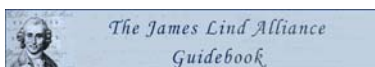


The James Lind Alliance Guidebook

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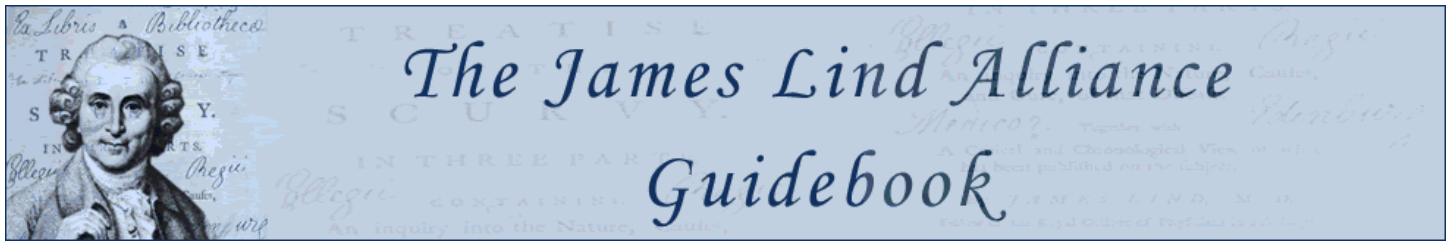
Written by Katherine Cowan and Sandy Oliver

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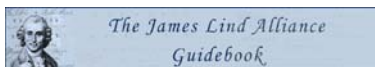
Welcome to the James Lind Alliance Guidebook.

The Guidebook provides step-by-step guidance to establishing Priority Setting Partnerships. These bring patients, their carers and clinicians together to identify and prioritise treatment uncertainties for research, using James Lind Alliance (JLA) methods.

This is the printable version of the Guidebook. The Guidebook, along with its links and downloadable documents, is also available online at www.JLAGuidebook.org.

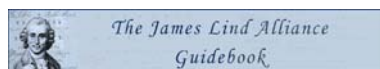
Contents

Section 1: INTRODUCTION	4
About the Guidebook.....	4
Introduction	4
Who is the Guidebook aimed at?	5
Using the Guidebook.....	5
The James Lind Alliance	6
Acknowledgements.....	7
Contact and feedback	7
About treatment uncertainties	7
What are treatment uncertainties?	8
The UK Database of Uncertainties about the Effects of Treatments (UK DUETs)	8
Section 2: HOW TO	9
How to establish a priority setting partnership	9
Overview of Priority Setting Partnerships.....	9
Who’s who in the Priority Setting Partnership?	11
Setting up the steering group	11
What does the steering group commit to?.....	12



Planning to work with UK DUETs	12
Identifying partners.....	13
Initial awareness meeting	14
Affiliation.....	16
Declaration of interests.....	16
Exclusions.....	16
Managing the partnership	17
Managing values and perspectives	17
Working with patients.....	18
Working with clinicians	19
Maintaining involvement and commitment	20
How to identify treatment uncertainties.....	21
Treatment uncertainties and the JLA process	21
Gathering treatment uncertainties.....	21
Patient-identified uncertainties	23
Clinician-identified uncertainties	24
Existing literature	24
Consent	25
Processing submitted uncertainties.....	25
Download the survey data	26
Remove out-of-scope submissions	27
Categorise eligible submissions	27
Format the submissions.....	28
Verify the uncertainties	30
Prepare the long-list of uncertainties	34
Preparing uncertainties for import into UK DUETs.....	35
How to prioritise uncertainties	37
The principles of JLA priority setting.....	38
Interim priority setting.....	38
Collating interim priorities	39
Final priority setting	41
Description of a final priority setting workshop	43

Final priority setting methods.....	46
Skills for setting research priorities.....	50
Transparency and fairness	51
How to evaluate	51
Why evaluate?	51
What and how to evaluate.....	51
Materials and events.....	52
Ways of working.....	52
Progress and achievements	55
After an evaluation	57
Ethics for setting research priorities.....	58
Participation ethics	58
Ethics when discussing rare conditions	58
Information ethics.....	59
Evaluation ethics	59
Ethics approval.....	60
How to take priorities to research funders.....	60
Getting research done	60
Finding appropriate funders	61
Opportunities to work with funders	61
Finding appropriate researchers.....	63
Opportunities to work with researchers.....	63
Influencing the wider research and policy community.....	63
How to publicise your priorities.....	64
Section 3: BACKGROUND	65
Why priority setting in research for health matters.....	65
Why set priorities for research; and why involve patients and clinicians?	65
Knowledge for developing research agendas.....	66
Priority setting within the UK health research system	66
Priority setting by research teams or priority setting for research teams?.....	67
A growing literature	68
Consultations for priority setting	68



Collaborations for priority setting.....	69
Resources.....	69
Bibliography	70
Links	73
Section 4: JLA PROTOCOL.....	76
Section 5: Annexes.....	81
Annexe 1: Template: steering group terms of reference	81
Annexe 2: Declaration of Interests forms	84
Annexe 3: Uncertainties form and survey template.....	90
Annexe 4: Interim prioritisation template.....	94

Section 1: INTRODUCTION

About the Guidebook

Introduction

Welcome to the James Lind Alliance Guidebook.

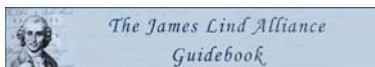
The Guidebook provides step-by-step guidance to establishing and managing Priority Setting Partnerships. These bring patients, their carers and clinicians together to identify and prioritise unanswered questions about the effects of treatments ('treatment uncertainties') for research, using James Lind Alliance (JLA) methods.

A key component of the Guidebook is the JLA **Protocol**. This is for Priority Setting Partnerships to follow if they want to work with the JLA.

Research on the effects of treatments often overlooks the shared priorities of patients, carers and clinicians. The pharmaceutical and medical technology industries and academia play essential roles in developing and testing new treatments, but their priorities are not necessarily the same as those of patients and clinicians. Many areas of potentially important research are therefore neglected.

Focusing on specific conditions, or areas of healthcare, the JLA facilitates Priority Setting Partnerships which:

- bring patient, carer and clinician groups together on an equal footing
- identify treatment uncertainties which are important to both groups
- work with both groups jointly to prioritise the uncertainties
- produce a 'top 10' list of jointly agreed uncertainties as research questions to be presented to funders



A growing body of research¹ suggests that bringing patients and clinicians together to prioritise questions in treatment uncertainty is rare.

The Guidebook explains how to undertake this process, and the principles behind it.

Who is the Guidebook aimed at?

The Guidebook is primarily for **patients** and their **carers, clinicians** and the **organisations** that represent them.

However, it is also relevant to anyone who has an interest in or is directly affected by, clinical research, from researchers themselves to the bodies that fund them, so they can review their processes for setting priorities and deciding what to fund.

The Guidebook is intended to help Priority Setting Partnerships work effectively using tested methods to ensure credible and useful outcomes. It is based on evidence and draws on the experiences and evaluation of JLA Priority Setting Partnerships.

The JLA method is designed to lead to changes in the way research funding is granted, with a view to raising awareness of research questions which are of direct relevance and potential benefit to patients and the clinicians who treat them.

The most positive long-term outcome for any JLA Priority Setting Partnership will be that research into one or more of the uncertainties it identifies is commissioned, and that this goes on to have a life-changing impact on the treatment available to patients and the way in which clinicians can deliver this.

As an example, the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme reviews recommendations for research emerging from JLA Priority Setting Partnerships and those that fall within the remit of the Programme are considered for prioritisation. From April 2013 the JLA process was integrated into the NIHR Evaluation, Trials and Studies Coordinating Centre, as one of the methods it uses to identify research topics for its many programmes to fund.

Using the Guidebook

The Guidebook contains four key areas:

- practical guidance - How To (Section 2)
- information and evidence – Background (Section 3)
- the JLA Protocol (section 4)
- the annexes – a set of templates for priority setting partnerships to use

¹ Hazel Thornton. Patient and public involvement in clinical trials. BMJ 2008;336:903-904: notes that encouragement is still needed to promote institutional collaboration and avoid duplication of effort in Patient and Public Involvement in clinical trials. Cites the JLA as a rare example of lay people and health professionals prioritising research questions together.

These areas and the detail within them can be navigated via the contents page.

The Guidebook covers each step in the process, from establishing a Priority Setting Partnership to finalising a top 10 list of prioritised research questions. It also provides further context and evidence of research priority setting.

The Guidebook contains:

- practical examples of Priority Setting Partnerships
- downloadable documents
- useful resources for Priority Setting Partnerships

The different sections can be taken in order, from start to finish, or consulted in any order likely to meet the specific needs and circumstances of those involved.

While there is no 'one size fits all' route for JLA priority setting, the following are integral features of all JLA Priority Setting Partnerships:

- the principle of patients, carers and clinicians working together
- methodological transparency
- the declaration of interests
- working with the UK Database of Uncertainties about the Effects of Treatments (UK DUETs - www.library.nhs.uk/duets)

A template for a JLA protocol provides clarity about the nature of the work undertaken by each member and describes the underpinning principles to be observed by partners. Capturing this in a protocol has helped ensure that all partners 'own' and understand their chosen process.

The JLA method is continuously evolving. As evidence of new approaches and good practice emerges, the Guidebook will be updated.

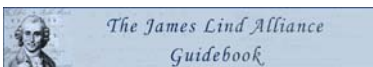
The James Lind Alliance

The JLA is a non-profit making initiative which was established in 2004. It brings patients, carers and clinicians together to identify and prioritise the unanswered questions about the effects of treatments that they agree are most important.

This information will help ensure that those who fund health research are aware of what matters to both patients and clinicians.

The JLA is managed and coordinated by the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC) at the University of Southampton.

Input to the JLA comes from a mix of lay people, healthcare and clinical research professionals and experts in patient and public involvement.



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Over 500 organisations and individuals are currently affiliated to the JLA. Affiliation is a cost-free way to demonstrate support for the JLA's values and stay up to date with its activities.

For further information please visit www.jla.nihr.ac.uk.

Or follow the JLA on Twitter at www.twitter.com/lindalliance.

JLA on Wikipedia: http://en.wikipedia.org/wiki/James_Lind_Alliance.

Acknowledgements

The Guidebook was written by Katherine Cowan, Senior Adviser to the James Lind Alliance, and Sandy Oliver, Professor of Public Policy at the Social Science Research Unit and EPPI-Centre, Institute of Education, University of London.

Many thanks to all those who contributed to the process, particularly the Critical Friends Group - Judy Birch, Ivor Cook, Ron Marsh and Dr Douglas Tincello - whose thoughts, advice and guidance were invaluable.

Contact and feedback

We welcome your feedback on this Guidebook, including any suggestions for improvements to the content or design. Please use the feedback form at www.JLAguidebook.org.

For any enquiries about the James Lind Alliance:

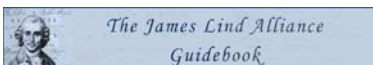
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About treatment uncertainties



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What are treatment uncertainties?

People have suffered and died unnecessarily because uncertainties about the effects of treatments have not been addressed in research (*Confronting Therapeutic Ignorance*²; *Well informed uncertainties about the effects of treatments*³; *Testing Treatments*⁴). Patients and the public have a right to expect that research funders, researchers and health professionals will identify uncertainties about whether treatments are doing more harm than good or whether one treatment is better than another, and should expect them to organise the research needed to reduce the most important of these uncertainties.

The JLA definition of a treatment uncertainty is that:

- no up-to-date, reliable systematic reviews of research evidence addressing the uncertainty about the effects of treatment exists
- up-to-date systematic reviews of research evidence show that uncertainty exists

It can include other health care interventions, including prevention, testing and rehabilitation.

Systematic reviews are based on worldwide searches for reliable, relevant evidence. They are comprehensive summaries and analyses of comparable published and unpublished studies of effectiveness, prepared by a team of authors. Systematic reviews are used to inform health and social care service development, policy development, and research.

More detailed information about systematic reviews and fair tests of the effects of treatments is available in the James Lind Library (www.jameslindlibrary.org). Further information is also available at www.senseaboutscience.org.uk.

To help ensure that treatments do more good than harm, gaps in knowledge about their effects - uncertainties - must be identified, and those deemed sufficiently important must be addressed in research.

Research on the effects of treatments is usually led by researchers or funders. This can mean that it can fail to address questions that matter to patients and to the clinicians to whom patients look for help. This is why the JLA process focuses on patients and clinicians.

The UK Database of Uncertainties about the Effects of Treatments (UK DUETs)

Provided by NICE, the UK Database of Uncertainties about the Effects of Treatments (UK DUETs) (www.library.nhs.uk/duets) publishes uncertainties about the effects of treatment. This means these uncertainties cannot currently be resolved by referring to reliable up-to-date systematic reviews of existing research evidence.

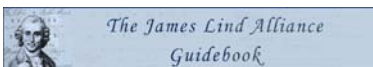
The aim of UK DUETs is to provide open access to a repository of uncertainties, allowing those prioritising research in the UK to take account of the information needs of patients, carers and clinicians.

UK DUETs draws on three main sources to identify uncertainties about the effects of treatments:

² Chalmers, I. Confronting therapeutic ignorance. *BMJ* 2008;337:a841

³ Chalmers, I. Well informed uncertainties about the effects of treatments. *BMJ* 2004;328:475-6

⁴ Evans, I., Thornton, H., Chalmers, I. *Testing Treatments: better research for better healthcare* (2010).



- patients', carers' and clinicians' questions about the effects of treatments
- research recommendations in reports of systematic reviews and clinical guidelines
- ongoing research, both systematic reviews in preparation and new original studies

To promote access to the uncertainties identified by the Partnerships via UK DUETs, JLA and UK DUETs have worked together to ensure that uncertainties are prepared and formatted for inclusion in UK DUETs. Partnerships will be expected to ensure the identified uncertainties are prepared for entry into UK DUETs on completion of their priority setting exercise.

Treatment uncertainties may include treatment at all stages of an illness, including prevention, testing and rehabilitation. Where a Partnership decides to have a wider scope, for example, frequency, cause, diagnosis and prognosis, these uncertainties will not be included in UK DUETs. However, where diagnostic testing has the ability to alter the course of an illness, or has its own adverse effects, it is eligible for inclusion in UK DUETs. For examples, please visit www.library.nhs.uk/duets and search the database using 'diagnostics' as the search term.

Section 2: HOW TO

How to establish a priority setting partnership

Overview of Priority Setting Partnerships

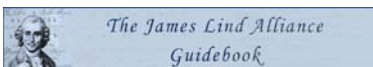
Priority Setting Partnerships bring patients and clinicians together to work through the JLA process. The aim of a Priority Setting Partnership is to identify patients' and clinicians' shared priorities for research into the treatment of specific health problems. The JLA's current portfolio of Priority Setting Partnerships can be viewed at www.lindalliance.org.

Priority Setting Partnerships' objectives are to:

- bring patients and clinicians together to identify uncertainties about the effects of treatments
- agree by consensus a prioritised 'top 10' list of those uncertainties, for research
- publicise the methods and results of the Priority Setting Partnership
- draw the results to the attention of research funders, independently of the JLA

Advocates of the following groups are invited to take part in a Priority Setting Partnership:

- people who have or have had the health problem in question
- carers of those affected
- medical doctors, nurses and allied health professionals with experience of caring for people with the health problem



The Priority Setting Partnership is led by a steering group. To see a template of a steering group's terms of reference, go to Annexe 1.

The overall structure and role of the partnership is set out in the Protocol. An overview of the key roles and required competencies can be downloaded from www.JLAguidebook.org.

The time scale for a Priority Setting Partnership will vary depending on scope and resources. Normally the process will usually take between 12 and 18 months to complete. Example timetables from existing Priority Setting Partnerships can be downloaded from www.JLAguidebook.org.

The role of the JLA is to support and guide the Priority Setting Partnership, as a neutral facilitator, ensuring that the process is followed in a fair, transparent way, with equal input from the perspectives of patients, carers and clinicians. While the JLA will be on hand to offer advice where needed, its practical involvement in the process (including chairing and facilitating meetings) reduces once the top 10 priorities have been agreed.

Members of the Partnership and the steering group are responsible for publicising the priorities to research funders.

Please contact the JLA if you are interested in establishing a Priority Setting Partnership and would like to discuss it with us: www.lindalliance.org.

Examples of JLA Priority Setting Partnerships:

Further information on each of the following Priority Setting Partnerships, as well as others not mentioned below, can be found at www.jla.nihr.ac.uk.

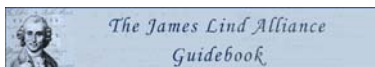
The **Asthma Priority Setting Partnership** brought together two partners: Asthma UK, representing patients, and the British Thoracic Society, representing clinicians. Fourteen of their members participated in the priority setting exercise. Further information, including reports, articles and evaluations, are on the JLA website.

The **Urinary Incontinence Priority Setting Partnership** was led at steering group level by the Bladder & Bowel Foundation, representing patients, and the Cochrane Collaboration, representing clinicians. There were 21 partner organisations involved in identifying and prioritising treatment uncertainties.

The **Vitiligo Priority Setting Partnership** was coordinated by the Centre for Evidence Based Dermatology, representing clinicians, and the Vitiligo Society, representing patients.

The **Prostate Cancer Priority Setting Partnership** was led by the Prostate Cancer Support Federation and Prostate Action (formerly the Prostate Cancer Research Foundation, now merged with Prostate UK) and included input from individual clinicians and representatives of 20 patient organisations. The **Lyme Disease Priority Setting Partnership** was coordinated by a patient group, Lyme Disease Action (LDA), with input from clinician partners.

The **Pressure Ulcer Priority Setting Partnership** was initiated by the National Institute for Health Research (NIHR) Wounds Research for Patient Benefit Programme (WRPB). WRPB is a research initiative involving NHS Leeds Community Healthcare and the University of York. A website dedicated to the partnership is at www.jlapressureulcerpartnership.co.uk.



The **Tinnitus Priority Setting Partnership** was coordinated by the British Tinnitus Association. Further information is at: www.tinnitus.org.uk/JLA.

The **Sight Loss & Vision Priority Setting Partnership** oversaw the prioritisation of research topics for 12 areas of eye disease, including glaucoma, cataract, macular degeneration and ocular cancer. Go to www.sightlosspsp.org.uk to find out more.

The **Multiple Sclerosis Priority Setting Partnership** is being coordinated by the MS Society: www.mssociety.org.uk/jla.

Who's who in the Priority Setting Partnership?

Steering Group: a small group that coordinates and implements the activity of the Priority Setting Partnership. It includes representatives of patients and clinicians, as well as JLA staff.

Partner: a member of the Priority Setting Partnership participating in the prioritisation of treatment uncertainties for research. A partner represents and can advocate for patients, carers or clinicians. They can be an individual or from an organisation.

Patients: individuals with experience of the health problem and those who represent them, including carers, relatives and charities.

Clinicians: all types of health professionals with experience of caring for people with the health problem, including organisations or groups who represent them.

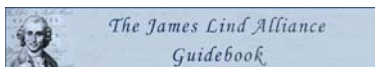
Setting up the steering group

A steering group is required to coordinate the Priority Setting Partnership and organise its activities. The steering group generally includes and is led by the individuals or representatives of groups who have made the initial approach to the JLA to carry out a priority setting exercise. They are usually organisations with resources to offer to the process, such as funding, staff, time and expertise. They will have thought about and started to prepare the following:

- a strategy for ensuring collaboration between patient, carer and clinician groups
- sources of funding to run the Priority Setting Partnership
- resources to undertake the process of checking the uncertainties and preparing them for entry into UK DUETs
- resources for the day-to-day running of the Partnership
- the anticipated outcomes of the process, including plans for dissemination

Ideally the administration and coordination of a Partnership should be undertaken by one person or organisation on the Steering Group. This would include maintaining the partnership contacts database, setting up meetings and taking action notes, coordinating Partnership activities and communications and being a first point of call for enquiries. The value of this vital role being held centrally and consistently throughout the process cannot be overstated.

