bostock
Carer	Deb Smith

Clinical representative/s:

HF nurse specialist	Bev Mumford
HF nurse specialist (pall care)	Mary Brice
Cardiologist	Eleanor Wicks
Geriatrician	Kit Byatt
Palliative medicine consultant	Amy Gadoud
GP	Sara McKelvie

Observers:

Observer (retired GP and researcher)	Richard Lehman
Observer (academic GP trainee)	Nick Jones

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

- The James Lind Alliance (JLA)
 - Toto Anne Gronlund

The Steering Group includes representation of patient/carers groups and clinicians¹.

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:

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: Priority Setting Partnership Protocol – January 2016

- people who have had advanced HF
- carers of people who have had advanced HF
- medical doctors, nurses and professionals allied to medicine with clinical experience of advanced HF.

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 Advanced Heart Failure 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 ²

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

- to welcome and introduce potential members of the Advanced Heart Failure 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.

² 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.

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 advanced HF. A period of three months will be given to complete this exercise.

The uncertainties in managing patients with advanced HF will be identified through two routes: an online survey and a review of the literature. The online survey will be hosted by the Primary Care Health Sciences website at the University of Oxford but have a web address which is easy to remember. Each member of the steering group will facilitate the completion of the survey by partners in their networks. For example, patient groups may wish to include an e-mail link to the survey in their newsletter or on their social media page and clinicians could display posters in their HF clinics. Twitter will also be used by the project leads to promote the survey more widely. Paper surveys will be available, including a return freepost address, for those unable to use the electronic format.

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.

Step 4: Refining questions and uncertainties

The Advanced HF PSP information specialist Dr Alyson Huntley, in collaboration with the Steering Group, will be responsible for this stage. 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 the information specialist 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 information specialist 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 - i.e. 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 Advanced Heart Failure PSP will keep a record of these 'answerable questions' and deal with them separately from the 'true uncertainties' considered during the research priority setting process.³

Uncertainties which are not adequately addressed by previous research will be collated and recorded on a template supplied by the JLA by the information specialist. This will demonstrate the checking undertaken to make sure that the uncertainties have not already been answered. The data will then 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 advanced HF. This will be carried out by members of the Steering Group and the wider partnership that represents patients and clinicians.

³ Steering Group members should insert information on how they intend to do this.
James Lind Alliance: Priority Setting Partnership Protocol – January 2016

- The interim stage will be to proceed from the longer list of uncertainties generated in Step 4 to a shorter list of up to 30 priorities. This will be done using a second ‘prioritisation’ survey. The third steering group meeting will be used to agree the long list of priorities, including appropriate wording and format, to be included. The survey will then be launched on the PSP website and partners from the wider network will be asked to rank the long list of uncertainties in the order of importance to them.
- The final stage will be conducted in a face-to-face meeting with 30 key stakeholders chosen by the steering group from their wider partner networks. This will start with a plenary session to present the short list of priorities generated by the interim prioritisation process. Then through group discussion, using the nominal group technique¹³ and facilitated by experienced JLA advisers, a top 10 list of prioritised uncertainties will be agreed.

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

The top 10 uncertainties will be published on the JLA website and disseminated to key stakeholders through the steering group member networks and the PSP website. All of the data from the PSP will be available to researchers.

A final steering group meeting will be held to develop the prioritised uncertainties into research questions. The findings of the Advanced Heart Failure PSP will then be reported to funding and research agenda setting organisations such as the NIHR and the major research funding charities including the British Heart Foundation.

Publicity

As well as alerting funders, partners and Steering Group members will disseminate the findings of the Advanced Heart Failure 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. The project leads will also write up and publish the key findings of the PSP. The research questions will be used to develop grant applications which will address the research questions arising from the priority setting exercise.

7. Agreement of the Steering Group

Signed by the Steering Group

The undersigned agree to follow the Advanced Heart Failure Priority Setting Protocol.

Clare Taylor, University of Oxford

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Date:

Rachel Johnson, University of Bristol

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Date:

Toto Anne Gronlund, The James Lind Alliance

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Date: