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## **Hair Loss Priority Setting Partnership**

Establishing and Prioritising Research Questions for the Treatment of  
Hair Loss (Alopecia)

### **PROTOCOL**

**Version 1.7 (5 June 2014)**

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On behalf of the  
British Hair and Nail Society

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## **I. Purpose**

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

Whilst doctors typically consider hair loss (alopecia) as a group of disorders with a broad spectrum of severity, many people with physiological or mild hair loss as defined by a doctor will manage their condition without medical help and will not consider themselves to be a patient. The intention of this PSP is to include everyone with hair loss of whatever severity. For simplicity, the term hair loss is used throughout this protocol to include everything from a small patch to extensive disease. Similarly, the phrase 'people with hair loss' is used instead of patients in recognition of the fact that many people with hair loss do not consult a doctor.

## **II. Steering Group**

The hair loss PSP will be lead and managed by a Steering Group including people with hair loss, health care and allied professionals involved in treatment delivery as well as facilitators with expertise in relevant research methods. 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. The Steering Group members and who they represent are listed in Appendix 1.

## **III. Background to the hair loss PSP**

The James Lind Alliance (JLA) is a project which is funded by the National Institute of Health Research with support from the Medical Research Council. The aim of the JLA 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. It is perhaps more helpful to think of an uncertainty as something unknown about an intervention that, if known, could improve or change practice.

Hair loss (alopecia) is a common problem that has been shown to have a significant impact on psychological well-being and quality of life, and can sometimes also signify an underlying medical problem. Treatment of hair loss disorders is often challenging due to a number of factors, including limited understanding of the natural history of the condition, poor disease definitions,

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lack of validated severity scales and generally poor quality of evidence for treatment. Only a limited number of hair loss disorders have good quality randomised controlled trial (RCT) evidence to guide treatment choices. Further, access to supportive therapies (e.g. psychological support, wig provision, etc) can vary across the country and evidence for the most effective use of these interventions are generally poor.

The British Hair and Nail Society (BHNS) is an organisation of UK clinicians interested in the management of hair disorders. The growing recognition of treatment uncertainties in hair loss, highlighted by numerous review articles, treatment guidelines and clinical experience, led this group to realise the urgent need for more research in this area. Key to this is the identification of uncertainties that people with hair loss and care professionals agree are the most important. It is hoped that this hair loss PSP, made possible by support from the hair loss charity Alopecia UK, will help open funding streams to address these important research questions.

#### **IV. Aims and objectives of the hair loss PSP**

The aim of the hair loss PSP is to identify the unanswered questions about hair loss treatment from the perspective of those with the disorder, their partners / parents / carers and treatment providers, and then prioritise those top 10 questions that participants agree are the most important.

The hair loss PSP will address both scarring and non-scarring alopecia within the same process.

The objectives of the hair loss PSP are to:

- work with people with hair loss, their partners / parents / carers and care providers to identify uncertainties about the effects of hair loss treatments
- survey the research literature to identify uncertainties and research recommendations
- identify any ongoing research studies addressing submissions and research recommendations
- agree by consensus a prioritised list of those uncertainties
- translate these prioritised uncertainties into research questions that can be tested
- publicise the results of the PSP and process of obtaining them
- take the results to research commissioning bodies to be considered for funding

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## **V. Partners**

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

- people who have had, or still suffer with hair loss
- partners / parents / carers of people with hair loss
- medical doctors, nurses and professionals allied to medicine with clinical experience of hair loss

It is important that all organisations which can reach and advocate for these groups should be invited to become involved as partners in the PSP. The JLA will take responsibility for ensuring the various stakeholder groups are able to participate equally within the process. A preliminary list of stakeholders will be reviewed and modified as necessary by the Steering Group.

Organisations wishing to participate in the PSP will be required 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](http://www.lindalliance.org).

## **VI. 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 in the prioritisation process but they can submit uncertainties.

## **VII. 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](http://www.JLAguidebook.org).

The methods will be adapted from the traditional JLA approach to capture learning from previous PSPs in eczema and vitiligo. The main difference is the addition of one or more extra workshops after the identification of the top 10 uncertainties to translate at least some of these into an initial list of mutually agreed research questions.

As hair loss encompasses a diverse group of disorders with greatly differing frequencies within the population the steering group anticipates that there may

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be one or more groups that dominate the process due to the larger numbers of people affected (e.g. chemotherapy induced hair loss). In this scenario, the steering group will look at the proportion and number of disease specific responses. If necessary these groups will be analysed separately. Further, due to the cost implications of running multiple prioritisation workshops additional funding may need to be secured before these analyses can take place

### **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 hair loss PSP and invited to attend and participate in an initial stakeholder meeting.

The JLA can draft the invitation, and an agreement should be reached as to the best organisation to distribute it. All documentation relating to the PSP will include the JLA, BHNS, NIHR and Alopecia UK logos. Alopecia UK has provided financial support for this PSP.

### **2. Initial stakeholder meeting (*Optional*)**

The initial stakeholder meeting will have several key objectives:

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

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

Following the meeting, organisations that have decided to participate in the PSP will be asked to complete a declaration of interests, including disclosing relationships with the pharmaceutical industry.

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### **3. Identification of treatment uncertainties – *harvesting survey***

A self-completion on-line survey will be used to identify uncertainties from people with hair loss, parents/guardians/partners, healthcare and other professionals involved in the delivery of medical or non-medical treatments for hair loss. The survey will also be made available in hard copy for anyone who wishes to complete it off-line. The format suggested in the JLA guidebook will be used as the starting point for design of the survey and modified following advice from individuals with expertise in this area and by reference to surveys used by previous PSPs available via the JLA web site. Specifically, ways of capturing uncertainties that may lead to the identification of more specific research questions will be explored. The survey will be open for up to **eight weeks** depending on the response rate and the need to chase under-represented groups; in principle we will continue to collect submissions until no new themes emerge.

The methods used to publicise the survey and encourage participation 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.

The participant information sheet and survey text will be designed to be easy to understand and provide all the relevant information for self-completion. Submitting the completed survey will be considered consenting to participate in the research and agreement to publication of the uncertainties provided on the UK Database of Uncertainties about the Effects of Treatments (DUETs).

Existing sources of information about treatment uncertainties for patients and clinicians will be searched. These can include question-answering services for patients and carers and for clinicians; research recommendations in systematic reviews and clinical guidelines; protocols for systematic reviews being prepared and registers of ongoing research. The starting point for identifying sources of uncertainties and research recommendations is NHS Evidence:

[www.evidence.nhs.uk](http://www.evidence.nhs.uk).

NICE Guidance and Research recommendations

BMJ clinical evidence

BAD Guidelines

Relevant college guidance

### **4. Refining questions and uncertainties**

The JLA will participate in this process as an observer, to ensure accountability and transparency. Abby Macbeth will take the lead role in data handling, with

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input from Matthew Harries and volunteers from the UK dermatology clinical trials network (UK DCTN) Trainee group.

Submissions will be downloaded or manually entered into an Excel spreadsheet. Those which are out of scope i.e. relate to prevention or delivery of care, are not recognised means of managing hair loss or are not uncertainties will be excluded from the list of collated indicative questions and kept separately. Similar or duplicate submissions will be combined where appropriate and with agreement from the Steering Group. The remaining raw submissions will be refined via a series of steps into "collated indicative questions" which are clear, addressable by research, understandable by all and suitable for entry into the UK DUETs database. Existing sources of information, in particular systematic reviews, evidence based guidelines and prospective trial registers, will be searched to see to what extent these refined questions have, or have not, been addressed by previous or ongoing research.

Sometimes, uncertainties are expressed that can in fact be resolved with reference to existing research evidence – i.e. they are "unrecognised knowns" and not uncertainties. If a question about treatment effects can be answered with existing information but this is not known, it suggests that information is not being communicated effectively to those who need it. A record of these 'answerable questions' will be kept and deal with separately from the 'true uncertainties' considered during the research priority setting process. If deemed necessary by the Steering Group, they will be brought to the attention of UK organisations that produce and disseminate hair loss treatment guidelines/ recommendations.

## **5. Entry into Database of Uncertainties about the Effects of Treatments (UK DUETs)**

Uncertainties which are not adequately addressed by previous research will be collated and entered into a hair loss section within the UK DUETs ([www.library.nhs.uk/duets](http://www.library.nhs.uk/duets)). This will ensure that the uncertainties have been actually checked to be uncertainties. This is the responsibility of the Steering Group, and coordinated by Abby Macbeth, Matthew Harries and the UK DCTN Trainee group. **This is a key component of the JLA process, and the next stage of prioritisation can only proceed upon its completion.**

## **6. Ranking survey**

The refining process will result in a long list of indicative uncertainties, the number of which is hard to predict. This long list will be reduced to a short-list of 20-25 uncertainties by a UK wide process of consultation. If the long list is unduly long, the Steering Group will decide whether they wish to adopt some mechanism for reducing it to a more manageable number (the interim list).