The JLA offers support, facilitation and guidance. The practical work is carried out by the other members of the steering group. They are responsible for:



- publicising the initiative
- checking and collating the uncertainties
- taking the final priorities to research funders

The steering group must include representatives of patients and clinicians. This usually includes representatives from some form of “umbrella” group, such a charity or professional association.

In accordance with the JLA’s fundamental aims, only those representing patients and clinicians (who would not normally be involved in setting the clinical research agenda) are able to participate in the priority setting exercise.

What does the steering group commit to?

Members of the steering group will need to agree the resources, including time and expertise, that they will be able to contribute to each stage of the process. These stages include:

- publicising the initiative to potential partners
- publicising and participating in an initial awareness meeting
- developing and distributing information and forms to gather uncertainties
- collecting and collating uncertainties
- checking uncertainties against existing systematic reviews
- entering confirmed uncertainties into UK DUETs
- managing interim priority setting
- collating and aggregating interim prioritised uncertainties
- publicising and participating in the final priority setting exercise
- publicising the final top 10 uncertainties as research questions to funders

Steering group members should be prepared to approach and utilise their established contacts and networks. They will be individuals who are able to listen to, respect and incorporate into the process different perspectives. They will be committed to the principle of *shared* priority setting as well as the values of fairness and transparency. These values underpin the culture of the JLA priority setting process and are equally embedded in the JLA facilitator’s approach.

The key roles and associated resources can be found at www.JLAGuidebook.org.

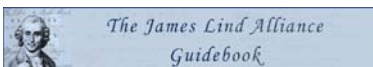
An example of a steering group Terms of Reference is at Annexe 1. You can save and adapt it to reflect the make-up of your steering group.

The management of these roles should be agreed and documented in the JLA Protocol.

Planning to work with UK DUETs

To promote access to the uncertainties identified by the Partnerships via UK DUETs, Partnerships are expected to ensure that uncertainties are prepared and formatted for inclusion in UK DUETs on completion of their priority setting exercise.

This requires identifying resources to:



- consult their membership and others to identify uncertainties, for example through surveys, focus groups or workshops
- collect and collate responses, then check that responses are relevant and legitimate
- prepare the uncertainties for ingestion into UK DUETs

The importance of establishing how this will work cannot be over-emphasised. It is key to the success of the process. Putting the treatment uncertainties through the UK DUETs system will verify that they are uncertainties, and will ensure the work of the Partnership is credible and up-to-date.

The process of working with UK DUETs requires people with experience of:

- survey methodology
- critical appraisal skills
- data management
- database entry

Clear instructions on the steps to prepare and format the uncertainties for inclusion in UK DUETs are detailed in the section *How to Identify Treatment Uncertainties*. An example of a completed Excel spreadsheet with data ready for ingestion is on the guidebook website, as is a blank one ready for use by PSPs. For more information on formatting and style of presentation of the data go to www.library.nhs.uk/duets.

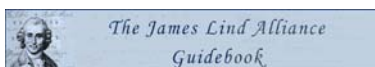
Identifying partners

It is important that all the organisations that can reach and advocate for patients, carers and clinicians should be invited to become involved in the Priority Setting Partnership. As far as possible, the numbers involved should represent patients and clinicians equally. This helps partnerships to demonstrate in subsequent publications and research applications that the exercise was unique and transparent, and the agreement of the priorities fair.

The JLA process accommodates the needs of patients who do not want to participate directly, but can feed in their views through a membership organisation, or directly to the JLA, confidentially.

Organisations and individuals with an interest in the health problem are normally invited to attend an initial awareness meeting, with a view to finding out about joining a Priority Setting Partnership. Where constituent groups are spread out geographically, or where patients and carers may face challenges in attending a meeting, Priority Setting Partnerships have found innovative solutions. For example, the **Stroke in Scotland Priority Setting Partnership** ran a series of awareness-raising roadshows. They made their presentation available on the internet, in an accessible audio-visual format and they also provided an aphasia-friendly leaflet for those recovering from stroke – go to www.askdoris.org/D_JLA.asp to find out more. The **Sight Loss and Vision Priority Setting Partnership** held an initial awareness meeting and made videos of the presentations available online for people who were unable to attend: www.sightlosspsp.org.uk.

While anyone with an interest in the condition can submit an uncertainty, only partners can be involved in the priority setting process itself. Partners should represent the following groups:



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- people who have or have had the health problem
- carers of those affected
- doctors, nurses and allied health professionals with experience of helping people with the health problem

They may therefore include:

- charities or support groups focusing on patients or carers
- Royal College-related groups whose members' work involves helping people with the health problem
- other professional organisations involved in the care of people with the health problem

An organisation's participation is likely to be encouraged if it is contacted by a known colleague, rather than approached 'cold'. Steering group members should be prepared to approach and utilise their established contacts and networks, as well as reaching out to new ones. The **Pressure Ulcer Priority Setting Partnership's** press release publicising the project can be viewed at www.JLAGuidebook.org.

Finally, a Partnership can greatly benefit from the involvement of the relevant **Cochrane Review Group**.

The Cochrane Collaboration is a worldwide endeavour to prepare, publish and update systematic reviews of evidence of effectiveness. This is primarily achieved via Cochrane Review Groups that support and edit reviews of effectiveness in particular areas of health and social care. Methods groups support methodological development of reviews and ensure that they reach quality expectations. The UK Cochrane Centre supports Cochrane Review Groups that are based in the UK, Ireland and Bahrain. Some of the uncertainties prioritised by a JLA Partnership will require a new or updated Systematic Review to address the uncertainty so working with a Cochrane Review Group can be very helpful. Information about Cochrane Review Groups can be found at: <http://www.cochrane.org/contact/review-groups> and many are based in the UK. The best people to approach are the Managing Editors or the Coordinating Editors, their contact details are easy to find on the Cochrane Collaboration website.

The JLA is unusual in involving both patients and clinicians in setting priorities for research. You can read more in the Guidebook about how other people consult or collaborate with patients and clinicians to set research priorities.

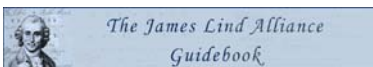
Initial awareness meeting

Some JLA Priority Setting Partnerships have held an initial awareness meeting in order to raise the profile of and garner support for the priority setting process. While this meeting is not compulsory, and may be dependent on the resources available to the Partnership, it can present the potential priority setting exercise to a wider audience. It is an opportunity to gauge interest and, if appropriate, secure involvement as partners.

Potential attendees are usually identified through the steering group members' networks and contacts. They may also be identified through the JLA register of Affiliates.

It is important that attendees know the purpose of the initial awareness meeting: to understand more about the process of research priority setting and to find out about the Priority Setting Partnership. It is also a chance to ask questions.

Documentation to help attendees make the most of the session should include:



Information sent in advance	Delegate packs on the day
Agenda	Agenda
Background information on the JLA	Presentation slides
Delegate biography request to explain interest in the condition	Delegate biographies
	Glossary of commonly-used terms
	Evaluation form

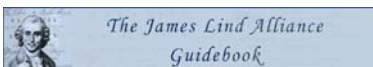
While the format may vary depending on the nature and number of attendees, the key elements to include are:

- information about the JLA and its aims and achievements
 - context - how research is traditionally commissioned
 - what treatment uncertainties are
 - why the JLA process is significant
- how the steering group became involved
- introduction to UK DUETs and its role in the priority setting process
- prioritising treatment uncertainties
 - how priority setting works - the practical steps
 - potential outcomes of a priority setting process
- feedback, including how to access the relevant communities
- what happens next
 - how to join the Priority Setting Partnership
 - commitment required of partners
 - timescales

The format should also include time for questions and discussion.

Numbers permitting, it can also be helpful to break into small groups to discuss uncertainties in particular areas. These will have been identified in advance, and delegates will have indicated where their interests lie, to ensure everyone can participate in a discussion which is relevant to them.

This will give people the opportunity to put their points across and serve as a rough indicator of the areas and focus of uncertainties which the partnership is likely to uncover. It will also ensure delegates begin to understand their practical role as partners within the JLA process.



Go to www.JLAguidebook.org to download agendas and meeting materials from previous JLA Initial Awareness Meetings. Videos of presentations and slides from the Sight Loss and Vision Priority Setting Partnership can be viewed at www.sightlosspsp.org.uk.

Affiliation

Partners are asked to affiliate to the JLA, to demonstrate their support for its aims and objectives.

Affiliation is free and can be done online at www.jla.nihr.ac.uk/Affiliates-Programme.asp.

Affiliates can decide whether or not they want their details added to the JLA website. They will receive a quarterly newsletter. To see archive copies of the newsletter, go to www.jla.nihr.ac.uk.

Declaration of interests

In order to participate in the voting stages of priority setting, partners will also be required to complete a form declaring their interests.

The purpose of this is to ensure transparency and to identify at an early stage of the process any potential competing interests. It is also an opportunity to identify capacity and preferred methods of communication with members. This will help the steering group plan how the Partnership will operate on a practical level.

Potential partners will be sent a form to complete and return. This will include questions such as:

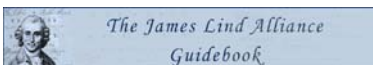
- if they share the JLA's vision for the partnership
- how they intend to represent members' views in the prioritisation process
- who will be nominated as the lead contact, and a deputy
- their preferred mode of communication
- any barriers to participation they may face
- if they have any competing interests
- if they have publicly-declared strong opinions about treatment
- if they are in receipt of funding which may influence their contribution to the prioritisation process

The steering group can develop its competing interest form to cover the relevant aspects within their specific sphere.

A basic template for a Declaration of Interests form (for individuals and for organisations) can be found at Annexe 2.

Exclusions

The JLA does not invite representatives of the pharmaceutical industry or those in the research community who are not also clinicians, patients or carers to participate in the priority setting process.



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Traditionally the health research agenda has been largely determined by the pharmaceutical industry and researchers themselves. This has usually been with minimal input from patients or patients and clinicians combined.

The JLA exists to address this imbalance.

Managing the partnership

It is important to be sensitive to partners' varied capacity and individual support needs.

Some organisations may be working on the issues full time. In other cases a Priority Setting Partnership member may be an individual who is having voluntary input and also has an unrelated 'day job'.

Effective communication is key to ensuring people are both kept informed and able to participate fully. This can be guided by early discussions about partners' capacity and preferences for communication. The Declaration of Interests form is one tool for gathering this information – see Annexe 2.

The JLA encourages steering group members to work in a consultative way. This ensures all members are able to contribute to decision-making. They should be transparent about how decisions are made.

It is also important that no one party or organisation is allowed to dominate the process, regardless of size or resource. Part of the JLA's role is to ensure the process is fair and inclusive. Partners should be made aware of this from the outset.

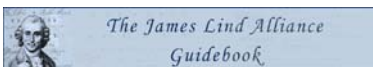
Managing values and perspectives

It is likely that groups and individuals in a Priority Setting Partnership may have particular issues which they want the priority setting exercise to address. For some this may be intensely important to them on a personal level. It is important for the facilitators to state and encourage understanding of the differing perspectives of patients, carers and clinicians. **No one group should feel marginalised or perceive that their views are less valid than any other, whether they speak as someone with the condition, as someone caring for another person with the condition or as a healthcare professional working with people with that condition.** It is the JLA facilitator's role to ensure that this principle is maintained, and the responsibility of the Steering Group to model it.

Acknowledging this, it is essential to be clear about the distinction between:

- patients', carers' and clinicians' individual priorities, based on personal experience
- priorities which potentially have an impact on a larger group of people, and may reduce the collective burden of a health problem

Everyone will have equal opportunities to submit their particular uncertainties. When it comes to priority-setting, however, participants may have to relinquish personal agendas and work with priorities that will deliver benefit overall. It is important to ensure people are treated fairly and with sensitivity and support during this process.



Being open about how and why decisions are made will help to head off any concerns about fairness. Steering group members should encourage a culture of openness and feedback. In doing this, they should encourage Partners to raise any concerns at the earliest possible opportunity, so that they can be addressed. This can be done directly with the steering group, by talking to a JLA representative or by using meeting evaluation forms.

Working with patients

Patients, carers and the networks which represent them are diverse. Some will be highly professionalised and accustomed to contributing to open debate. Others may be smaller and entirely dependent on volunteers and very little funding. Individual involvement may be very dependent on the nature of the patients' condition, as well as their age group.

It is important to identify the preferred methods of communication and involvement of patient and carer groups. While some will operate fully online, others may not use email. Even for those that do, the option of receiving paperwork through the post should be offered. Printing documents may not always be easy.

Tips for inclusive communication and involvement include:

- **Correspondence** should be clear, concise and easy to understand.
- Always include a **named person** and **phone number**, not just an email address, when providing contact details.
- Offer to **post** copies of documents/attachments. Ensure these are formatted to allow space for forms to be filled out by hand if necessary.
- When providing paper copies of documents, give people the option of requesting them in **large print** or other accessible formats (go to www.askdoris.org/D_JLA.asp to see the **Stroke in Scotland Priority Setting Partnership's** aphasia-friendly information leaflet).
- If requested, **take time to talk** people through any online tools over the phone which they may be using for the first time.
- Partnerships should always be willing to accept responses to anything (including formal consultations) in **paper copy** or in **electronic formats** or over the **telephone**. This will encourage response and ensure the process does not discriminate against people unable to use or unfamiliar with certain formats.
- For meetings or workshops where places are allocated on a first-come-first-served basis, keep **separate reservation lists** for people responding online and by post.
- A **travel bursary** may be built into the project at the planning stages, where Partners have the resources to provide this, and be available to individuals without the resources to attend. For example, patient organisations without financial resources may deselect themselves from participating if they have financial limitations. Guidance from INVOLVE on **payment** for patient and public involvement, including travel, can be found at www.invo.org.uk.

Facilitators and chairs should ensure patients and carers have equal voices to those of clinicians in meetings and workshops. However, it is also important to recognise that the views of patients and carers may vary. Neither group should feel that their voice is more or less valid than the other's. The environment of any Priority Setting Partnership meeting should be respectful. Taking extra time to support patients before, during and after meetings will ensure people are able to contribute equally and comfortably present their views, particularly because they may be talking about very personal issues.

Examples of support include:

- early provision of information
- opportunities to meet the chair and talk through the format of meetings beforehand
- evaluation forms on which patients and carers can comment on their experience, anonymously if preferred

Many patient organisations will have a great deal of expertise and good practice experience of involving patients and carers. This should be shared across the Partnership.

Further reading:

Good practice in active public involvement in research, INVOLVE, 2009

Patient and Public Involvement in UK Clinical Research Collaboration Advisory Groups, UKCRC

Working with clinicians

The clinical world is made up of established networks. Clinicians will have good contacts which can be used to recruit partners.

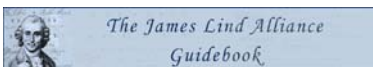
Partners should consider who they can influence to participate, and the best way to do this. Arranging brief one-to-one meetings with clinicians whose input is particularly wanted for the Partnership is an effective way of securing their support. It is an opportunity to raise their awareness of the importance of the priority setting process and to explain the value of their contributions for influencing the research agenda.

It is important to give clinicians as much notice as possible about meetings and other arrangements. This will enable them to arrange for colleagues to cover their work commitments such as clinics. Clinicians working with the JLA have suggested that at least six weeks' notice is required.

Consider whether or not meeting attendance could merit **Post Graduate Medical Education (PGME) points**. Deaneries and medical schools can authorise a request for this. The JLA can support an application if required. Partnership members may also be aware of similar points systems for other medical professionals at different grades.

Facilitators of meetings should ensure that clinicians are able to make contributions to the discussion equal to those of patients/carers. Sometimes there are high levels of dissatisfaction with available clinical treatments. It is important that sessions do not become a forum for criticising or berating those clinicians present. Equally, it is important that clinicians, who may be more used to speaking in an open forum, do not dominate the discussion at the expense of less confident members of the group.

It is also important to ensure that **clinical diversity** for the condition in question is taken into account when recruiting partners and inviting representatives to participate in prioritisation. For example, the **Schizophrenia Priority Setting Partnership** ensured that a range of viewpoints were captured in prioritisation, including psychiatrists, psychologists, social workers and advice line staff.



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Clinicians who have been involved in JLA Partnerships to date have reported finding it very rewarding to be able to listen to patients' views outside the normal consultation environment.

A clinician's account of being involved in a JLA Partnership was published in Nature in June 2011. A copy is available on the JLA website: www.lindalliance.org/JLASchizophreniaPSP.asp.

Maintaining involvement and commitment

The JLA encourages steering groups to hold monthly meetings (by telephone if most convenient) to update, plan and agree next steps.

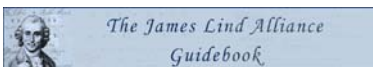
The steering group must also keep all interested Partners informed of progress, and of the impact of their contribution. This is especially important to keep momentum during stages when Partners would not otherwise receive information through involvement.

Some parts of the priority setting process will require active involvement from all Partners. For example, identifying uncertainties and priority setting. However, some stages will involve only the steering group and those who have been recruited to oversee particular parts of the data management, such as checking uncertainties and entering them into UK DUETs.

Partners should be aware of how the work of a Priority Setting Partnership will effect them, and be reminded that they are playing key roles in ensuring patients', carers' and clinicians' concerns become integrated into the research agenda. This will encourage them to continue to be actively engaged in the process and is important for priority setting but also at the next stage: raising research funders' awareness of the outcomes of Partnerships' work.

Below are some simple tips for ensuring that Partners are informed and involved at every stage of the process and do not lose interest in or commitment to the aims of the Partnership:

- Send regular updates via email and/or post from the steering group or the JLA. Examples of newsletters are at www.JLAGuidebook.org.
- Write regular articles and updates for in-house publications and the JLA newsletter to maintain interest and accountability. See www.jla.nihr.ac.uk/JamesLindAllianceNewsletters.asp
- Remind partners of their specific role and importance within the priority setting process, and what they can expect to gain.
- Ensure information is shared which is relevant and accessible, written in plain English suitable for anyone without medical or technical knowledge.
- Ensure materials are produced and distributed in formats which are accessible and appropriate to the audiences you wish to engage. Ask partners to nominate deputies to attend in their absence, to encourage involvement and reinforce the importance of meeting attendance. This is essential for the final priority setting meeting.
- Develop a Partnership web page or website where documents and be posted and activities described. For example, **the Sight Loss & Vision Priority Setting Partnership's** www.sightlosspsp.org.uk, **Pressure Ulcer Priority Setting Partnership's** www.ilapressureulcerpartnership.co.uk, the **Tinnitus Priority Setting Partnership's** microsite at www.tinnitus.org.uk/JLA or the **Childhood Disability Research Priority Setting Partnership's** www.bacdis.org.uk/research/psp.htm.



- Use social media, such as Twitter, Facebook or YouTube, to raise awareness of the Partnership’s activities. For example: <https://twitter.com/PretermBirth> and <https://twitter.com/JLAPUP>.

How to identify treatment uncertainties

Treatment uncertainties and the JLA process

Treatment uncertainties include treatment at all stages of an illness, including prevention, testing and rehabilitation, are imported into the UK Database of Uncertainties about the Effects of Treatments (UK DUETs).

Please note: if a Partnership decides to have a wider scope and gather additional uncertainties that are not related to treatment, such as those about frequency, cause, diagnosis and prognosis, these uncertainties will not be included in UK DUETs. The Partnership will therefore need to make plans at an early stage about how they will store and potentially share that wider dataset with stakeholders including the research community.

Uncertainties must be checked and verified as true uncertainties before prioritisation can begin. **This is one of the most labour-intensive stages of the JLA process and the steering group needs to identify how it will be resourced and actioned.**

To check that an uncertainty is a genuine uncertainty, a search needs to be undertaken for relevant and reliable systematic reviews or guidelines, alongside any ongoing studies which might address the uncertainty.

The citations of the systematic reviews, guidelines and studies, in Vancouver referencing style, need to be recorded for entry into UK DUETs.

Please go to www.JLAGuidebook.org for an example of a file used for ingestion into UK DUETs.

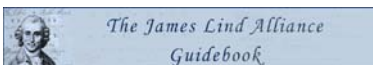
As part of this process of verifying genuine uncertainties, two criteria must be met: (1) the UK DUETs measure of an uncertainty must be met, which is when a reported confidence interval in a systematic review does not cross the line of no effect or line of unity, and (2) a clinician or person with relevant clinical knowledge must confirm that the outcome being reported as statistically significant in (1) is also clinically relevant.

Gathering treatment uncertainties

Uncertainties will come from four sources:

- patients
- carers
- clinicians
- existing literature

Organisations and individuals participating in a Priority Setting Partnership should approach their members and the people they represent to ask them to submit their uncertainties. This is usually done using surveys, in electronic and paper formats. Alternatively, people can be consulted face-to-face.



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An example of a JLA uncertainties information form and survey, which can be adapted to suit the needs of individual Priority Setting Partnerships, can be found at Annexe 3.

While the JLA can offer guidance on gathering uncertainties, Partnerships should use a method which is suited to their membership, resources and infrastructure.

Priority Setting Partnerships should endeavour to gather their uncertainties from as wide a range of potential contributors as possible. They must ensure patients are as confident and empowered as clinicians to submit questions about treatments.

In practice, this means ensuring that:

- information and forms are clearly written
- participation can take place over email, internet or by post
- responses are confidential

Steering Groups may consider including collecting demographic information and information on clinical setting within the survey. This will help them to identify whether or not particular groups are under-represented, and to target their publicity accordingly to encourage their participation. The **Type 1 Diabetes Priority Setting Partnership's** survey asked for a range of demographic data. To download a copy of the survey go to www.JLAguidebook.org.

It is helpful to set a time-scale that ensures maximum response while still retaining the momentum of the project. A deadline of between two and three months has been recommended, as this is when most Steering Groups have agreed that saturation point has been reached since no new themes were emerging.

Examples of JLA Priority Setting Partnerships – for further information go to www.JLAguidebook.org.

The **Urinary Incontinence Priority Setting Partnership** (originally referred to as a Working Partnership) developed a questionnaire which could be completed electronically and emailed back, or printed out and posted. Incontact (now the Bladder & Bowel Foundation) distributed the questionnaire by posting information on its website, then adding a link to this from various online message boards and fora, on other urinary incontinence charities' websites, and by providing the link and information in various continence magazines and newsletters. The questionnaire was also posted to the Foundation's 1000 members.

The **Vitiligo Priority Setting Partnership** developed an online survey which included information about the exercise, written in plain English, and a form for people to submit their uncertainties. This was also available in paper copy. It was promoted to the Vitiligo Society's members, in the national ethnic minority press and in local newspapers for areas with large ethnic minority populations.

The **Prostate Cancer Priority Setting Partnership** developed a questionnaire which incorporated examples and information. This was hosted on the website of the Prostate Cancer Research Foundation and promoted to partner organisations via email and post.

The **Type 1 Diabetes Priority Setting Partnership** developed an online survey using Survey Monkey software (www.surveymonkey.com), which was hosted on the UK Diabetes Research Network's website. A promotional flyer was produced and this was promoted by the steering group members throughout the diabetes communities, on email, in newsletters and at conferences.

The **Ear Nose & Throat - Aspects of Balance Priority Setting Partnership** was led by ENT UK and the British Society for Academic Otolaryngology. Their aim was to identify questions that are most important to people who suffer from balance disorders, their carers and clinicians. An invitation to participate in the exercise and the paper version of the survey, which was also available online, can be downloaded from www.JLAguidebook.org.

The **Cleft Lip and Palate Priority Setting Partnership** set up an online survey on Survey Monkey. The link, plus accompanying information, was hosted on the Cleft Lip and Palate Association's website. A screenshot of the survey web page and the paper version of the survey can be downloaded at www.JLAguidebook.org.

The **Eczema Priority Setting Partnership** decided to take a slightly different approach. Their survey asked patients, carers and clinicians to identify five uncertainties, and to indicate the type of treatment they referred to. Go to www.JLAguidebook.org to see the survey, the participant information sheet and a promotional flyer setting out details on the full priority setting process.

The **Preterm Birth Priority Setting Partnership** and the **Sight Loss and Vision Priority Setting Partnership** set up a website and developed a flyer for distribution to patients, families and clinicians. These can be accessed at www.JLAguidebook.org.

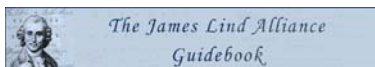
Patient-identified uncertainties

It is important to ensure patients are as confident and empowered as clinicians to submit their questions about treatments.

In practice, this means ensuring information and forms are clearly written, and that participation can take place over email or online, by post or telephone.

Someone's treatment uncertainty may be published on UK DUETs, with their consent, but their personal identity will remain confidential. To find out whether questions for research are gathered from the full range of people who have a stake in the topic of interest, you will need to collect some information about people who submit the questions. This information might distinguish professional backgrounds, or different demographics (for, instance by asking questions about age, gender or ethnic background). Personal information needs to be stored securely. Ethics approval may be required from institutional ethics committees. For more information about ethical practices, and ethics approval, see the background section on How to evaluate.

Most Priority Setting Partnerships develop a survey (internet/email-based, and paper-based) which partners distribute to their members and other interested parties. The Steering Group needs to consider how the survey can meet any need to target specific participants. This might include: those at a different stage of illness, such as acute or long term; or participants of a particular age, for example children or adults.



Reaching patients does not need to be costly or time-consuming. Most patient organisations can use existing communication mechanisms, including newsletters, email networks and online message boards. The **Cleft Lip and Palate Priority Setting Partnership** launched its survey at the Cleft Lip and Palate Association's (CLAPA) patient and carer conference. A video of the event can be watched at <http://vimeo.com/29111443>.

Communication should be appropriate and accessible with language inclusive for those unfamiliar with medical terminology.

Ethics approval might be required in certain NHS settings. It can be applied for through the Integrated Research Application System (IRAS): www.myresearchproject.org.uk.

Clinician-identified uncertainties

Clinicians are requested to identify uncertainties which are immediately relevant to treating a patient with the particular health problem. They are asked to recall and share any issues which they have encountered during discussions or consultations between patients and those caring for them.

It is worth noting that this is not the same as recalling an area where research is lacking. What the JLA process is looking for is the uncertainty during a consultation where the doctor thinks "How am I going to treat this? I'm not sure."

A challenge for some clinicians may be admitting to clinical doubt. This is why it is important that respondents know that uncertainties which they raise will not be attributed to them as individuals, or their admission of uncertainty seen to reflect unfavourably on them.

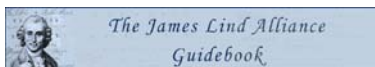
Approaching the relevant Royal College for contact details of an individual or small group of people who can coordinate the dissemination of information will often be the easiest way to gain access to a group of clinicians. Many Colleges have smaller committees or associated societies made up of clinicians with expertise in caring for people with a specific health problem. For example, for the Urinary Incontinence Priority Setting Partnership, these included the British Society of Urogynaecology within the Royal College of Obstetricians and Gynaecologists and the British Association of Urological Surgeons within the Royal College of Surgeons.

Also, health problem charity groups will often have good relationships with interested clinicians and can provide contact details if required.

Existing literature

As well as uncertainties submitted by patients and clinicians, documented sources of information need to be searched for evidence of uncertainty, as these may then be included in the prioritisation exercise. Steering group members should decide who is best placed to carry out this task, in terms of time and expertise.

Documented sources of uncertainties include question-answering services; research recommendations in systematic reviews and clinical guidelines; protocols for systematic reviews being prepared; and registers of ongoing research.



Patient helplines may also be a helpful source of uncertainty. Partnership have gathered this information while using the literature to check the veracity of the survey-submitted uncertainties.

Consent

When each uncertainty is entered into UK DUETs, it might be edited for clarity. If changes are made to a submission, all efforts are made to capture the original submission to allow publication of the unedited text within the record. This is to demonstrate fidelity to the original submission.

Submitted uncertainties are tagged according to their originator, whether patient, carer, professional or research recommendations. However, the originator can remain anonymous. If they do provide their contact details these will be kept securely and confidentially. Individual names are not published in association with any uncertainty.

The **Cleft Lip and Palate Priority Setting Partnership** told respondents that participation in the survey would automatically indicate consent for anonymous publication of their uncertainties on UK DUETs. To see how they worded this on their survey form, go to www.JLAguidebook.org.

Processing submitted uncertainties

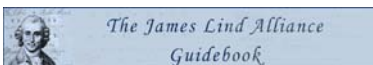
To enable open access to the full list and prioritised uncertainties identified by the Partnerships, the Partnerships are expected to ensure that, on completion of their priority setting exercise, uncertainties are prepared and formatted for inclusion in the UK Database of Uncertainties about the Effects of Treatments (UK DUETs)

Uncertainties generally fall into four categories:

- uncertainties from patients, carers or clinicians
- indicative uncertainties, consisting of those submitted separately but which are similar to or duplicated by others formed by the PSP
- uncertainties from treatment guidelines, research recommendations and systematic reviews – these may be gathered at the same time as the literature is consulted to verify the uncertainties submitted via the survey
- uncertainties being addressed by ongoing research as confirmed by a relevant and reliable systematic reviews in study protocols or protocols for systematic reviews

Uncertainties from patients, carers and clinicians collected via the survey can be very numerous. The table below shows examples of the number of submissions received from previous JLA survey respondents:

JLA Partnership	Number of Survey respondents	Number of Submissions
Sight loss and vision	2220	4461
Dementia	1563	4116



Tinnitus	835	2483
Vitiligo	461	1427
Type 1 diabetes	583	1141
Stroke	106	548

It is therefore essential to adopt a systematic approach to managing and processing the survey submissions in order to create a list of uncertainties for prioritisation, and which will be entered into UK DUETs.

This section is divided into six stages.

- Download the survey data
- Remove out-of-scope submissions
- Categorise eligible submissions
- Format the submissions
- Verify the uncertainties
- Prepare the long-list of uncertainties

Thank you to Viktoria Eleftheriadou, Mark Fenton and Carrie Thomson for their assistance in writing this section.

Download the survey data

On completion of the survey, the data collected needs to be organised into an Excel file. This will include the suggested uncertainty and the type of submitter, including any background details collected. This will require data to be downloaded if collected online or entered manually if paper and telephone submissions have been gathered.

The dataset then needs to be cleaned and organised as detailed in the following steps:

- remove incomplete or blank rows
- where one respondent has submitted more than one uncertainty, ensure these are separated so there is one submission per row, always ensuring demographic data is copied across so the origins of each submission are retained
- anonymise the data by removing any personal details (ie name and address)

Please note that additional information will be added to this dataset in order to prepare it for ingestion into UK DUETs.

Remove out-of-scope submissions

The Partnership's scope will have been defined in the Protocol. Submissions which do not fall into the scope must be removed. Scope may relate to the area of the disease, a particular type of patient (eg adults or children) or the type of uncertainties being addressed. Partnerships should keep a record of submissions which are removed and ensure members of the Steering Group including patients, carers and clinicians and their representatives, are happy with the decisions taken prior to any interim prioritisation.

Treatment or intervention questions are within the normal remit of what is collected by Partnerships and included within UK DUETs. However, some Partnerships may choose to look at other issues, such as prognosis or cause. Where uncertainties about these are gathered but there is no associated intervention (treatment), they are not eligible for inclusion in UK DUETs. However, prognosis after an intervention would be included, as it is viewed as being essentially a treatment uncertainty with an outcome. For example, active intervention or watchful waiting for prostate cancer are both considered as treatments, and the prognosis after these is an uncertainty.

The definition of treatment uncertainty may thus extend fairly wide and could include, as well as the above, organisation of services, service delivery or diagnostic tests, where these have the potential to change the course of an illness.

Where submissions are out of scope, however, Partnerships need to have decided what to do with them. Some have made arrangements with relevant organisations to pass them on. For example, the Sight Loss and Vision Partnership agreed to send submissions better suited to social research to a partner organisation which was interested in addressing these. The Dementia Priority Setting Partnership removed submissions which were not uncertainties, but were indicative of a need for better information sharing, and passed them to the Alzheimer's Society communications team.

Categorise eligible submissions

Once out-of-scope submissions have been identified and removed, the remaining submissions need to be allocated into categories, also known as a taxonomy. This is a helpful way to organise data in part to reveal instances of duplication. It also provides an overview of the nature of the submitted data in terms of people's interests and priorities.

It is recommended that taxonomies from existing literature are used where possible, such as 'topics' used by Cochrane Systematic Review Groups or the UK Clinical Research Collaboration Health Research Classification System (www.ukcrc.org/researchcoordination/classificationsystem/).

Some categories of treatment which may not be found in existing taxonomies, including diet, vitamins, complementary therapies and lifestyle, may need to be adapted and added to as the data is entered. It may be useful to consider stage of illness or age at diagnosis as additional methods of data organisation.

This categorisation process may identify further ineligible submissions, for example, topics better suited to social research, which can also be removed. As above, the person/people managing this stage of the process should keep a record of these and refer them back to the Steering Group.

Format the submissions

Submissions from patients, carers and clinicians may need to be rewritten or rephrased, which can be very labour intensive. The format used by the JLA is described in the section below. This is to clarify the precise uncertainty, which may have been submitted with a lot of narrative text, to ensure consistency in the language used. Any rewording should ensure that the language is accessible to a lay or non-medical audience but also accurate enough to engage clinicians and specialists.

It is advised that this work is carried out by one or more individuals skilled in identifying systematic reviews and who have clinical knowledge, or by an information specialist. However, it is vital that Steering Group members are also offered opportunities to contribute to and comment on the process to ensure they are satisfied that the interpretation of the submissions is fair and neutral.

Rephrasing the submissions

The PICO structure is used to re-write submissions, ensuring that each is worded, where possible, to include:

- the Patient or Population
- the Intervention
- a Comparator or Control
- an Outcome.

It is important to note that not all the PICO variables will necessarily be available. The two most difficult variables to identify are the comparator and outcomes. [Guidance and examples can be downloaded [here](#).]

In addition to the PICO structure, submissions require the outcomes to be listed separately for import into UK DUETs. If outcomes have not been stated in a submission, the Partnership can list generic outcomes tailored to reflect the submission.

For example, for submissions to the **Cleft Lip & Palate Priority Setting Partnership**, the generic list of outcomes became:

Articulation; adverse effects or complications; efficacy; growth; development; quality of life; major congenital abnormality; structural-morphological birth defect; birthweight; body length; foetal growth restriction; other outcomes related to foetal growth; preterm delivery (delivery before 37 completed weeks gestation); stillbirth; mild congenital abnormality: structural-morphological birth defect requiring medical intervention but with good life expectancy (such as congenital dislocation of the hip or undescended testes); low Apgar score (less than 7 at 5 minutes); economic outcomes.

These outcomes were then tailored to the particular submission, i.e. an intervention for speech development would only list the following outcomes: *Articulation; adverse effects or complications; efficacy; development; quality of life; economic outcomes.*

Combining duplicates

Duplicates and very similar submissions can be combined within one indicative uncertainty. Combining submissions can greatly reduce the volume of data that need to be checked for systematic reviews:

JLA Partnership	Number of submitted uncertainties	Number of verified uncertainties	Total after combining: indicatives
Type 1 diabetes	1141	890	650
Eczema	1070	718	65
Balance disorders	669	348	146
Stroke	548	386	226

This process is also likely to be repeated after the verification of uncertainties, and the removal of non-uncertainties, thus reducing the data further.

For example, in the Asthma Priority Setting Partnership over 100 survey submissions asked about the side effects of both medication to relieve symptoms and prevent symptoms developing used in asthma treatment. These 100+ questions were made into two indicative questions:

- What are the adverse effects associated with long term use of short and long acting bronchodilators (medication to relieve symptoms); inhaled and oral steroids (medication to prevent symptoms developing); and combination and additive therapies (combinations of the two types of medication) in adults? (N.B this includes children aged 12 years old and over)
- What are the adverse effects associated with long term use of short and long acting bronchodilators; inhaled and oral steroids; and combination and additive therapies in children?

The issue of combining can be a sensitive process because separate submitters may often feel that they would have wanted their specific interpretation of an uncertainty to remain. However, in order to manage the list of submissions it is necessary to combine similar uncertainties, especially at the final priority setting meeting where participants are often keen to include as many topics as possible in the top final top 10.

For example, multiple submissions about the effects of specific foods or drinks (eg fruit, coffee, tea etc) on a given condition can be combined in the final analysis to the collective theme of 'diet', retaining a link to specific examples that were raised earlier.

This process is more straightforward if submissions have been allocated to a taxonomy as outlined above. It is important to keep a record of the original submissions, so that their source (patient /carer, clinician, or both) and the frequency with which that particular uncertainty was submitted is accounted for.

Some partnerships have generated broad or non-specific submissions, or ones which do not have all the PICO components as above. These contrast with very specific uncertainties from the research community. It can therefore be helpful to create a broad indicative uncertainty to allow flexibility, keeping a record of the types of issues which have informed it. This record will be particularly useful at a later stage, when discussing the nature of the priorities with potential research funders.

Example

The Vitiligo Priority Setting Partnership developed the following structure to refine broad questions into indicative uncertainties:

Type of question	Format of question	UK DUETs Entry
Effectiveness of a single treatment	How effective is [treatment X] in treating vitiligo?	[Treatment x] for treating vitiligo
One treatment compared to another	Which treatment is more effective in treating vitiligo: [treatment X or treatment Y]?	[Treatment x or y] for vitiligo
One treatment combined with another	How effective is [treatment X] when combined with [treatment Y] in treating vitiligo?	[Treatment x] combined with [y] for vitiligo
Management of the disease, rather than “treatment” (e.g. camouflage or psychological interventions)	How much does [treatment X] help patients with vitiligo?	[Treatment x] for treating vitiligo
Speculative treatments not yet on the market (e.g. gene therapy, stem cell therapy)	What role might [treatment X] play in the treatment of vitiligo?	[Treatment x] for treating vitiligo

Verify the uncertainties

Each uncertainty submitted, including indicative uncertainties of combined submissions as described above, needs to be verified as a true uncertainty. For example, some uncertainties may have already been addressed by research without all patients or clinicians being aware of this.

To check that an uncertainty is a true uncertainty, a search needs to be undertaken for relevant and reliable systematic reviews or guidelines, alongside any ongoing studies which might address the uncertainty.

Priority Setting Partnerships will already have agreed and noted in their Protocol who will be responsible for this phase.

It is suggested that at the same time as verifying the submissions, uncertainties from research recommendations are recorded and added to the list of uncertainties for prioritisation. More detail on identifying research recommendations is below.

Treatment uncertainties submitted by patients and clinicians are identified as true uncertainties by checking them against existing systematic reviews and guidelines. For each verified uncertainty, the source of verification should be cited.

Where resources to undertake a PSP are limited, UK DUETs recommends using the resources listed below to check a submission is an uncertainty:

- The Cochrane Database of Systematic Reviews
- the Database of Abstracts of Reviews of Effects (DARE)
- NICE guidelines
- SIGN clinical guidelines
- Relevant Royal Colleges' guidance

When checking an uncertainty against a systematic review, the review needs to be relevant and reliable. This can be measured by seeing if the authors follow a published methodology for undertaking the review, and if the methodology has made provision for managing bias. With guidelines, the author needs to have made efforts to identify all relevant and reliable trials or systematic reviews. Relevance and reliability can be further ascertained with the population confidence interval, enabling an informed reader to agree or disagree with the result. Narrative reviews, which do not give details or numerical results, may fail the requirements of relevance and reliability.