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People who respond to the harvesting survey and give contact details will be invited to take part in the ranking exercise. In addition the ranking exercise will be advertised using the same mechanisms that were adopted during the first survey and will be promoted using every possible means to any groups under-represented in the first survey.

Participants in this ranking survey will be invited to choose up to five uncertainties from the long (or interim) list. They will not be asked to prioritise them. The responses obtained will be used to rank the uncertainties by number of votes. The top 20 - 25 or thereabouts will be taken forward into the priority setting workshop. The priorities of different categories of respondent will be listed separately and compared.

## **7. Priority setting workshop**

The aim of this stage of the priority setting exercise is to prioritise through consensus the most popular uncertainties relating to the management of hair loss. This will be carried out by eligible members of the Steering Group and the wider partnership that represents people with hair loss and care delivery professionals. The process will be facilitated by the JLA to ensure fairness, transparency and accountability. The methods to be used during the workshop will be determined by consultation with partner organisations and with the advice of the JLA.

The intention will be to produce a single top 10 which is agreed by people with hair loss and care providers. However, it is recognised that differences between the groups may not be reconcilable. If this should occur, the Steering Group will consider how best to address the problem.

Those attending the priority setting workshop that have not already done so, will be asked to complete a declaration of interests, including disclosure of relationships with for-profit organisations.

## **8. Translation workshop(s) to develop research questions**

The Steering Group will convene one or more translation workshops to which hair loss researchers and representatives of partner organisations will be invited to attend. Invitations will also be sent to selected care professionals and people with hair loss who have contributed positively to the hair loss PSP and expressed an interest in helping with this final stage.

Participants will be divided into four groups, each with an independent facilitator and including similar numbers of people with hair loss, care professionals, researchers and representatives of partner organisations. A pro-forma, based on a PICO format (**P**articipants, **I**ntervention, **C**omparator, **O**utcomes), will be used

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to assist groups in generating research questions in an appropriate way. The procedures to be adopted during the workshops will be decided by the Steering Group in consultation with the JLA.

It is recognised that several workshops may be required in order to generate mutually agreed research questions from all of the prioritised uncertainties. These questions will form the basis of funding applications.

### **9. Publicity**

The findings of the hair loss PSP will be publicised using a range of mechanisms. As well as a journal article and conference presentation, brief summaries will be included (with permission) in partner web sites and a fuller report will be placed on the Alopecia UK site ([www.alopeciaonline.org.uk](http://www alopeciaonline.org.uk)). The mechanisms put in place to promote the surveys will be adopted to publicise the findings and direct people to the location of information.

The JLA will publicise the top 10 priorities on the JLA web site ([www.lindalliance.org](http://www.lindalliance.org)). Dissemination of the findings will not be held up whilst journal articles are being prepared and submitted. Authorship of articles will be decided by the Steering Group based on two principles: (a) authorship is not an automatic right of Steering Group members and (b) individuals who are not members of the Steering Group may be invited to become co-authors in recognition of a significant contribution to the successful completion of the project.

### **VIII. Findings and research**

It is anticipated that the findings of the hair loss PSP will be reported to funding and research agenda setting organisations such as the NIHR 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.

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**IX. Signed by the Steering Group**

The undersigned agree to follow the Hair loss Priority Setting Protocol.

[Insert name and organisation]

.....

Date: .....

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[Insert name and organisation]

.....

Date: .....

[Insert name], The James Lind Alliance

.....

Date: .....

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## **Appendix 1**

### **Steering Group**

Patient representative/s:

- Jackie Tomlinson (Alopecia UK Lead)
- Donna Roper (Patient Representative; Nurse)
- Jennifer Chambers (Alopecia UK + Admin Support)
- Julie Rodgers (Patient Representative)
- Karena Moore-Millar (Patient Representative; Wig Technologist)

Clinical representative/s:

- Matthew Harries (Clinical Lead)
- Abby Macbeth (Data Handling)
- Andrew Messenger (British Association of Dermatologists (BAD))
- Paul Farrant (British Hair and Nail Society (BHNS))
- Carole Michaelides (Institute of Trichologists)
- Rachel Robinson (GP and Primary Care Dermatology Society (PCDS))
- Nigel Hunt (Psychology)

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

- Sheela Upadhyaya (Chair - The James Lind Alliance (JLA))