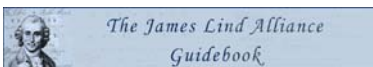
For import into UK DUETs, please record whether a systematic review or guideline is up-to-date ie no greater than three years old. Details of systematic reviews older than three years are included in UK DUETs with the recommendation that the review should be updated before any new research is commissioned.

An uncertainty is deemed genuine when a reported confidence interval in a systematic review does not cross the line of no effect or line of unity. In addition to ascertaining statistical significance of an uncertainty, clinical significance needs to be checked by a clinician or person with relevant clinical knowledge who can confirm that the outcome of investigating the uncertainty would be clinically relevant.

When recording the date of the systematic review/guideline please use the most up-to-date review from Cochrane where available.

Identifying research recommendations

Treatment uncertainties identified in the research recommendations from the following sources indicates that they are confirmed uncertainties.



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- The Cochrane Database of Systematic Reviews
- the Database of Abstracts of Reviews of Effects (DARE)
- NICE guidelines
- SIGN clinical guidelines
- Relevant Royal Colleges' guidance

The research recommendations may be reflected in the dataset generated by the survey, or they may be unique. There is a pragmatic decision to be made about how Priority Setting Partnerships identify uncertainties from these sources. For example, some guidelines are designed as guides for practice, not full explicit surveys of the literature to identify uncertainties and research recommendations. As such, these have sections including uncertainties and research recommendations. It is methodologically defensible to decide that these research recommendations should go forward into prioritisation. However, a more detailed read of a guideline will grade the evidence as being of high or low quality.

For example, using SIGN 126 (www.sign.ac.uk/guidelines/fulltext/126/), Diagnosis and management of colorectal cancer, the evidence table gives:

KEY TO EVIDENCE STATEMENTS AND GRADES OF RECOMMENDATIONS

LEVELS OF EVIDENCE

1++ High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias

1+ Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1 - Meta-analyses, systematic reviews, or RCTs with a high risk of bias

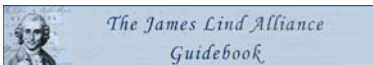
2++ High quality systematic reviews of case control or cohort studies, High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+ Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2 - Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3 - Non-analytic studies, eg case reports, case series

4 - Expert opinion



If the resources are available in the PSP, it is possible to identify those levels of evidence based on 1-, or 2 or less and say it is an uncertainty where the evidence is lacking.

SIGN also gives grades of evidence, such as:

GRADES OF RECOMMENDATION

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+

C A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++

D Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+

GOOD PRACTICE POINTS

Recommended best practice based on the clinical experience of the guideline development group.

It is realistic to say everything in a SIGN guideline graded at level C and D are uncertainties, as the evidence is not robust. It is perfectly acceptable to identify what the guideline says is an uncertainty and/or a research recommendation. However, when deciding what goes forward for prioritisation, and the associated workload, the Partnership's available resources will need to be taken into account.

Finally, some apparent uncertainties can in fact be resolved with reference to existing research evidence – ie they are 'answerable questions' 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. These findings may usefully inform future awareness-raising exercises and education programmes. **Accordingly, the JLA recommends strongly that Partnerships keep a record of these 'answerable questions' and deals with them separately from the 'true uncertainties' considered during the research priority setting process. We suggest incorporating this commitment in the Partnership's Protocol.**

Ongoing trials and studies

In addition to searching for relevant and reliable systematic reviews and guidelines, it is recommended that a search needs to be undertaken for ongoing studies which might address the uncertainty. The citation to the study also needs to

be recorded for each submission for entry into UK DUETs. This helps avoid waste in research by demonstrating where research is already commissioned that might address an issue and therefore does not need more research commissioning until the on-going research has been completed and reported the results.

Adding research which is undertaken in the context of a systematic review as a separate entity into UK DUETs allows a view of the research currently being funded. It is suggested that the International Clinical Trials Registry Platform (ICTRP - <http://apps.who.int/trialsearch/>) is used to gather this information.

Prepare the long-list of uncertainties

The verified uncertainties and research recommendations will become a long-list which will go forward for interim prioritisation. The Steering Group will need to decide how to present the list of verified uncertainties to patients, carers, clinicians and their representatives. For example, uncertainties which are organised into categories will be easier to navigate. However long-lists of more than 100 treatment uncertainties may require a different approach, as reviewing lists of over 100 treatment uncertainties may be off-putting for those invited to participate, being a potentially time-consuming and complex task.

Priority Setting Partnership Steering Groups can review the long-list of treatment uncertainties and apply agreed criteria to reduce it to a more manageable number. Criteria that can be used could include:

- the prevalence of treatment uncertainties – high prevalence = higher priority
- whether uncertainties have been submitted by both clinicians and patients
- whether uncertainties submitted by clinicians and/or patients overlap with those from research recommendations
- whether the issue raised reflects what Steering Group members know to be the concerns of groups which are under-represented among the survey respondents
- whether the uncertainty has been commonly expressed in other fora, such as patient helpline services

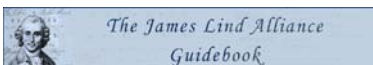
It is important that no single agenda or perspective dominates this decision-making process. There must be input from patient, carer and clinician representatives. The JLA's role is to ensure the discussions and decisions are conducted in a fair and transparent way.

Example of a JLA Priority Setting Partnership

Within the **urinary incontinence** priority-setting process, a total of 519 submissions were gathered of which 102 came from existing sources and 417 were submitted by partner organisations which had gathered them internally and from their members.

These were refined to remove duplicates and non-uncertainties, leaving a total of 226. Of these:

- 79 came solely from patients and carers



- 37 came solely from clinicians
- six were submitted by patients and clinicians simultaneously
- two were from patients and research recommendations
- 102 were derived solely from research recommendations

For the **type 1 diabetes** priority setting process:

- 583 people submitted 1141 uncertainties
- 890 were true uncertainties
- 118 uncertainties came from research recommendations/literature
- Combining duplicates, there were 350 verified uncertainties

Preparing uncertainties for import into UK DUETs

To enable open access to the prioritised uncertainties identified by the Partnerships, the Partnerships are expected to ensure that, on completion of their priority setting exercise, uncertainties are prepared and formatted for inclusion in the UK Database of Uncertainties about the Effects of Treatments (UK DUETs)

Resources required to undertake this task will vary depending on the number and type of submissions returned.

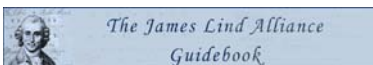
Uncertainties can sometimes be more detailed than simple research recommendations. This phase of data management and checking can be complex and requires data management skills, critical appraisal skills, clinical knowledge and information retrieval skills.

Please use the UK DUETs template at www.JLAguidebook.org to record the information required to import the list of uncertainties into UK DUETs.

Please use the list of UK DUETs controlled values at www.JLAguidebook.org for relevant columns i.e. Comparison, Health Topic, Age of patients/population.

In order for the uncertainties to be included in UK DUETs, the data must be prepared in a file that includes the following standard columns:

- PICO Title
Formatted title using at least the Intervention and Patient/Population part of the PICO structure. Where possible, structure the entry using the full PICO structure. Software restrictions and UK DUETs good practice limit this field to 240 characters, including spaces.
Examples of this structure can be seen in UK DUETs under research recommendations.
- PICO Outcomes are also captured in a separate column
- Original uncertainty
Original submission or submissions before changes. To be included in the same cell, separated by ~



If lots of submissions have been put together (indicative questions), all the entries or submissions can be put in here for inclusion in UK DUETs. This allows transparency of interpretation, so the end-user of UK DUETs can see both what was originally submitted and how that has been framed by the PSP.

- Source

i.e. the name of the Priority Setting Partnership

Where possible, UK DUETs will show the origin of the uncertainty, and again if possible, allow the end-user of UK DUETs to see the contributors' impact on UK DUETs content. This is also a field used to organise the data.

- Source URL

URL/web link to where details of the Partnership and the survey can be seen on the internet, such as the relevant JLA web page. This information is used to allow the source field in UK DUETs to hyperlink to details of who the contributor is, and, if possible the survey methodology used to populate the database.

- Outcomes to be measured

In addition to the PICO structure, submissions require the outcomes to be listed separately for import into UK DUETs. If outcomes have not been stated in a submission, the Partnership can list generic outcomes tailored to reflect the submission. UK DUETs contains a separate field for listing outcomes that should be addressed in future research. See earlier discussion on 'Outcomes'.

- Reference to up-to-date systematic review

Citation to up-to-date systematic review which is relevant and reliable and which verifies the uncertainty. Citation needs to be given in Vancouver style and include the Digital Object Identifier (DOI), or database identifier (PMID) where possible. Where there is no up-to-date systematic review, defined as published in the last three years, out-of-date systematic reviews can be captured in the next column. Providing the citation to an up-to-date relevant and reliable systematic review demonstrates that there is continuing uncertainty. In so doing, this information provides transparency in that the end-user can seek out the document to see if they agree or disagree and it is also information the end user of the database will need to reference an uncertainty. Where the DOI or PMID is included, this allows the software to hyperlink to the document.

- Reference to out of date systematic review

Citation of an out of date (ie older than three years) systematic review which is relevant and reliable which verifies the uncertainty. Citation needs to be given in Vancouver style and include the Digital Object Identifier (DOI), or database identifier (PMID) where possible. UK DUETs presents the full citations to systemic reviews that are out of date, as the resource required to update or extend an existing systematic review, are far less than those needed for commissioning new research.

- Ongoing studies

Citation of any on-going studies which might address the uncertainty: give the title of the study and either clinical trials.gov reference id or ISRCTN reference number, or website url (WHO International Clinical Trials Registry Platform - <http://apps.who.int/trialsearch/>). Partnerships should search to see if there are any ongoing studies which might address the uncertainty. Having ongoing trials in the submission serves two purposes for UK DUETs. The first is that it enables users of the database to see if there is any research currently commissioned to address the

issue of the uncertainty, and the second that users of the database might use the information to find out if there is any research they can contribute to as a study participant. It may be the case that there are multiple relevant ongoing trials, UK DUETs recommends limiting listing to no more than three relevant ongoing trials.

- **Comparison - Controlled vocabulary.**
To list the comparator the intervention should be compared against using the controlled vocabulary list- UK DUETs Fields. This is a software requirement for information presentation in UK DUETs.
- **Health Topic – Controlled vocabulary**
To list the relevant health care condition from the controlled vocabulary list – UK DUETs’ Fields. This is a software requirement for information presentation in UK DUETs. See www.JLAguidebook.org for a downloadable file.
- **Uncertainty from Patient/Carer/Clinician/Research Recommendation or multiple sources**
Who the uncertainty came from: patient/carers/clinician/research recommendation. Where there are multiple sources please list them all. This is a software requirement for information presentation in UK DUETs.
- **Age of patients/population - Controlled vocabulary**
Identify the age of patients/population from the controlled vocabulary list – UK DUET’s Fields.
This is a software requirement for information presentation in UK DUETs.

In order for the uncertainties to be included in UK DUETs, the data must be prepared in the UK DUETs template (available at www.JLAguidebook.org) using the fields described above.

NB: This template captures the requirements for data import into UK DUETs. These requirements are very specific and, even small changes made to a file can prevent import and require additional resource from the Partnership to re-edit.

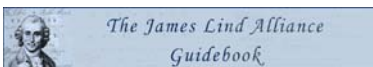
For example, controlled vocabularies should be copied and pasted to avoid errors like the use of ‘Device’ instead of ‘Devices’ or ‘Child’ instead of ‘Child/Adolescent’, and citations need to be recorded in the Vancouver referencing style.

Partnerships should discuss any changes to this dataset in advance with the UK DUETs project manager.

Partnerships should also be aware that any changes made to the uncertainties during final prioritisation (e.g. merging or rewording submissions, where agreed by the Partnership) will need to be reflected in the data which is entered into UK DUETs. Partnerships are therefore advised to ensure their uncertainties are UK DUETs-ready prior to commencing priority setting, but that the process of ingestion into UK DUETs begins after priority setting has been concluded.

For more information on UK DUETs go to www.library.nhs.uk/duets.

How to prioritise uncertainties



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The principles of JLA priority setting

The research agenda is commonly set by researchers themselves, or the pharmaceutical and medical technology industries. Questions important to patients, their carers or the clinicians who treat them may differ from the questions important to these groups, and may be overlooked or neglected.

The JLA process aims to address these imbalances.

JLA Priority Setting Partnerships bring patients, carers, clinicians and their representative groups together on an equal footing. Research suggests that such approaches are rare.

To ensure consistency and maximum learning, the JLA asks each partnership to ensure that their methods address a set of underpinning principles. These are:

- transparency of process
- balanced inclusion of patient, carer and clinician interests and perspectives
- exclusion of non-clinician researchers for voting purposes, but who may be involved in all other aspects of the process
- exclusion of groups/organisations that have significant competing interests, for example pharmaceutical companies
- audit trail of original submitted uncertainties, to final prioritised list
- recognition that making priority decisions does not create new knowledge, but reviews existing evidence of uncertainty

Remember, priority setting can only occur if the identified treatment uncertainties have been checked to ensure that they have not been answered by an up-to-date systematic review.

Interim priority setting

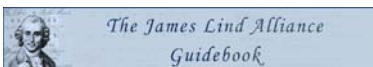
An exercise to gather treatment uncertainties for prioritisation can yield a large amount of information. The most practical approach is to initially shortlist the uncertainties, in an interim priority setting exercise, and then proceed to a final priority setting workshop. Some Priority Setting Partnerships have gathered up to 2000 raw individual submissions (including duplicates and non-uncertainties). After checking, these have been refined to around 500 unique treatment uncertainties.

The interim priority setting stage may be carried out by the whole Partnership, or in the initial stages by the representative Steering Group.

Where the whole partnership is involved interim priority setting can be conducted by email and/or post or online, depending on the communication preferences of the partner organisations.

Partners ask their members, colleagues or peers to:

- examine the long list of treatment uncertainties



- choose those which they would most want to see prioritised for research – usually this is 10, although Partnerships may opt for a lower number if this is deemed more manageable
- rank them

The approach is dependent on the number of valid uncertainties gathered and the total number of uncertainties the Partnership has agreed to short list. Given the varied structures of different organisations, the JLA does not impose a strict method for this stage. It does however ask Partners to submit a detailed explanation of how they consulted their members and how they agreed their rankings. It may be necessary to offer an alternative to returns by email, such as phoning in ranked uncertainties or postal returns.

An interim prioritisation form template is at Annexe 4. An example of an interim prioritisation scoring spreadsheet can be downloaded from www.JLAguidebook.org.

Examples of JLA Priority Setting Partnerships

The **Vitiligo Priority Setting Partnership** developed a website to enable partners to carry out the interim shortlisting of their priorities. To see the Partnership's invitation to participate in the interim prioritisation exercise, and screen shots of the site, go to www.JLAguidebook.org.

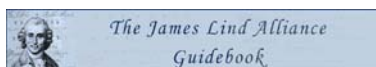
The **Type 1 Diabetes Priority Setting Partnership** sent out a long list of 47 uncertainties, which the Steering Group had shortlisted from a much longer list, based on the original number of submissions. The form which describes these, and enables partners to rank their interim top 10, is at www.JLAguidebook.org.

The **Cleft Lip and Palate Priority Setting Partnership's** interim prioritisation documents can be downloaded from www.JLAguidebook.org.

Collating interim priorities

Returns of interim prioritisation forms should be grouped into patients and/or carers, and clinicians, and separate scores kept to ensure a fair weighting of the constituent groups. The most straightforward approach is to apply a reverse scoring system to each submission:

Rank	Score
1	10
2	9
3	8
4	7



5	6
6	5
7	4
8	3
9	2
10	1

The Steering Group should look at the totals for both patients/carers and clinicians, record these for future reference, and then rank them again and reverse score them as above. It is those ranked scores which are then combined, to work out the final interim prioritised list.

Submissions are only considered to have been submitted more than once if they have been received from different sources. In other words, if a single-issue organisation submits the same uncertainty multiple times, this can be noted but not counted towards prioritisation as it will bias the overall ranking.

Steering group members will need to have agreed who will be responsible for coordinating, collating and listing the interim prioritised uncertainties.

This process is closely monitored by the JLA to ensure transparency and minimisation of bias.

Examples of a JLA Priority Setting Partnerships

The **Urinary Incontinence Priority Setting Partnership** interim priority-setting process, conducted by email, had 11 partner organisations choosing their top 10 uncertainties from the 226 submitted, and ranking them in priority order.

A range of techniques was used by the participating organisations to reach their top 10, including consulting members, pooling knowledge and combining the shortlists of colleagues. These priorities were then scored, with the highest ranked uncertainty being assigned 10 points, and the lowest gaining 1 point. In addition, the following rules were agreed:

- Uncertainties which were submitted more than once by different organisations were assigned additional points for frequency, with the most frequently submitted uncertainty being assigned extra points.
- Uncertainties which were identified by more than one organisation were ranked according to the number of organisations identifying them independently and these uncertainties were then further weighted in their favour if they were nominated by both patient and clinician organisations.

Next, a shortlist of 29 uncertainties, which proved to be an appropriate cut-off point, was developed. Finally, organisations planning to attend the final priority setting workshop were asked to choose and rank their top 10 from that shortlist as a precursor to that workshop.

Although this worked well, the evaluation suggested that 29 uncertainties may have been too many, and that giving partners 15-20 uncertainties to consider at the final meeting may be more manageable.

The **Schizophrenia Priority Setting Partnership** conducted its interim prioritisation exercise over email. Partners were asked to choose and rank their top 10 schizophrenia treatment uncertainties from a long list of 237, which was organised into a taxonomy agreed by the Steering Group.

Eleven partners responded either as individuals, on behalf of an organisation or having consulted with colleagues and/or members. The submitted rankings were collated. Separate running totals were recorded for patient, carer and clinician submissions. This enabled the Steering Group to examine each groups' rankings, as well as their combined ranking, which ultimately determined the make-up of the shortlist. This was provided as background information and was a useful discussion point at the final priority setting workshop.

A shortlist of 26 treatment uncertainties was developed as this was the logical cut-off point. This was sent out to partners to rank once again in advance of the final priority setting workshop.

Final priority setting

The final stage is to agree 10 prioritised uncertainties. The JLA recommends methods based on research⁵ and practical experience.

So far, the JLA has conducted this in face-to-face meetings, or workshops, using small and full group discussions.

The final workshop is an opportunity for different parties to:

- express their views
- hear different perspectives
- think more widely about treating or helping people with the health problem

The format is rigorous, but flexible enough to allow people to revise their opinions, raise concerns and correct through consensus any perceived imbalance emerging from the interim stage. This is the stage at which any concerns about fairness or representation can be openly discussed and addressed. The JLA actively encourages participants to take ownership of this debate.

There are challenges, such as:

- ensuring the choice of participants is balanced

⁵ Murphy MK, Black NA, Lamping DL, McKee CM, Sanderson CFB, Ashkam J, Marteau T. (1998) "Consensus development methods, and their use in clinical guideline development" *Health Technology Assessment*, 2 (3).

- avoiding domination by any one person
- cost
- finding unanimity, even where there may have been disagreement during the decision making process

The JLA's experience suggests that participants may want to debate or even dispute the shortlisted uncertainties, for example the wording, or whether or not any questions could be considered duplicates of each other. **It is essential that the Steering Group is confident that it can defend the shortlist which goes to the final workshop.** It is worth the Steering Group reflecting on the following questions:

- How confident are we that the questions will be understood?
- Is there scope for confusion?
- Are any of the questions too similar?
- Are there any which may be better combined into one question?

Reaching decisions with large groups of people can be challenging, but also exciting. The JLA is pragmatic about these challenges, which are not insurmountable, and encourages open debate and transparency when resolving them.

Preparation and a well organised meeting are key to ensuring good outcomes.

Examples of JLA Priority Setting Partnerships

Materials, briefings and documentation for the **Vitiligo Priority Setting Partnership's** final priority setting workshop included the following, which can all be downloaded at www.JLAGuidebook.org.

- a workshop programme
- a briefing paper for facilitators
- a background information sheet for participants
- a glossary for participants
- a ranking form for individuals to fill out in preparation for the workshop, containing the uncertainties short listed in the interim prioritisation exercise
- cards for each short listed uncertainty, printed double-sided to also include background information and data on the back of each one, to help group discussion
- a ranking form for the group discussions, to be filled out by each facilitator

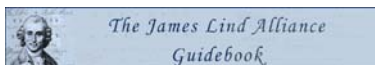
The agenda and cards from the **Schizophrenia Priority Setting Partnership**, as well as a good example of clear directions to the workshop venue, can also be downloaded at www.JLAGuidebook.org.

There are reports on the JLA website describing the final priority setting meetings and listing the top 10 priorities of:

- the **Asthma Priority Setting Partnership**
- the **Urinary Incontinence Priority Setting Partnership**
- the **Tinnitus Priority Setting Partnership**

Go to www.lindalliance.org.

There are further journal and newspaper articles on the outcomes of the priority setting exercises for stroke, urinary incontinence, prostate cancer and schizophrenia. Go to www.JLAGuidebook.org for details.



Description of a final priority setting workshop

This section describes what happens in a standard JLA final priority setting meeting. The literature suggests that a nominal group meeting be facilitated either by an expert on the topic or a credible non-expert, and that the meeting should be structured as sequential steps of consensus building. The meeting is held in person, although the JLA has experience of including participants who have only been able to take part via Skype.

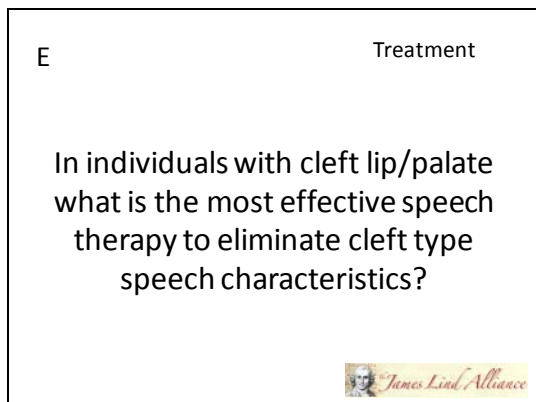
Phase 1

- The short list of treatment uncertainties is provided for participants before the meeting.
- Participants are asked to rank these and consider their views about each treatment uncertainty - before the group meeting.

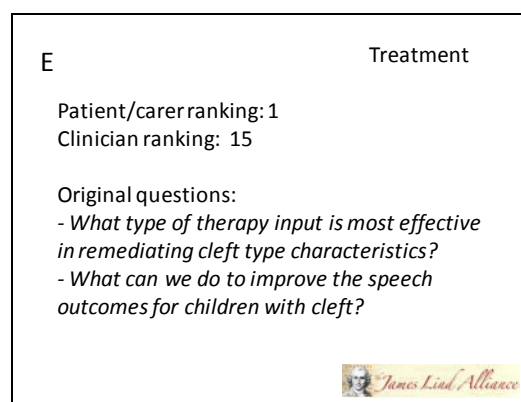
A4 cards with the uncertainties on them are introduced at this point. These are double-sided. The front has the uncertainty to be prioritised, and the back has interim voting results and examples of original survey submissions.

Below is an example of an uncertainty card used in the Cleft Lip and Palate PSP final workshop:

Front



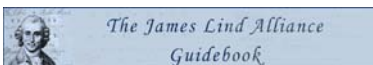
Back



Phase 2

- In small groups (3-4 groups of up to 8 people – equal mix of patients, carers and clinicians), each participant, in turn, contributes their views on the treatment uncertainties they feel most and least strongly about. These are noted down by the facilitator. This continues until all ideas/views have been expressed.
- There the discussion is reviewed by the group to clarify any aspects of the uncertainties.

Phase 3



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- The same small groups move the discussion to ranking the short list of uncertainties.
- During the break, the facilitator should lay out the cards in rough groups: those which were thought to be most important, those thought to be least important and those not mentioned or where there was divergence of view.
- Groups are **not allowed to merge uncertainties at this stage** – where they feel that there are similarities between uncertainties they can be ordered sequentially (ie kept next to each other on the list), and noted by the facilitator to be discussed in plenary.
- It is important that all small groups achieve a ranked order of all the uncertainties
- Participants are also encouraged to take account of the contextual information on the back of the uncertainty cards – such as examples of original survey submissions and interim voting results.
- Each groups' ranking is entered into an Excel database, which are tabulated and a first overall (aggregate) ranking of the list is achieved at this point. This and individual group results are presented and discussed as a whole group, usually after a lunch break. An example of the spreadsheet used can be downloaded at www.JLAguidebook.org.
- This overall (aggregate) ranking is taken back into second round of *different small groups* for discussion (although again, equal balance of patient, carer and clinician input). Facilitator should lay all the cards out in the aggregate order, although the discussion should focus more on the top 15 and any 'outliers' that participants feel strongly about. A full ranking must be done and recorded.



Phase 4

- These small group scores are again entered into the Excel spreadsheet, tabulated and presented to the whole group. An aggregate ranking is presented.
- This final ranking is discussed in the large group, with the aim of agreeing the top ten by the end of the discussion session. **At this stage uncertainties can be merged.** Some PSPs have also decided on more than 10 for the final list.

- It is helpful to make notes on the final set of cards being used to note changes in emphasis to the uncertainties (by consensus), for example the wording may be changed from “maternal bonding to parental bonding”



Alongside the consensus process, there may be a non-participant observer collecting qualitative data on the process. Whilst the Nominal Group Technique focuses on a single goal (for this purpose the selection of the ten most important treatment uncertainties) and is less concerned with eliciting a range of ideas or the qualitative analysis of the group process *per se*, the JLA has found an observer account of the process helpful in review and analysis.

Who should take part and how many?

Each participant must be justifiable in some way as an “expert”. They will be affiliated in some way to one of the partner organisations. We suggest a minimum of 12 people and a maximum of 30.

They may be:

- Clinician e.g. consultant or Senior Registrar, paediatrician, GP, specialist nurses, physiotherapists, dieticians, advice line nurses, speech therapists etc
- A patient or carer/parent with direct experience of the health problem(s), patient group staff.

The JLA has always considered achieving a balance of clinical and patient viewpoints more important than the representativeness of each participant. This is important, because most examples of priority setting show “*clinicians are*

*more involved than patients in the whole process*⁶. Participants are encouraged to share biographical information about themselves and their perspectives of the condition under discussion, before the workshop.

Actions that enhance the Nominal Group Technique Approach

- Establish a clear structure for the priority setting meeting and the ‘taking turns’ aspect of the feedback – this should help restrict any dominance of particular individuals.
- Agree ‘ways of working’ (ground rules) at the outset of the meeting (to include aspects of communication and use of jargon).
- Ensure everyone is aware of the nature of consensus decision making: it requires pragmatism and compromise.
- Provide a glossary of research terms prior to the workshop
- Provide biographical information about participants ahead of the meeting
- Ensure that all participants are familiar with the items to be discussed – offer them an opportunity to discuss these beforehand with JLA team members or relevant partners

The final priority setting should achieve the following:

- An informed, structured and purposeful debate amongst people who have previous experience and/or direct experience of treatment uncertainties in question
- A list of the most important shared priorities for future clinical and health research – we suggest that Priority Setting Partnerships aim for 10 but some have agreed 12.
- A description of where there is disagreement, and why.
- Further developments sharing the priorities with a wider constituency and plans to refine and submit the uncertainties for further research
- JLA partners may choose to continue to work together on related issues.

Final priority setting methods

After considering the various methods available, the JLA has decided to support a *Nominal Group Technique* for Partnerships choosing their top ten priorities. One benefit of this technique is that it prevents the domination of discussion by a single person and encourages the participation of less assertive group members. This has now been trialled by a range of Partnerships, including the Asthma, Urinary Incontinence, Vitiligo, Prostate Cancer and

⁶ Stewart R and Oliver S (2008) A systematic map of studies of patients' and clinicians' research priorities. London: James Lind Alliance

Schizophrenia Partnerships. Observation reports and evaluations are available on the JLA website: www.lindalliance.org.

However, there are a number of other methods for reaching decisions together which are described briefly here.

Nominal Group Technique

The Nominal group technique is a well established and well described approach to decision making^{7, 8}. It can be used by groups that want to make decisions quickly, for example, by voting, but want everyone's opinions to be taken into account. Each participant reviews the items for discussion, and gives their view. A shared voting or ranking exercise is undertaken with further structured small group discussions followed by ranking or voting. The ranked orders for each item from each contributor are totalled, and the priority with the lowest (ie most favoured) total ranking is selected as the top priority.

It has been suggested that Nominal Group Technique can be useful when:

- some group members are much more vocal than others.
- some group members think better in silence.
- there is concern about some members not participating.
- the group does not easily generate many ideas.
- all or some group members are new to the team.
- the issue is controversial or there is heated conflict

Delphi Technique

Consensus development and prioritisation using the Delphi technique are well described.⁹ The process is undertaken predominantly by a questionnaire. Selected participants answer questionnaires in two or more rounds. After each round, an anonymous summary of the results from the previous round is circulated, with the reasons for judgments. This encourages participants to revise their earlier answers in light of the replies of other participants in the process. During the process, the range of the answers decreases and the group will converge towards a consensus. This approach could be adapted for use in JLA interim priority setting, simply by ranking uncertainties in the order of their perceived importance.

The Delphi approach helped to establish common research priorities in mental health across mental health service users, informal carers, mental health practitioners and service managers.¹⁰

⁷ Jones J, Hunter D (1995) Consensus methods for medical and health services research, *BMJ*, 311:376-80

⁸ Rowe G, Wright G, Bolger F (1991) Delphi: a re-evaluation of research and theory. *Technological Forecasting and Social Change* 39:235-51

⁹ Phill J. (1971) The Delphi method: substance, context, a critique and an annotated bibliography. *Socio-Economic Planning Science* 5:57-71

¹⁰ Owens C, Ley A, Aitkeen P, (2008) Do different stakeholder groups share mental health research priorities? A four arm Delphi study *Health Expectations*, 11, pp418 -431

Expert Panels

Expert panels in the Health Technology Assessment Programme prioritise and refine research questions at the same time before health technology assessments are commissioned.¹¹ Expert panels are assisted by briefing papers, and background information about the proposed research topic under scrutiny (called 'vignettes'). These review the extent of the health problem, outline existing or planned research, and clarify the research question. These vignettes are prepared by consulting key sources of research and topic and lay experts. Expert panels follow normal committee rules.

Discussion has been considered more inclusive when chairs have invited panel members who are not experts to introduce each topic for discussion. Decisions are made at two stages: first, by deciding which topics are sufficiently important to deserve a vignette to inform discussions; second, to decide which vignettes and their integral research questions should lead to commissioned research. Decisions are made through private voting/ranking.

Expert panels include three public advocate members who are well placed to influence individual decisions and the culture of the panel meetings. A formal evaluation¹² found that public members offered unique contributions. Moreover, public members, other members and staff perceive a change in attitudes and sensitivity towards public perspectives in health technology assessment decision making.

Consensus Development Conference

A consensus development conference is a meeting that debates summary statements of health care and treatment then seeks consensus on the most important of these.

The ASQUAM group (Achieving Sustainable Quality in Maternity) decided to choose a new set of research priorities for the year 2000, and to ascertain the voting pattern of service users compared with health professionals.¹³ There were 10 discussion groups, each with approximately 10 participants from a mixture of backgrounds, including obstetricians, senior midwifery staff, general practitioners, paediatricians and service users. In all there were 90 health professionals and 11 consumers. The leader of each group introduced key research issues and welcomed novel ideas from participants.

From the many topics discussed during the one-hour session, each of the 10 groups agreed on two topics they wished to propose (framed within the terms of health technology assessment). Following short presentations on all 20 topics, all delegates voted on paper for up to 10 topics, without ranking, in order to identify the 10 most popular.

Electronic Nominal Group and Online Voting

¹¹ Oliver S, Milne R, Bradburn J, Buchanan P, Kerridge L, Walley T and Gabbay J. (2001) Investigating Consumer Perspectives on Evaluating Health Technologies, *Evaluation* 7 (4): p 468-486.

¹² Oliver S, Armes DG, Gyte G. Public involvement influences a national research agenda. *The Patient: Patient-Centered Outcomes Research* 2009 2 (3): 179-190.

¹³ Johanson R, Rigby C, Newburn M, Stewart M, Jones P (2002) Suggestions in maternal and child health for the National Technology Assessment Programme: a consideration of consumer and professional priorities. *Journal of the Royal Society for the Promotion of Health*, 122 (1):50-54

The advent of the Internet has provided an online platform for priority setting. In the BRISK trial prioritisation was achieved with an electronic nominal group and online voting.¹⁴ Key steps included:

1. Create a website that provides the list of topics in random order (changes every X minutes) and so takes out any availability bias
2. Invite people to join a prioritisation panel
3. Give each participant a unique login access via password (one login allowed) – if incomplete vote – new login issued and try again.
4. Post hoc analysis of groups by age, sex and any other variables that are important to consider (collect as part of request to vote).
5. If the panel is large enough and diverse enough, there will be a good possibility for subgroup assessment of various influences.

Interactive Research Agenda Setting

Colleagues from the Athena Institute in Holland have collaborated with the JLA in sharing their research agenda-setting work in asthma and chronic obstructive pulmonary disease (COPD).¹⁵ This work included patients, researchers and health professionals.

Below is a summary of their approach undertaken between 2003 and 2004.

Preparation and initiation: reviewing the literature and semi-structured interviews with 'relevant actors' in the field of asthma and COPD, identifying barriers to involving patients and ways of overcoming them. Identified three key groups to work together patients (through a national asthma organisation), scientists/researchers and health professionals.

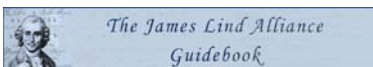
Consultation: process of taped discussion meetings resulting in the three groups developing their research priorities for research on COPD and asthma. Also five semi-structured interviews with socio-cultural scientists, resulting in four priority lists.

Collaboration: integration of the priority lists, through a meeting of 32 people from the aforementioned groups. Summaries of consultation phase were sent out by post beforehand and lay summaries provided. After a plenary session of the results of the consultation three, mixed, parallel groups prioritised using different coloured posts on flip charts. This was followed by further prioritisation (to avoid pseudo-consensus) using a personal prioritisation matrix.

Outcome: the resulting societal research agenda is being used for the formulation of research policies and programmes and "will eventually result in the actual funding of research projects as well as possible lobbying activities towards the pharmaceutical industry, government and other actors".

¹⁴ Edwards A, Thomas R, Williams R, Elwyn G, (2004) Evaluating different formats to represent medical risks in online information for patients with diabetes – a randomised controlled trial, Report to BMJ Publishing Group Experimentation Committee

¹⁵ Caron-Flinterman J, et al (2006) Patients priorities concerning health research: the case of asthma and COPD research in the Netherlands. Health Expectations, 8, pp253 -263



Focus Groups

The National Cancer Research Institute supported the consultation exercise that involved 17 focus groups using Nominal Group Technique across the UK to involve people affected by cancer in cancer research prioritisation.¹⁶

The research generated 15 broad research themes, with three identified as high priority based on the number of 'votes' cast by the 105 participants.

Special consultation groups were run with people under-represented in research; patients from ethnic minorities; those receiving palliative care; and those aged over 75 years. There is no current information available about the pros and cons of prioritising in this way, and this study concerned patients only.

The Wales Epilepsy Research Network and Mental Health Research Network Wales organised 5 focus groups (two for professionals and three for patients and carers) to gather epilepsy treatment uncertainties.¹⁷ They were then asked to rank the most important of these. The research team conducted a thematic analysis of the questions and standardised the ranking, by using a statistical package that analyses the variance between rankings. This gave them a table of uncertainties in rank order.

Skills for setting research priorities

The JLA facilitates the final priority setting process to ensure transparency, accountability and fairness. It is important that patients, carers and clinicians can contribute equally. As such, membership of the small discussion groups should be determined in advance, to ensure an even mix of both groups.

Facilitators need to be aware that some patient and carer representatives may be less experienced than professional clinicians at contributing to open debate, and should therefore be careful to actively include patients and carers and ensure they have opportunities to share their views and experiences.

Information such as participant biographies, glossary of research terms and a clear structure for discussion and decision making must be sent to participants ahead of the workshop to help with this process. There is no hierarchy between the different participants; no one group's views or experiences are more valid than another's.

Overall, the JLA has developed a neutral style of facilitation, adopting a non-prescriptive approach to small group discussion about prioritisation, but maintains the ranking approach across all small groups. This helps to ensure that groups develop their own ways of working and make their decisions without being influenced by the JLA.

There is more advice available in the *Managing Values and Perspectives* section.

¹⁶ Wright D, Corner J, Hopkinson J, Foster C, (2006) Listening to the views of people affected by cancer about cancer research: an example of participatory research in setting the cancer research agenda. *Health Expectations* 9 (1) 3-12

¹⁷ Lloyd K, Cella M (2009) Final Report to the Wales Office of R & D on the DUETs project: the Database of Uncertainties about the Effects of Treatment (DUETs) for schizophrenia and epilepsy

Transparency and fairness

The JLA's role within the priority setting process is not only to facilitate. It is also to ensure, as an impartial party, that activity and decision-making are fair and transparent.

The work of the JLA is new and groundbreaking. It is not without challenges.

One issue which Partnerships may need to address is potential imbalance in the number of patients and clinicians involved throughout the process, and especially during the final priority setting meeting. It is vitally important to recruit representative patient and clinician organisations, and enable both groups to contribute equally.

Nevertheless, the proportion of representatives may vary according to individuals' availability. This can be a problem even when organisations have been asked to nominate a deputy to ensure attendance at key meetings, notably the final priority setting workshop.

Partnerships should therefore factor in a contingency to address over-representation of either group at the final priority setting meeting, for example, by weighting the responses of the under-represented group.

How to evaluate

Why evaluate?

As the JLA priority setting approach is relatively new, practical evaluation is particularly helpful in ascertaining what works, what does not, and to gather ideas about how to do things better.

Also, as Priority Setting Partnerships are carried out within the medical world, in which evidence gained through some form of evaluation is seen as paramount, a rigorous approach to evaluating the JLA method is expected.

What and how to evaluate

There are a number of elements within the activity of priority setting which can benefit from evaluation. These include:

- materials and events
- ways of working
- progress and achievements

The aim of this section is to act as a practical guide, but also to explain clearly the theories supporting such approaches. This approach to evaluation fits within a framework that has been piloted with patients, clinicians and researchers, covering process criteria (stakeholder representation, process structure and management), direct outcome criteria (a

consensus agenda that acknowledges participants' perspectives and offers practical directions for research), and indirect outcome criteria (learning about procedures and each others' ideas)¹⁸.

Materials and events

It is essential to know whether Priority Setting Partnership events are 'fit for purpose' and whether participants find the materials useful, easy to use and relevant.

Materials, such as background information and correspondence, need to be routinely reviewed and approved by the Steering Group. If Priority Setting Partnerships have time and resources, it can also be useful for such materials to be assessed by a small group of those who will be involved before they are finalised, ensuring clarity from the start.

After **events and meetings**, when drawing discussions to a close, it can be invaluable to invite feedback as to what went well and what could have been improved. A questionnaire may also capture useful thoughts.

The JLA always distributes **feedback forms** after its Priority Setting Partnership meetings. Go to www.JLAguidebook.org to see an example.

The JLA also carries out an anonymous **online survey** after the priority setting process has been completed. This enables participants to give an honest view on how the process worked for them, and where improvements can be made. Go to www.JLAguidebook.org to see the report of the online evaluation of the **Urinary Incontinence Priority Setting Partnership**.

External assessment by an invited observer brings added benefits. The observer records proceedings, describes activities, observes how people work together and reflects on the strengths and weaknesses of approaches. The observer's report of the **Asthma Priority Setting Partnership** can be read at www.JLAguidebook.org.

It is important that evaluation feedback is acted upon, where feasible, to improve Priority Setting Partnerships. The JLA encourages the sharing of good practice between different Partnerships, both directly and through this Guidebook.

To share your feedback and lessons learned, contact us via www.JLAguidebook.org or at the James Lind Alliance.

Ways of working

Priority Setting Partnerships in which patients and clinicians agree research priorities are a new idea, but they can learn from partnerships set up for similar purposes.

¹⁸ Caron-Flinterman F, Broerse JEW, Teerling J, van Alst MLY, Klaasen S, Swart LE, and Bunders JFG (2006). Stakeholder participation in health research agenda setting: the case of asthma and COPD research in the Netherlands. *Science and Public Policy*, 33 (4): 291–304

As set out more fully below, partnerships can be evaluated in terms of:

- the degree of involvement of patients and clinicians in planning and decision-making
- moral, ethical, and practical principles for involving the members
- standards of good practice recognised for priority setting more widely

Degrees of involvement: the minimum degree of involvement in research is simply being consulted about it, while collaboration implies a more equal status of participants. Greatest involvement is being in control.

Degrees of involvement were first distinguished in an analysis of citizens' involvement in American urban planning¹⁹. In **Arnstein's 'ladder of involvement'** (Figure 1) a prior step to any potential influence is being informed about what is happening. Consultations that capture public opinions may be through surveys, neighbourhood meetings or public enquiries. Closer collaboration may be tokenistic placation or meaningful partnership. Delegated power (and its associated accountability) and citizen control are the two top rungs in the ladder where citizens have a role in making decisions.

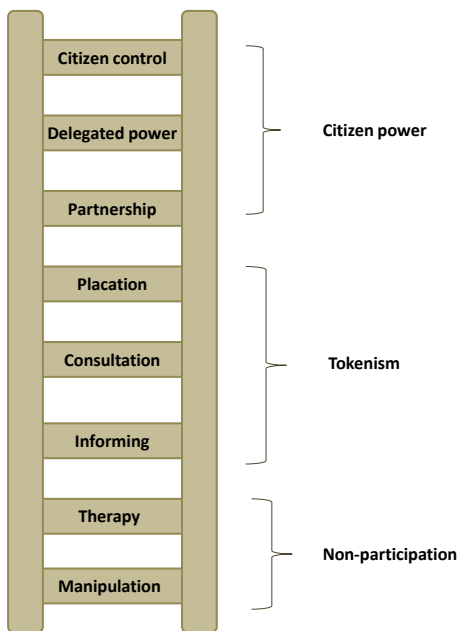


Figure 1 Arnstein's ladder of involvement

Evaluating priority setting partnerships in these terms is useful, both at the planning stage and later, as it helps participants to be clear about and reflect on their roles. Were their views and opinions invited appropriately? Were they partners sharing decisions? Did they feel some control over the process?

¹⁹ Arnstein, Sherry R. "A Ladder of Citizen Participation," *Journal of the American Planning Association*, Vol. 35, No. 4, July 1969, pp. 216-224.

Principles and indicators of successful involvement: more detailed suggestions for how to involve patients and clinicians have been adapted from a study of good practice for involvement in research²⁰. These include:

Principle	Indicator
The roles of patients and clinicians in priority setting are agreed within the partnership.	The roles of patients and clinicians in the partnership were documented
Patients and clinicians are involved in decisions about how people are both recruited and kept informed about the progress of the priority setting.	Patients and clinicians gave advice to the partnership on how to recruit people for priority setting. Both groups gave advice to the partnership on how to keep participants informed about the progress of the priority setting.
Patient and clinician involvement is described in priority setting reports.	The involvement of patients and clinicians in the priority setting reports and publications was acknowledged. Details were given in the priority setting reports and publications of how patients and clinicians were involved in the priority setting process
Priority setting decisions are available to patients and clinicians, in formats and in language they can easily understand.	The distribution of the priority setting decisions to relevant patient and clinician groups was in appropriate formats and easily understandable language. Patients and clinicians involved in the priority setting gave their advice on the choice of methods used to distribute the priority setting decisions.

Standards for priority setting: assessing whether the ways of working meet recognised standards for priority setting can include asking the following questions:

- Is there a strong commitment to engaging a full range of relevant stakeholders using multiple methods, with stakeholders well satisfied by the processes?
- Is there a clear plan that is followed in order to enhance trust and confidence in the processes?
- How is information found, collated and presented to the decision-makers; and what is considered lacking?
- Are decisions based on clear reasons?
- Is there a formal mechanism for reviewing decisions and addressing disagreements constructively?

²⁰ Boote J, Barber R, Cooper C (2006) Principles and indicators of successful consumer involvement in NHS research: results of a Delphi study and subgroup analysis. *Health Policy*, 75 (3), 280-297

These questions for assessing ways of working are based on research about priority setting for health services.²¹

Important processes for judging success include:

- Stakeholder engagement: a strong commitment to engaging a full range of relevant stakeholders using multiple methods, with stakeholders well satisfied by the processes
- Explicit processes: adhering to a clear plan in order to enhance trust and confidence in the processes
- Information management: how information was found, collated and presented to the decision-makers; and what was considered lacking
- Consideration of values: with decisions based on reasons grounded in clear value choices, and those reasons made explicit
- Revision or appeal mechanism: a formal mechanism for reviewing decisions and addressing disagreements constructively

There is a link to more information about how these questions were developed at www.JLAguidebook.org.

Progress and achievements

Evaluating procedures or ways of working is only part of the picture. It is also important to assess whether people were able to engage with the issues and with each other; what each contributed and the decisions they influenced; what they achieved, and/or whether this was what they set out to achieve²².

Patient or clinician involvement in setting research priorities might change the patients or clinicians themselves: what they learn about research and each other. It might influence the research priorities or the costs of identifying them, and ultimately the commissioned research or the costs of conducting it.

The success of a Priority Setting Partnership rests in large part on enabling participants to debate fairly amongst themselves. They thus need a situation that helps them to:

- engage with the issues
- share a common language, using expressions in the same way
- speak without being suppressed or excluded
- have equal opportunities to introduce new ideas
- accept no force other than strong argument supported by convincing evidence
- understand that their own views come from a particular perspective
- listen to each other

Evaluation is therefore highly relevant to assess this and a questionnaire can capture some of the issues by asking for example:

- Were there terms or phrases that participants did not understand?
- Did participants feel free to speak, and did they feel heard?

²¹ Sibbald SL, Singer PA, Upshur R and Martin DK. Priority setting: what constitutes success? A conceptual framework for successful priority setting. BMC Health Services Research 2009, 9:43 doi:10.1186/1472-6963-9-43

²² Renn, O., Webler, T. and Wiedemann, P. (1995) Fairness and Competence in Citizen Participation: Evaluating models for environmental discourse. Kluwer Academic: London.

- What did participants learn from each other?

However, questionnaires tend to miss how positions, values and decisions are shared during an encounter²³. If funds allow, an experienced independent observer may be more sensitive to the dramatic turns of some debates and provide invaluable feedback on these.

Input and influence: Neither having a seat at the table nor responding to a request for information guarantee being able to influence decisions. Whether this is achieved may be seen from observing people's interactions, inspecting and comparing records of contributions and of decisions, or by asking contributors or those alongside them whether influence was exerted. Influence may be immediate, by commanding attention during a discussion, or delayed, by influencing what appears on a list of priorities and ultimately when one of these priorities is translated into funded research.

Influence at all these stages was observed in an evaluation of public involvement in the NIHR Health Technology Assessment programme:

NIHR Health Technology Assessment Programme

Taken from Oliver S, Armes D, Gyte G. *Public involvement influences a national research agenda. The Patient: patient centred outcomes research*. (In press).

"Routine management records of the HTA programme were examined for public influence of research topics. The nature and influence of contributions from the public were compared with those of other experts. Structured observations of Advisory panel meetings investigated how discussion and decisions related to patient and public perspectives and how panel members responded to public input to the programme. Semi-structured interviews gathered perceptions of staff and Advisory Panel members.

"[This work found that] public involvement has influenced decisions about research commissioned by the HTA programme with only relatively minor changes to the procedures and resources for managing the programme. This results in outcomes research that incorporates patients' and publics' preferences and values being freely available for evidence-informed health services."

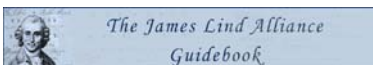
Priority Setting Partnerships' records of uncertainties can be analysed to find out who makes original suggestions, whether these suggestions attract support from others during discussions or rounds of voting, and whose suggestions appear in the top 10 priorities. An independent observer can record who initiates each discussion and who contributes to it. An independent interviewer can ask subsequently how participants see their role, contributions and influence and how they see that of others.

Achievements: examples of questions for finding out what has been achieved include²⁴:

- Do participants have greater insight into priority setting and each others' priorities?

²³ Harvey M. Drama, Talk, and Emotion: Omitted Aspects of Public Participation Science, *Technology & Human Values* March 2009 34: 139-161

²⁴ Sibbald SL, Singer PA, Upshur R and Martin DK. Priority setting: what constitutes success? A conceptual framework for successful priority setting. *BMC Health Services Research* 2009, 9:43 doi:10.1186/1472-6963-9-43.



- Did priorities change or did participants have more confidence in priorities, thereby making clear that time was well spent and shared decisions not merely 'rubber stamping'?
- Were decisions made with appropriate use of evidence, consistent reasoning, with priority setting integrated into wider systems and decision-making aligned with agreed goals and procedures?
- Were participants satisfied with the process and willing to continue participating and accept decisions even if they did not agree with all the outcomes?

Whether or not these outcomes have been achieved can be addressed in interviews or by analysing routine records or other documents.

Partnership goals: assessing the extent to which a partnership has reached the goals set by its own participants is vital. Successful partnerships need to be clear about what they are trying to achieve. If partners develop and agree clearly defined objectives at the outset, whether or when these objectives are met can be a central part of an evaluation.

Commentary on the goals and achievements of the JLA Asthma Priority Setting Partnership:

Extract from Petit-Zeman S. Society Guardian, Monday 21 May 2007:

"In August 2004, in the imposing marbled halls of London's Royal Society of Medicine (RSM), doctors, patients and carers met to discuss the current state of play in asthma research and treatment. By the end of the day there was collective agreement that these traditionally separate bedfellows might do well to forge a new relationship: working together to agree research priorities... It has taken almost three years to move the [JLA] asthma partnership to where it is now: an agreed list of ten research priorities that matter most to both sides."

Go to www.JLAGuidebook.org to find a link to the full article.

An independent reflective report of the Asthma Priority Setting Partnership can be downloaded from www.JLAGuidebook.org.

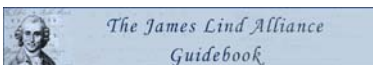
After an evaluation

Good evaluation provides lessons that can usefully be shared within the partnership and with other Priority Setting Partnerships. It is likely to highlight what has worked well and what could be improved.

Sharing these findings within the partnership and with others gives people an opportunity to discuss problems and suggest changes. Some changes may be easy, such as changing a circulation list or the format of documents. Others, such as managing group discussions, may be more challenging and need a commitment to try new ways of working.

As the JLA priority setting process matures, better ways may be found to involve people and to gather and discuss their ideas. Evaluation and reflection have a role here.

This approach was taken by the NIHR Health Technology Assessment programme, which has involved patients and clinicians in setting research priorities since 1997:



Version 5

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NIHR Health Technology Assessment Programme

Successive cycles of planning, action and critical reflection adopted since public involvement was first introduced [in 1997] have led to:

- increased information and financial support for service users;
- increased training and support for panel researchers seeking and recruiting service users
- provision of feedback to all referees about comments on research proposals
- increasing service user membership from 2 to 3 per Advisory Panel
- strengthening guidance for public involvement in individual commissioned research projects

Extract taken from: Oliver S, Armes D, Gyte G. Evaluation of public influence on the NHS Technology Assessment programme. Executive Summary. Social Science Research Unit, Institute of Education, University of London. June 2006.

Ethics for setting research priorities

Setting priorities for research raises ethical questions about how to work together, whether face-to-face or virtually, and how to evaluate priority setting exercises.

Participation ethics

The 'how to' section of this guidebook offers transparency and fairness as guiding principles for Partnerships, and emphasises the role of facilitators for managing differences in values and perspectives.

It is common practice for group discussions to follow 'ground rules' that participants have chosen together. These often include listening to and respecting other people's ideas, and sharing news of the event with other people but not ascribing individual names to specific statements. This last is known as the "Chatham House Rule".

This is because people may feel more at ease sharing their ideas, or asking for explanations about other people's ideas if there is an agreement about how contributions are reported. The benefit of such ground rules is not only greater ease in sharing fully formed ideas but also in providing a safe, legitimate space for sharing and developing ideas together (Davies et al. 2006). Indeed, some priority setting exercises are designed to allow groups of patients or groups of professionals to share and develop their ideas separately before bringing them together²⁵.

The International Association for Public Participation has a code of ethics for public participation practitioners which emphasises trust, openness, opportunity to participate and respect. Its purpose is to support public participation as "a process to make better decisions that incorporate the interests and concerns of all affected stakeholders and meet the needs of the decision-making body".

Ethics when discussing rare conditions

Additional challenges are raised by rare diseases. Here there are few patients and they may know the clinicians personally. Both patients and clinicians may prefer methods that preserve their anonymity, such as successive rounds of questionnaires and sharing of responses in a Delphi study.

²⁵ Nierse CJ, Abma TA. (2011) Developing voice and empowerment: the first step towards a broad consultation in research agenda setting. *Journal of Intellectual Disability Research* 55 (4): 411–421. doi: 10.1111/j.1365-2788.2011.01388.x

Information ethics

Collecting and sharing information raises ethical questions about how to protect personal information and how to acknowledge ideas from other people. Some people, when responding to questionnaires, describe their uncertainties about the effects of treatment by telling a personal story. Their consent is required to publish their uncertainty in UK DUETS (UK Database of Uncertainties in Effects of Treatments), omitting their name and any other identifiable features to protect their privacy. When collecting and storing identifiable data about individuals there are legal requirements under the Data Protection Act 2000. At the same time, the valuable contributions of the many un-named individuals deserve acknowledgement in reports. Naming partners organisations indicates the range of people contributing ideas.

Evaluation ethics

Agreements about anonymity are even more important if there are to be formal evaluations and written reports. Any information kept about individuals needs to be held securely and with their permission. When reports are written, even if names are not to be included, descriptions of individuals also need to be unrecognisable. Although this means individual names are not associated with particular contributions, reports should acknowledge those who have given time and effort to the partnership.

Evaluations about a group of people working together raise particular challenges. It is often very difficult, if not impossible, to share findings or write reports in such a way that participants do not recognise each other. Any critical comments need to be constructive and supportive, whether or not anonymity is attempted.

Another challenge arises when people responsible for the evaluation also have other roles in the partnership. For instance, anonymity may be meaningless if with the interviewer for the evaluation also has responsibilities for progressing the partnership.

Acting ethically is challenging, particularly because there is no single right way of working. Thinking through how to be fair and supportive with people from very different backgrounds is not easy - indeed, feeling uncomfortable about how best to do it is a sign of ethical thinking.

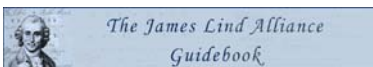
More on evaluation ethics...

Evaluating partnerships is challenging not only because relationships and team work are complex, but also because collecting and analysing data about those relationships raises ethical questions. Confusion may arise when roles and responsibilities for partnerships overlap or possibly clash with roles and responsibilities for evaluations²⁶. Is participation voluntary and informed, or are some people obliged, by virtue of their organisational role, to participate in an evaluation that will improve overall performance?²⁷ Can anonymity and confidentiality be assured, or are they not always appropriate, when people work together closely?²⁸ Effort is required to share findings sensitively and constructively if there is to be useful learning from evaluation.

²⁶ Mirvis, P. H. & Seashore, S. E (1982) Creating ethical relationships in organisational research. In (ed) Sieber JE. The ethics of social research: surveys and experiments. Springer-Verlag New York. 1982:79-104.

²⁷ Holian R and Brooks R. The Australian National Statement on Ethical Conduct in Research: application and implementation for 'insider' applied research in business. Action Research International 2004. paper 7.

²⁸ Zeni J. A guide to ethical issues and action research. Educational Action Research 1998. 6 (1) 9 – 19.



Ethics approval

Although it is important to choose and apply priority setting methods ethically, these do not normally come under the remit of the NHS Research Ethics Service (NRES), where research priority setting has been seen as service evaluation and development. The leaflet, *Defining Research* (<http://www.nres.nhs.uk/applications/is-your-project-research/>), helps distinguish between how the NRES sees research, audit or service evaluation and public health surveillance. In certain NHS settings, approval may be required from NRES; Applications can be submitted through the Integrated Research Application System (IRAS): www.myresearchproject.org.uk

Ethics advice and approval can be sought from within institutions hosting a priority setting exercises.

How to take priorities to research funders

Getting research done

The first step in getting research done is being able to explain clearly what patients and clinicians want to know - the questions they ask and the outcomes by which they want to judge the success of treatments. The core elements for describing priorities for research about the effects of treatment are²⁹:

- Evidence available (what is the current state of the evidence, and on-going research?)
- Population (what is the population of interest?)
- Intervention (what are the interventions of interest?)
- Comparison (what are the comparisons of interest?)
- Outcome (what are the outcomes of interest?)
- Time stamp (date of recommendation)

Other key information is:

- the health care setting in which treatments are used, and
- why this research or evidence is important to patients and clinicians.

Early work with the UK Database of Uncertainties about the Effects of Treatments (UK DUETs) will have prompted partnerships to be clear about their uncertainties. It is worth looking at records of the priority setting process to check why the top ten uncertainties are important. Using NICE Evidence Services (www.evidence.nhs.uk) will check whether there are still no systematic reviews addressing the top ten uncertainties. **The response required to a priority topic may be to commission a systematic review, or to update an existing one, rather than necessarily starting with designing and doing primary research.**

As well as identifying important questions, priority setting discussions may have identified important outcomes or measures for health research. For example, patients and clinicians have been involved in standardising outcomes for assessment in clinical trials on arthritis and fatigue is recommended patient-centred outcome measure.³⁰ As a result of

²⁹ Brown P, Brunnhuber K, Chalkidou K, Chalmers I, Clarke M, Fenton M, Forbes C, Glanville J, Hicks NJ, Moody J, Twaddle S, Timimi H, Young P. How to formulate research recommendations. *BMJ* 2006;333:804–6

³⁰ Tugwell P, Boers M, Brooks P, Simon L, Strand V, Idzerda L. OMERACT: An international initiative to improve outcome measurement in rheumatology. *Trials* 2007; 8(38).

patient input, fatigue is now one of the core set of recommended outcomes for assessing a range of treatments for rheumatoid arthritis.³¹

Once there is clarity about important questions and outcomes, JLA Priority Setting Partnerships can make research happen by promoting their top 10 priorities to key people:

- patients and carers
- research funders
- researchers and
- the wider research and policy community.

Finding appropriate funders

Partnerships seeking funders for their top 10 research priorities need to find those funders with an interest in: **particular health problems** or in the **effects of treatment**; and who have **funds** for a systematic review, a pilot study or a controlled trial or other relevant forms of primary research.

Funders of research addressing treatment uncertainties can be found in the public sector and the charitable sector, largely under two umbrella organisations:

- The National Institute for Health Research (NIHR) (www.nihr.ac.uk)
- The Association for Medical Research Charities (AMRC) (www.amrc.org.uk)

A comprehensive list of sources for research funds can be found at www.rdfunding.org.uk. Information is also available at www.researchresearch.com and at www.esrc.ac.uk.

Opportunities to work with funders

Finding out how funders work is essential before working with them and influencing their decisions.

A few research programmes set their priorities for research then advertise for research teams to conduct the research. These are **commissioning research programmes**.

Commissioning research programmes

The NIHR Health Technology Assessment programme commissions research. Its scope matches the interests of the James Lind Alliance particularly well. The Programme commissions research on the effectiveness of different healthcare treatments and tests for those who receive, manage and provide care in the NHS. The HTA programme funds evidence synthesis and primary research.

³¹ Kirwan JR, Minnock P, Adebajo A, Bresnihan B, Choy E, de Wit M, Hazes M, Richards P, Saag K, Suarez-Almazor M, Wells G, Hewlett S. Patient perspective: fatigue as a recommended patient centered outcome measure in rheumatoid arthritis. J Rheumatol. 2007 34 (5): 1174-7.

It invites visitors to its website to make suggestions for research. Other ways of getting involved with the HTA programme are as members of one of its expert advisory panels, which make recommendations on which research suggestions should be given priority, or as referees of research proposals. For more information go to www.hta.ac.uk/workwithhta.

The NIHR Public Health Research Programme also invites suggestions for research. If a top ten priority fits within public health, one route to obtaining funding is through the website suggestion form - www.phr.ac.uk/suggest. The HTA programme has committed to considering whether any of the top 10 priorities from JLA Partnerships are should be commissioned by the programme.

Far more often, whether or not research programmes or funding bodies set priorities of their own, they invite researchers or teams to submit their own ideas for conducting research, and thus respond to these ideas within **responsive research programmes**.

Responsive research programmes

Within the public sector, the NIHR Research for Patient Benefit Programme recognises that ideas for projects come from patients themselves, from the observations of experienced practitioners and practitioner researchers, as well as from the health research community. Although it does not fund large trials, it will fund the essential first step of a pilot study to investigate how to deliver the intervention and how to recruit people into a trial.

Patients and clinicians who have identified important research questions, particularly when playing a part in JLA Priority Setting Partnerships, are well placed to apply for funding. To ensure a high quality application they are advised to work in partnership with researchers who have methodological expertise. Patients can also express an interest in working with the programme's commissioning or peer review processes. To find out how, go to www.rfpb.nihr.ac.uk.

The NIHR Health Technology Assessment Programme, the NIHR Public Health Research Programme and the NIHR Health Services and Delivery Research (HS&DR) Programme also respond to researchers' proposals for studies. They welcome proposals from teams that combine the expertise of service users, practitioners and researchers.

There are also many charitable funders of medical research. These too are mainly responsive research programmes. They have usually considered applications based on researchers' own ideas of what is important even if these fall outside the charities' own priorities for research.³² However, as many charities thrive on the energy of patients and clinicians, they are a 'natural ground' for greater involvement in how research funds are spent. There is a growing interest amongst organisations belonging to the Association of Medical Research Charities in greater patient and public involvement in developing their research strategies, in making research funding decisions, and in the whole research cycle.³³ Opportunities for influencing decisions differ among the 120 member organisations, so each needs investigating individually, starting with its web site.

³² Staley K, Hanley B. Scoping research priority setting (and the presence of PPI in priority setting) with UK clinical research organisations and funders. Prepared for the James Lind Alliance, 2008.

³³ Association of Medical Research Charities. Natural Ground: Paths to patient and public involvement in medical research charities. London, 2009

If funds are to be found from commissioning programmes, the people to influence are the programme managers. If funds are to be found from responsive programmes, the people to influence are research teams.

Finding appropriate researchers

If funding is to come from responsive research funders, a research team must be found to develop a proposal for a top 10 priority. They might be found individually by searching the internet for research centres, university departments or medical schools.

Alternatively researchers may be found through their networks. Particularly appropriate for research addressing treatment uncertainties are:

- **UK Clinical Research Networks** which coordinate and support research in: Cancer, Dementias and Neurodegenerative Diseases, Diabetes, Medicines for Children, Mental Health, Primary Care, Stroke. A Comprehensive Clinical Research Network supports research in all areas of disease and clinical need. (www.ukcrn.org.uk).
- **The Cochrane Collaboration**, which aims to improve healthcare decision-making globally, through systematic reviews of the effects of healthcare interventions, published in The Cochrane Library (www.cochrane.org).

Opportunities to work with researchers

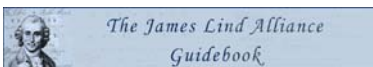
Clinical research networks provide researchers with a forum to discuss research. Each network has a clinical studies group to ensure it develops a balanced portfolio of high quality clinical research studies and has a route through which new studies can be developed. Each network also has a strategy for involving patients and the public.

Where the need is not for a primary study, but for a systematic review, top ten priorities may be of interest to the Cochrane Collaboration review groups (www.cochrane.org). Patients and clinicians can work with experienced reviewers in preparing systematic reviews of the effects of treatment. They can also offer to help by commenting on reviews being prepared by other people. Contact details for all Cochrane review groups are available in The Cochrane Library (www.cochrane.co.uk/en/clib.html).

Influencing the wider research and policy community

Sharing ideas for research with the wider research community, and even political lobbying, can also influence what research is done.

A passive approach to sharing ideas is publishing them in a format familiar to the research community. For instance, mothers who had a hunch about a possible cause of hyperactivity in their sons conducted a local survey and published



their findings in the academic literature.³⁴ Their efforts attracted the interest of scientists who chose to investigate their research ideas further.³⁵

A more direct approach is communicating with researchers directly. In maternity care, service user organisations have developed long standing relationships with researchers, service users and clinicians. Together they have influenced research and, subsequently, research-informed practice. For instance, surveys of care during childbirth conducted by the National Childbirth Trust in 1981 and 1993 prompted trials of care that eventually changed practice.³⁶

Some groups throw their energies into **political activism**. Lobbying in Canada by a national coalition of women prompted the Government to convene a Royal Commission on new reproductive technologies. This established a public consultation and informal discussions with academics, practitioners and advocates together, to develop a framework for research and development and identify research gaps.³⁷

How to publicise your priorities

It is important for Priority Setting Partnerships to publicise the results of their priority setting exercise.

This will increase the exposure of the priorities to potential funders and researchers. It is also an opportunity to promote the priority setting process itself.

Members of Priority Setting Partnerships have access to existing ways of communicating their work. These include:

- newsletters
- websites
- established relationships with sector publications
- conferences and speaker events

Articles on various Priority Setting Partnerships, ranging from newsletters to mainstream press to peer-reviewed journals can be downloaded from www.JLAGuidebook.org.

Priority Setting Partnerships may also consider submitting an article about their work to an academic medical journal, such as the British Medical Journal or The Lancet.

- Go to <http://resources.bmj.com/bmj/authors> for advice on submitting an article to the British Medical Journal.
- Go to <http://www.thelancet.com/writing-for-the-lancet> for advice on submitting an article to The Lancet.

³⁴ Colquhoun I, Bunda S. A lack of essential fatty acids as a possible cause of hyperactivity in children. *Med Hypotheses* 7:673-9.

³⁵ Stevens LJ, Zentall SS, Deck JL, Abate ML, Watkins BA, Lipp SR, et al. Essential fatty acid metabolism in boys with attention-deficit hyperactivity disorder. *Am J Clin Nutr* 1995;62:761-8.

³⁶ Oliver S, Clarke-Jones L, Rees R, Milne R, Buchanan P, Gabbay J, Gyte G, Oakley A, Stein K. Involving consumers in research and development agenda setting for the NHS: developing an evidence-based approach. *Health Technology Assessment* 2004; 8 (15) 1-148 [page 101].

³⁷ Roberts JH. Coalition building and public opinion. *New reproductive technologies and Canadian civil society*. *Int J Technol Assess Health Care* 1999;15:15-21.

The JLA actively encourages Priority Setting Partnerships to keep us informed of any publicity generated by their priority setting activities. Please contact us to share this information (patkinson@lindalliance.org or go to www.JLAguidebook.org).

Section 3: BACKGROUND

Why priority setting in research for health matters

Why set priorities for research; and why involve patients and clinicians?

Good research takes time and money. This is best spent where the need for more understanding is greatest. Such a need may arise because:

- new technologies are developed and little is known about their effects
- knowledge is already well advanced, but knowing a little more might have important impacts on health
- studies are readily available, but have not taken into account issues that are important to patients and clinicians
- considerable research has been conducted, but the total knowledge is unclear because isolated studies need considering together

Unfortunately some research has limited use for either patients or clinicians. For example, the ‘new technologies’ for osteoarthritis of the knee of interest to patients, general practitioners, physiotherapists and rheumatologists were not the drugs that were attracting most attention from clinical trials; there was greater interest in knee replacement and education³⁸. Similarly, cancer patients favour research about the management of practical, social, and emotional issues over investigating the biology or treatment of cancer³⁹

Focusing research where it will be most useful requires finding out what patients and clinicians want to know from research, and which of their requests for research are most important and urgent.

Patients and clinicians have ideas about which new technologies they would like to be fully tested, which current treatments warrant further testing, and which criteria they would use to judge success or failure.

Research by INVOLVE, *Exploring Impact: Public involvement in NHS, public health and social care research*, found that **patient involvement** in clinical research is of particular value in ensuring acceptability of trials, and that participants feel them to be ethical, well-designed and have relevant outcome measures. It also found that public involvement was reported to help increase recruitment to all types of research and was reported to be of value in qualitative research.

For a summary of *Exploring Impact: Public involvement in NHS, public health and social care research*, go to www.JLAguidebook.org.

³⁸ Tallon D, Chard J, Dieppe P (2000). Relation between agendas of the research community and the research consumer. *Lancet* 355:2037-40.

³⁹ Corner J, Wright D, Hopkinson J, Gunaratnam Y, McDonald JW, Foster C (2007). The research priorities of patients attending UK cancer treatment centres: findings from a modified nominal group study. *Br J Cancer* 96:875–881.

Knowledge for developing research agendas

Methods for developing research agendas are based on knowledge that comes from different sources: knowledge about who to involve and what procedures to follow that is accrued within organisations or by research; and tacit knowledge about how mixed groups of people interact that is held by participants and facilitators⁴⁰.

Constructive discussions require facilitators to pay attention to seating arrangements, eye contact, language, tone, body language, active listening, nonverbal communication, and teleconference etiquette⁴¹.

These discussions between patients and clinicians bring together different worlds where people have different types of expertise and speak different languages. The group facilitators act as teachers, researchers, organisers, Socratic guides, mediators and bridge builders; they are required to be reflexive, analytical, creative, open to new ideas, tolerant of ambiguity, flexible and empathetic **Abma and Broerse 2007**.

Priority setting within the UK health research system

Most clinical research is funded by industry, which sets its own agenda for research and development. Health research is also supported by public funds and by charities.

A formal process for setting priorities for NHS research began in 1991. All NHS research programmes engaged clinicians, patients and carers in deciding research priorities. Within 10 years, many of them had engaged patients.⁴² There is also growing enthusiasm for involving patients in research programmes funded by charities.⁴³

A survey of public and charitable funders of clinical research provides a picture of current approaches to priority setting in the UK. This found that funders commonly set priorities by “consulting patients and researchers and/or other stakeholders through surveys, focus groups or meetings; relying on informal communication with patients/members, or asking a group of experts (eg a Board or Scientific Committee) to make recommendations”.⁴⁴

Some funders have found researchers resistant to formal strategy development or priority setting. Some have tried working with patients to do so, and have found it challenging. Understanding and summarising patients’ responses has been difficult. There is also a risk of raising unrealistic expectations.

⁴⁰ Petit-Zeman S, Uhm S (2012). Editorial: Identifying research priorities in preterm birth. *Infant* vol 8, Issue 3

⁴¹ Cartwright, J. and Crowe, S. Patient and Public Involvement Toolkit, EBMT-EBM Toolkit Series (2011)

⁴² Oliver S, Clarke-Jones L, Rees R, Milne R, Buchanan P, Gabbay J, Gyte G, Oakley A, Stein K. Involving consumers in research and development agenda setting for the NHS: developing an evidence-based approach. *Health Technology Assessment* 2004; 8 (15) 1-148.

⁴³ Natural Ground: Paths to patient and public involvement for medical research charities. Association of Medical Research Charities 2009.

⁴⁴ Staley K and Hanley B. Scoping research priority setting (and the presence of PPI in priority setting) with UK clinical research organisations and funders. James Lind Alliance, December 2008.

Priority setting by research teams or priority setting for research teams?

Research funders use a range of approaches to decide what to fund. Some rely largely on researchers who are well informed about advances in their areas of interest - '**responsive**' **research programmes** - where individuals or teams submit plans for research that are within the funder's broad scope of interest, and the funder decides which to support. The funder may include patients or clinicians in that decision, and encourage researchers to include patients or clinicians in planning research.⁴⁵ The NIHR Research for Patient Benefit Programme is a responsive programme funding high quality, investigator-led research with and for health service staff about their day-to-day practice.

The NIHR Research for Patient Benefit Programme

This programme encourages researchers to work with patients and clinicians when planning, conducting and reporting research.

Indeed, research applications were rejected where the research team had not made contact with the clinicians and other service providers whose co-operation was clearly going to be vital, not only for securing access to patients but for generating interest in and 'ownership' of the findings that would emerge. Patients and patient groups were also often neglected. Consultation over findings was considered insufficient. Involvement of patients in the development of proposals and the conduct of the research was often perceived as crucial to the success of a project.

"Health care practitioners are in daily touch with patients and their needs. Both groups deserve a role in shaping the research agenda and creating the evidence base that will improve patients' lives. This new NIHR programme is about exactly this, and I am delighted to be associated with it."

Professor Celia Davies, Director of NIHR Research for Patient Benefit Programme, 2006-2009.

Go to www.rfpb.nihr.ac.uk to read more.

Those responsible for other research programmes decide what research they would like conducted, and advertise for researchers to conduct it - '**commissioned**' **research programmes**. Several teams may bid for the work, and the funder chooses between them. Commissioned programmes may involve patients and clinicians in deciding what research needs to be done, or which team should do it, and encourage researchers to work with clinicians and patients in deciding how the research is then done.⁴⁶ For example, the NIHR Health Technology Assessment Programme is a commissioned programme producing independent research about the effectiveness of different healthcare treatments and tests for those who receive, manage and provide care in the NHS.

The **NIHR Health Services and Delivery Research (HS&DR) programme** aims to produce rigorous and relevant evidence on the quality, access and organisation of health services, including costs and outcomes. The programme will enhance the strategic focus on research that matters to the NHS including research on implementation and a range of knowledge mobilisation initiatives. It will be keen to support ambitious evaluative research to improve health services.

⁴⁵ Staley K and Hanley B. Scoping research priority setting (and the presence of PPI in priority setting) with UK clinical research organisations and funders. James Lind Alliance, December 2008.

⁴⁶ Staley K and Hanley B. Scoping research priority setting (and the presence of PPI in priority setting) with UK clinical research organisations and funders. James Lind Alliance, December 2008.

A growing literature

There is a growing literature about setting priorities for health research with patients and clinicians.⁴⁷

Researchers often draw conclusions about research needs from studying patients' and clinicians' experiences of health problems or health services. To be sure that these research needs will serve patients and clinicians well, they need to be discussed and agreed with them.

At the turn of the century, only a handful of studies had been reported in which priority setting for research had involved patients or the wider public. By 2007, there were 27 such studies and nine of these also involved clinicians. These nine studies show that "methods have advanced over time, with all of them employing high quality participation methods: engaging participants directly and repeatedly in facilitated debate and most employing formal decision-making procedures."⁴⁸

The JLA Priority Setting Partnerships also include these features.

A checklist for setting priorities for health research captures nine themes of good practice⁴⁹:

- Decide which contextual factors underpin the process: resources; focus; values; health, research and political environment
- Use a comprehensive approach: structured, detailed, step-by-step guidance
- Inclusiveness towards participants
- Information gathering to inform the exercise
- Planning for information: translating priorities into research
- Select relevant criteria for deciding on priorities
- Plan evaluation: how and when
- Transparency: report clearly who set the priorities and how.

Consultations for priority setting

Researchers can listen to patients and clinicians views before making a decision about research priorities.

Diabetes priorities

Qualitative social research sought the research priorities of people with diabetes from an inner-city community in

⁴⁷ Oliver S, Gray J. A bibliography of research reports about patients', clinicians' and researchers' priorities for new research. London: James Lind Alliance, December 2006.

⁴⁸ Stewart R, Oliver S (2008) A systematic map of studies of patients' and clinicians' research priorities. London: James Lind Alliance..

⁴⁹ Viergever RF, Olifson S, Ghaffar A, Terry RF. A checklist for health research priority setting: nine common themes of good practice. Health Research Policy and Systems 2010, 8:36 <http://www.health-policy-systems.com/content/8/1/36>

Nottingham.⁵⁰ Thirty nine adult patients with diabetes from varying ethnic backgrounds were recruited from three general practices. Six focus groups were conducted with men and women from different ethnic groups. Patients were asked first to consider important areas in their lives and second how these would influence research they would like to see carried out in diabetes. They were asked to think about order of priority, but this was not a consensus-seeking exercise. Nine main themes emerged as important to the lives of people with diabetes. Each theme subsequently led to the development of specific research themes/questions.

More examples of consultations can be found in a map of the literature describing patients and clinicians priorities, at www.jla.nihr.ac.uk.

Collaborations for priority setting

An approach where researchers establish working relationships and share decisions with patients and clinicians, setting priorities collaboratively, is more radical than setting priorities through consultation.

Primary care mental health priorities

Approximately 30 participants, including GPs, psychiatrists, primary care nurses, a clinical psychologist, directors of the mental health charity MIND and users of primary care services participated in three rounds of proposing and commenting on possible research topics (a Delphi study).⁵¹

In the first round participants were asked to nominate up to five topic areas relating to mental health in primary care which they felt required further research. Their responses were used to construct questionnaires for rounds two and three, which required them to rate and re-rate the relative importance of items on a scale from one (essential) to five (unimportant). Where a participant's rating differed considerably from the group median, they were invited to comment further. No items received a median rating of one (essential) or five (unimportant). Twenty two items received a median rating of two (very important).

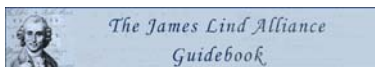
More examples of consultations can be found in a map of the literature describing patients and clinicians priorities. Go to www.jla.nihr.ac.uk.

The Cochrane Agenda and Priority Setting Methods Group (<http://capsmg.cochrane.org/>) is collating relevant research and providing a forum for international debate.

Resources

⁵⁰ Brown.K., Dyas J, Chahal P, Khalil Y, Riaz P, Cummings-Jones J. Discovering the research priorities of people with diabetes in a multicultural community: a focus group study. The British Journal of General Practice 2006; 56(524):206-213.

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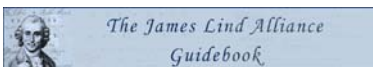
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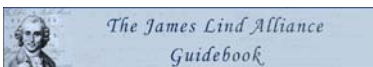
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Links

Association of Medical Research Charities (AMRC)

www.amrc.org.uk

The British Medical Journal

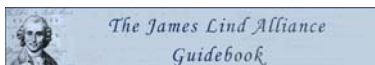
www.bmj.com

Chatham House Rule

www.chathamhouse.org.uk/about/chathamhouserule

The Cochrane Collaboration

www.cochrane.org



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The Cochrane Library
www.cochrane.co.uk/en/clib.html

The Cochrane Agenda and Priority Setting Methods Group
<http://capsmg.cochrane.org>

General Medical Council - Good Medical Practice
www.gmc-uk.org/guidance/good_medical_practice.asp

INVOLVE
www.invo.org.uk

Integrated Research Application System (IRAS)
www.myresearchproject.org.uk

James Lind Alliance
www.jla.nihr.ac.uk

James Lind Library
www.jameslindlibrary.org

JLA Pressure Ulcer Priority Setting Partnership
www.jlapressureulcerpartnership.co.uk

JLA Sight Loss & Vision Priority Setting Partnership
www.sightlossPSP.org.uk

The Lancet
www.thelancet.com

Medical Research Council
www.mrc.ac.uk

National Institute for Health Research
www.nihr.ac.uk

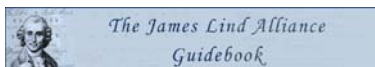
National Institute for Health and Clinical Excellence (NICE)
www.nice.org.uk

National Institute for Health Research
www.nihr.ac.uk

NIHR Evaluation Trials and Studies Coordinating Centre (NETSCC)
www.netscc.ac.uk

NIHR Health Technology Assessment (HTA) programme
www.hta.ac.uk

NIHR Public Health Research Programme



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www.phr.ac.uk

NIHR Research for Patient Benefit Programme

www.rfpb.nihr.ac.uk

NIHR Service Delivery and Organisation Programme

www.sdo.nihr.ac.uk

NHS Evidence

www.rsm.ac.uk

National Research Ethics Service

www.nres.nhs.uk/applications/is-your-project-research/

RD Funding

www.rdfunding.org.uk

ResearchResearch Ltd

www.researchresearch.com

Royal Society of Medicine

www.rsm.ac.uk

Testing Treatments Interactive

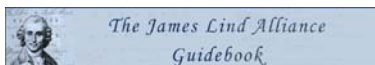
www.testingtreatments.org

UK Clinical Research Collaboration (UKCRC)

www.ukcrc.org

UK Database of Uncertainties about the Effects of Treatments (UK DUETs)

www.library.nhs.uk/duets



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Section 4: JLA PROTOCOL



[Insert health problem] Priority Setting Partnership

PROTOCOL [insert date]⁵²

Purpose

The purpose of this protocol is to set out the aims, objectives and commitments of the [health problem] Priority Setting Partnership (PSP) and the basic roles and responsibilities of the partners therein.

Steering Group

The [health problem] PSP will be led and managed by the following:

Patient representative/s:

- [Organisations/individuals]
 - [Named lead/s]

Clinical representative/s:

- [Organisations/individuals]
 - [Named lead/s]

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

- The James Lind Alliance (JLA)
 - [Named lead]

The Steering Group includes representation of patient/carer groups and clinicians⁵³.

⁵² 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.

⁵³ 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.

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 [health problem] 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.

[Insert description of how the PSP came together.]

Aims and objectives of the [health problem] PSP

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

The objectives of the [health problem] PSP are to:

- work with patients and clinicians to identify uncertainties about the effects of [health problem] 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

Partners

Organisations and individuals will be invited to take part in the PSP, which represent the following groups:

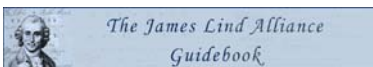
- people who have had [health problem]
- carers of people who have had [health problem]
- medical doctors, nurses and professionals allied to medicine with clinical experience of [health problem]

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 [health problem] 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 ⁵⁴

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

- to welcome and introduce potential members of the [health problem] 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 and management of [health problem]. A period of [insert timescale] 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;

⁵⁴ 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.

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 [insert name/s] 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 [insert name/s] 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.⁵⁵

Uncertainties which are not adequately addressed by previous research will be collated and prepared for entry into a [health problem] section within the UK Database of Uncertainties about the Effects of Treatments (UK DUETs - www.library.nhs.uk/duets) by [insert name/s]. 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 [health problem]. 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.

⁵⁵ Steering Group members should insert information on how they intend to do this.

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 [health problem] 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 those unanswered questions to use when approaching potential funders, or when allocating funding for research themselves, if applicable.⁵⁶

Publicity

As well as alerting funders, partners and Steering Group members are encouraged to publish the findings of the [health problem] 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.

Signed by the Steering Group

The undersigned agree to follow the [health problem] Priority Setting Protocol.

[Insert name and organisation]

.....

Date:

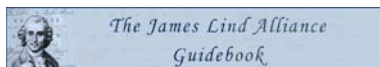
[Insert name and organisation]

.....

Date:

[Insert name], The James Lind Alliance

⁵⁶ Add further detail here about how and where the priorities will be developed and researched.



.....
Date:

Section 5: Annexes

Annexe 1: Template: steering group terms of reference



[Health problem] Priority Setting Partnership⁵⁷ Steering Group – background and Terms of Reference

Introduction to the James Lind Alliance and priority setting

The James Lind Alliance (JLA) is non-profit making initiative which was established in 2004 with the aim of enabling groups of patients/carers and clinicians to agree together on priorities in treatment uncertainty research. The JLA thus facilitates Priority Setting Partnerships (PSPs) in particular conditions.

Each PSP consists of patients/carers and their representatives, and clinicians, and is led by a steering group. Collaboration of this sort whereby patients and clinicians together set the research agenda is extremely rare, but vital in drawing issues to the attention of research funders which might not otherwise be suggested or prioritised.

The role of the PSP is to identify questions about treatment which have not been answered by research to date, and to then prioritise these. An interim priority setting exercise takes place over email/by post, and a priority setting workshop is then convened where partners debate and finally arrive at a top 10 list of shared uncertainties which are most important to them.

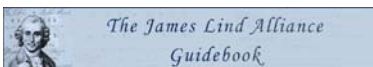
The aim is then to “translate” these uncertainties into research questions and obtain funding for that research.

Further details are at www.lindalliance.org.

The [health problem] Priority Setting Partnership

[Provide historical detail on the Partnership]

⁵⁷ These are generic terms of reference which should be updated to include relevant content of the Priority Setting Partnership. The document may be modified with agreement from the JLA to reflect the make-up of different PSPs and the steering groups driving them.



The wider aims and responsibilities of the [health problem] PSP are set out in the JLA Protocol [attached].

About the steering group

The steering group is responsible for coordinating and implementing the activity of the PSP. Drawing on members' expertise and networks, the steering group will help encourage membership to the wider PSP and, where members have the capacity and expertise, will carry out the practical work needed to collate the interim and final priority setting exercises. The steering group is also responsible for ensuring research funders are made aware of the final top ten uncertainties.

Membership of the steering group includes representatives of organisations which can reach and advocate for patients and clinicians, as well as JLA staff. Like the rest of the PSP, steering group members are expected to participate in the priority setting exercise.

Tasks

The [health problem] PSP steering group members are expected to participate in a number of specific tasks during the course of the priority setting process⁵⁸:

- Monthly telephone conference calls to update on progress.
- Working with UK DUETs to develop the [health problem] module.
- Publicising the initiative to potential partners to encourage them to join the PSP. This includes advising on membership of the PSP (to ensure a wide and representative group of patients and clinicians) and emailing contacts to invite them to participate.
- Managing the collection of treatment uncertainties from patients, clinicians and existing literature.
- Managing interim priority setting. This involves working with the JLA and UK DUETs to develop the interim priority setting questionnaire, based on the uncertainties in the [health problem] module in UK DUETs.
- Collating the results of interim priority setting and producing an "interim top 20-30" to take to the final priority setting workshop.
- Participation in the final priority setting exercise. A one-day workshop which brings partners together (one representative per organisation) to debate, rank and agree a final top ten.
- Publicising the final top 10 uncertainties to the sector and to research funders. This includes working with the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC) to develop applicable priorities into research questions.

Level of involvement and resources

Steering group members are asked to contribute, at a minimum, their expertise and their time. Basic involvement, as listed above requires:

- an interest in the initiative and outcomes being pursued in the project
- a broad understanding of project management issues and the approach being adopted
- commitment to working with other members respectfully and constructively
- advocacy for the project's outcomes
- prompt feedback on prioritisation materials
- participation in the monthly telephone conference calls
- the sharing of networks and contacts for membership of the PSP
- participation in the one-day final priority setting workshop

⁵⁸ Add and modify as appropriate.

- taking the time to bring the top ten [health problem] uncertainties to the attention of funders

Administration

[To be discussed and agreed]. This includes making arrangements for all meetings and workshops, and ensuring:

- requests for agenda items are discussed with the group
- papers will be available at least a week before meetings
- meeting notes will be circulated within two weeks

Timescales

[To be inserted]

Key contact

[To be inserted]

Annexe 2: Declaration of Interests forms

Below are two forms for declaring interests: one for individuals and the other for organisations.



Declaration of Interests: INDIVIDUALS

The James Lind Alliance (JLA) requests that all organisations and individuals in the Priority Setting Partnership who intend to vote for priorities complete this short questionnaire. The JLA strives to maintain a culture of openness and transparency among partners, to encourage dialogue within partnerships and also to meet the requirements of its funders, the National Institute for Health Research and the Medical Research Council. We seek these responses to help us to work most effectively with you, and to maximise your participation in the process.

The aim of the questionnaire is to ensure the following:

- confirmation of shared goals and values
- up-to-date contact details and information on communication preferences
- transparency about any potentially competing interests

In the interests of transparency, this information will be available to all other partners.

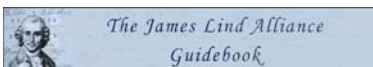
A shared vision for the partnership

1. The JLA's goal is to work with patients and clinicians as equal partners to 'tackle treatment uncertainties together'. In working with the Priority Setting Partnership, do your aspirations fit with this?

Yes No

1a. If you answered 'no', how do you see yourself working with the JLA?

Practical considerations



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2. Please provide us with up-to-date contact details

Name:

Contact details:

.....

3. What is the best way to communicate with you, including sending documents?

Email Post Other: please describe

4a. Do you have any special requirements? (eg large print)

.....

5. Are there any barriers to you participating fully in the priority setting process? (eg limited availability, capacity to attend meetings, etc)

Yes No

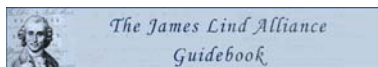
If yes, please explain how the Priority Setting Partnership can best work with you to address this:

Declaring interests

6. Do you have any competing interests which could be seen as to influence your participation which you feel we should be aware of?

Yes No

If yes, please describe how you will manage this.



7. Have or do you publicly declare any strong opinions about treatment in this area?

Yes No

If yes, please explain.

Thank you for taking the time to fill out this form. Please return it to: [insert contact details]



Declaration of Interests: ORGANISATIONS

The James Lind Alliance (JLA) requests that all organisations and individuals in the Priority Setting Partnership who intend to vote for priorities complete this short questionnaire. The JLA strives to maintain a culture of openness and transparency among partner organisations, to encourage dialogue within partnerships and also to meet the requirements of its funders, the National Institute for Health Research and the Medical Research Council. We seek these responses to help us to work most effectively with you, and to maximise your participation in the process.

The aim of the questionnaire is to ensure the following:

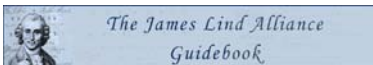
- confirmation of shared goals and values
- up-to-date contact details and information on communication preferences
- transparency about any potentially competing interests

In the interests of transparency, this information will be available to all other partners.

A shared vision for the partnership

1. The JLA's goal is to work with patients and clinicians as equal partners to 'tackle treatment uncertainties together'. Do your organisation's aspirations fit with this?

Yes No



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1a. If you answered 'no', how do you see your organisation working with the JLA?

Practical considerations

2. How will you represent your members'/stakeholders' views in the prioritisation process?

3. Who will be the lead person from your organisation with whom the Priority Setting Partnership can communicate and who will actively participate in the process?

Name:

Position:

Contact details:

3a. Please also nominate a deputy to ensure for succession planning and in the case of absence (this is vital for the final priority setting workshop):

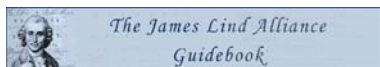
Name:

Position:

Contact details:

4. What is the best way to communicate with your organisation, including sending documents?

Email Post Other: please describe



4a. Do you have any special requirements? (eg large print)

5. Are there any barriers to your organisation participating fully in the priority setting process? (eg limited resources, availability, capacity, etc)

Yes No

If yes, please explain how the Priority Setting Partnership can best work with you to address this:

Declaring interests

6. Does your organisation have any competing interests which could be seen as to influence your participation which you feel we should be aware of?

Yes No

If yes, please describe how you will manage this.

7. Have or do you publicly declare any strong opinions about treatment in this area?

Yes No

If yes, please explain.

8. Does your organisation receive any funding or benefit in kind from organisations or individuals which we should be aware of (eg sources of funding which may cause undue influence on your contribution to the prioritisation process)?

Yes No

If yes, please explain.

Thank you for taking the time to fill out this form. Please return it to: [insert contact details]

Annexe 3: Uncertainties form and survey template

James Lind Alliance – inviting the submission of treatment uncertainties

The purpose of this paper is to agree basic wording to assist Priority Setting Partnerships request the submission of treatment uncertainties, to be included as a resource in the online Guidebook. It is intended that the wording is succinct, accessible and appropriate for a patient audience, as well as a clinical one. Partnerships will be able to tailor it to reflect and meet their individual needs.

There are two parts to this paper: background information and a pro forma, for the submission of uncertainties. Partnerships should adapt them to suit their purpose, then decide whether to present this as two separate papers, or web links, depending on how they decide to circulate them.

Prioritising treatment uncertainties in [health problem] for research - BACKGROUND INFORMATION

This paper provides background information on a study being carried out by [organisation] and the James Lind Alliance, in which you are invited to get involved. It accompanies the survey which you have been asked to complete.

What's the study about?

[Organisation], in partnership with the James Lind Alliance (JLA), is conducting a study to identify uncertainties about the treatment of [health problem] which are important to patients and clinicians, and then to work with patients and clinicians to prioritise them for research.

Why is this study important?

[Health problem-specific background on existing levels of research, knowledge and patient/clinician involvement].

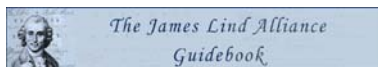
Who's involved?

The project is being led by [organisation and background]. It is being supported by the JLA. The JLA is a non-profit initiative funded by the National Institute of Health Research and the Medical Research Council to bring patients, carers and clinicians together to identify and prioritise the unanswered questions about treatments that they agree are most important. This information will help ensure that those who fund health research are aware of what matters to both patients and clinicians.

What are treatment uncertainties?

'Treatment uncertainties' occur when questions about treatment cannot be answered by up to date information based on research evidence – essentially they are unanswered questions about treatment. If you have a question about or are uncertain about any aspect of the treatment of [health problem], and you think these need to be answered by research, we want to know about it.

We are most interested in issues which you have encountered during discussions or consultations between medical staff and patients or those caring for patients with [health problem]. In other words, questions and uncertainties which are immediately relevant to treating someone with [health problem]



What will happen to the treatment uncertainties?

The treatment uncertainties which are submitted to the study will be checked to ensure they are true uncertainties, which have not been answered by existing research elsewhere. They will then be combined with uncertainties which have been identified through a review of existing research and literature. These will then be entered into the UK Database of Uncertainties of the Effects of Treatments (UK DUETs – www.library.nhs.uk/duets). They will then go through a process of prioritisation, in which you can also get involved, to identify ten priorities for research which are of the most importance to both patients and clinicians. This list will be published and provided to organisations that fund research.

Why patients, carers and clinicians?

Research on the effects of treatments often overlooks the shared interests of patients, their carers and the clinicians who treat them. As a result, questions they consider important are not addressed. The pharmaceutical and medical technology industries and academia play essential roles in developing new treatments, but their priorities are not necessarily the same as those of patients, carers and clinicians. For this reason many areas of potentially valuable research are neglected.

How can I get involved?

If you would like to participate in the study, you will be required to complete the accompanying short survey. It asks what questions and uncertainties you have about the treatment of [health problem]. The survey will need to be completed and submitted to [organisation] by [deadline].

Confidentiality and consent

You can complete the anonymously if you wish. If you do provide your contact details, they will be kept confidentially and securely, in accordance with the Data Protection Act⁵⁹. As part of the process, your uncertainty may be published in UK DUETs, and we will need your permission for this to happen. Your name/organisation will NOT be published in association with the uncertainty.

Contacts

For further information, or if you have any concerns or complaints about this process, please contact [individual, organisation].

Useful websites

[Organisation]

James Lind Alliance: www.lindalliance.org

UK Database of Uncertainties about the Effects of Treatments: www.library.nhs.uk/duets

Prioritising treatment uncertainties in [health problem] for research – SURVEY

This format may be adapted to be completed online or by hand. The basic minimum questions have been included, but the Guidebook will have examples of additional questions asked by previous PSPs.

⁵⁹ The Steering Group is advised to ensure that mechanisms are in place to store the data securely.

Introduction

[To include:

- background information on the study
- brief explanation of an uncertainty in the context of the health problem
- examples of treatment uncertainties, although not necessarily for the health problem itself]

What questions about the treatments for [health problem] would you like to see answered by research?

- 1.
- 2.
- 3.
- 4.

Are you...?

- A health professional working in the field of [health problem]
- A patient with [health problem]
- A carer of someone with [health problem]
- Other – please describe _____

Other details

[Profiling respondents, for example by collecting demographic information or clinical setting, is optional, as long as the lead organisation has robust reasons for doing so, explains this and is able to store the information securely.]

Consent

As part of this research process, we may publish the uncertainty you have identified in UK DUETS. (Your name or the name of your organisation will **NOT** be published in association with the uncertainty.) Do we have your permission to do so? *[Alternatively, the survey can state that completion of the survey constitutes consent for the respondent's uncertainties to be published in UK DUETS, although not their details.]*

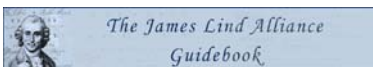
- Yes
- No

Signed _____

Date _____

Contact details

You do not have to give us your name and address. However, if you do so we will be able to contact you if we want to ask you for more details about the information that you send to us or if we feel that we can help with the uncertainty that you have identified.



Version 5

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Name _____

Postal / email address _____

Please tick if you would like to be kept informed of the progress of this study.

Please return this form to [organisation and contact details].

Forms must be received by [deadline].

Thank you for taking part in this important study.

Annexe 4: Interim prioritisation template

[Insert Priority Setting Partnership name]

The James Lind Alliance [insert name] Priority Setting Partnership has produced a 'long list' of [insert number] treatment uncertainties in [insert condition]. These have been taken from the consultation exercise in [insert date/details]. We now need to develop a shortlist of these treatment uncertainties for consideration at a priority setting workshop in [date]. We are asking all of the partners to do this exercise and tell us which of the treatment uncertainties they think should be prioritised for research, and should therefore appear in the shortlist. Each organisation represented gets one 'vote'. How you do this is up to you. For example, you might consult with members using existing user groups, or you might collaborate with colleagues to identify your priorities, or base them on your own knowledge or research. There is space at the end of this form to describe how you did it. If one person undertakes the task *then the chosen uncertainties will be viewed as their organisation's selection.*

Please can you do the following:

1. **Choose 10 uncertainties** that you would like to go forward for consideration at the priority setting workshop. Use the ID number in the document to show us your chosen ten in first column of the table below.
2. **Rank your ten** in the second column, using 1 = most important, working through to 10 = least important.
3. This is **optional** but interesting to us. Tell us, in the third column, why you made these choices.

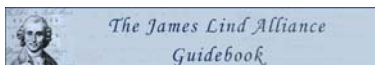
Chosen ten uncertainties <i>Enter ID here</i>	Priority <i>1 = most important 10 = least important</i>	Comments about my choices <i>We are interested in the reasons for your choices - please tell us here</i>
	1	
	2	
	3	
	4	
	5	
	6	
	7	
	8	
	9	
	10	

Your name:

Name of the stakeholder organisation that you represent/are a member of (if applicable):

Are you responding as (please circle): patient carer clinician

Did you do this exercise on your own? Yes / No



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If you involved other people in the exercise please describe this: