Acne Priority Setting Partnership

STUDY PROTOCOL

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I. Purpose

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

Whilst doctors typically consider acne as a skin disorder with a broad spectrum of severity, many people with physiological or mild acne as defined by a doctor will manage their skin condition without medical help and will not consider themself to be a patient. The intention of this PSP is to include everyone with spots of whatever severity. For simplicity, the term acne is used throughout this protocol to include everything from a few spots to severe disease. Similarly, the phrase 'people with acne' is used instead of patients in recognition of the fact that many people with spots do not consult a doctor. Although treatments for acne scars differ to a large extent from treatments for active acne, questions relating to acne scars will almost certainly be submitted and will be included in the prioritisation process.

II. Steering Group

The Acne PSP will be led and managed by a steering group including people with acne, 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 be able to advise on this.

III. Background to the Acne PSP

The JLA is a programme initially funded by the National Institute of Health Research with support from the Medical Research Council. Its aim is to provide an infrastructure and process to help patients and the "clinical" provider community 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". It is perhaps more helpful to think of an uncertainty as something unknown about an intervention that, if known, could improve or change practice.

The idea for an Acne PSP arose from conversations in spring 2012 between Dr Kim Thomas, Associate Professor in the Centre of Evidence Based Dermatology (CEBD) at the University of Nottingham and Dr Anne Eady, a Research Fellow in Dermatology at Harrogate and District NHS Foundation Trust. Anne was drafting outline proposals (vignettes) for randomised controlled trials in response to the UK Dermatology Clinical Trials Network (UK DCTN) themed call on acne and rosacea when it occurred to her that she had no idea how important these questions were to people with acne or to care professionals outside her own personal networks. It became obvious that an important first step in the process was lacking – a mechanism for identifying unanswered questions that matter most to people with the disorder and those who treat them. The Acne Support Group, a very pro-active advocacy group in the UK, was disbanded in 2007 and has not been replaced. In its absence, there is no obvious point of contact for healthcare researchers wishing to involve people with acne in their decision making. Kim's suggestion was to consider setting up an Acne PSP with support from the CEBD (which has completed two successful PSPs), but based in Harrogate, where the Head of the Dermatology Department, Dr Alison Layton, is a leading international expert on acne.

Systematic reviews and other published articles have repeatedly drawn attention to the shortcomings of the evidence base which underpins acne treatments. Until a decade ago, the UK was a leading global player in acne research. Since then, much expertise has been lost and it has become virtually impossible to obtain public funding for acne research in the UK. It is hoped that the successful completion of this priority setting exercise will put acne firmly back onto the UK research map and unlock funding to address those uncertainties that people with acne and care professionals agree are the most important.

IV. Aims and objectives of the Acne PSP

The aim of the Acne PSP is to identify the unanswered questions about acne treatment from the perspectives of those with the disorder, their parents/guardians/partners and treatment providers and then prioritise those that participants agree are the most important.

The objectives of the Acne PSP are to:

- work with people with acne, their parents/guardians/partners and care professionals to identify uncertainties about the effects of acne treatments
- survey the research literature to identify uncertainties and research recommendations
- identify any ongoing research studies that are in progress addressing submissions and research recommendations.
- agree by consensus a prioritised list of those uncertainties
- translate these prioritised uncertainties into research questions which are amenable to hypothesis testing
- publicise the results of the PSP and the process for obtaining them
- take the results to research commissioning bodies to be considered for funding
- address a number of supplementary research questions which are described in more detail in section XIII

V. Partners

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

- people who have had or who still suffer from acne of any severity
- parents/guardians of people who have had or still suffer from acne and who are under 16 years of age
- doctors, nurses and allied professionals with experience of managing acne with medical or non-medical interventions

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 ensure that, by support and challenge to the Project Manager, various stakeholder groups are able to participate equally to the process. A preliminary list of stakeholders for the Acne PSP 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 organisation. Details on the affiliation procedure can be found at www.lindalliance.org.

VI. Exclusion criteria

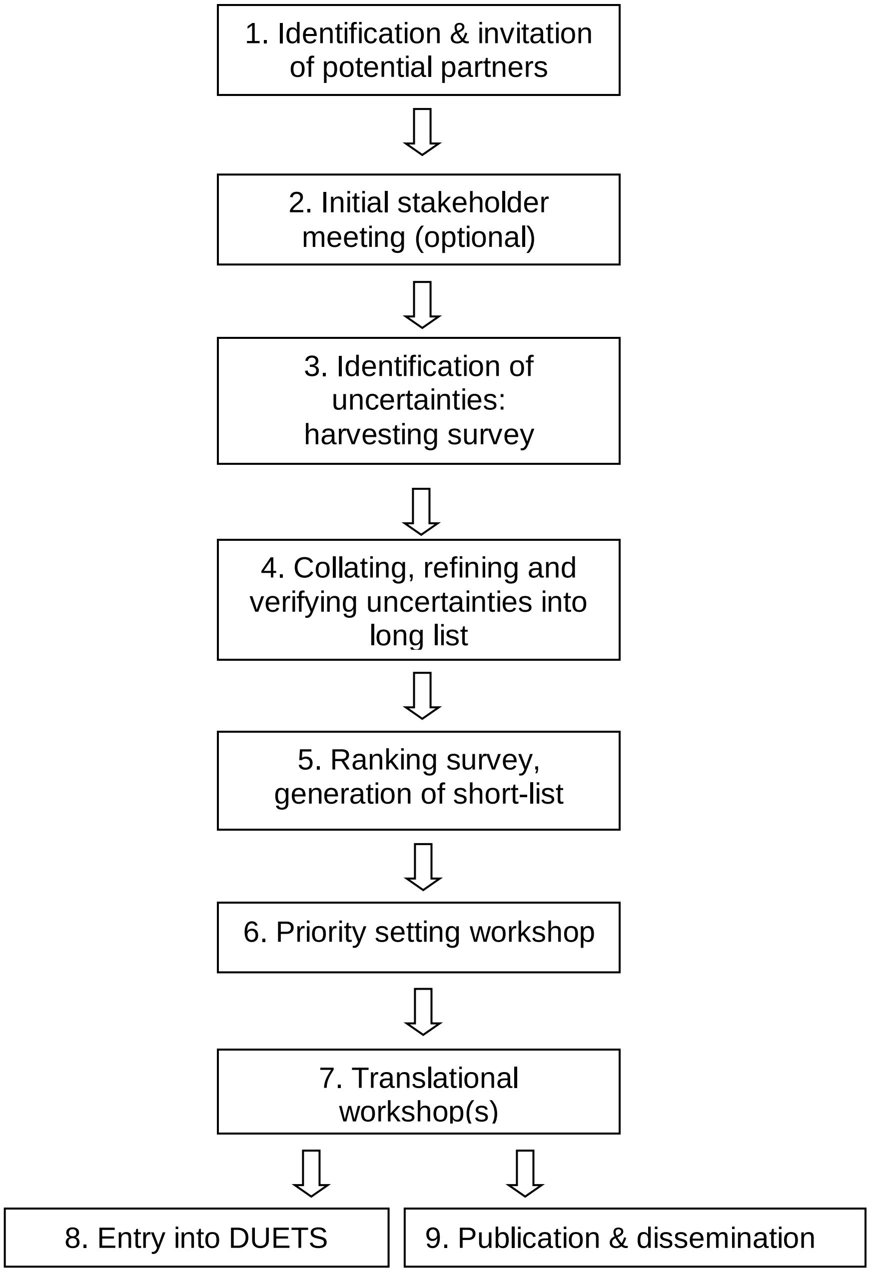
Some organisations may be judged by the JLA or the Steering Group to have conflicts of interest. These may be perceived to adversely affect those organisations' views, causing unacceptable bias. As there is a risk that this could affect the ultimate findings of the PSP, any such organisations will not be invited to participate in the prioritisation process although they can submit uncertainties.

VII. Methods

This section describes a schedule of proposed stages (Figure 1) 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. The methods will be adapted from the traditional JLA approach to capture learning from previous PSPs in eczema and vitiligo conducted by the CEBD. 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.

The prioritisation exercise will take place in the stages shown in Figure 1 and outlined below:

Figure 1. Diagram of the JLA prioritisation process



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 Acne PSP and invited to attend and participate in an initial stakeholder meeting. The JLA will help draft the invitation, which will be mailed out from Harrogate and District NHS Foundation Trust on notepaper with the Trust's logo as well as those of the JLA, the UK Dermatology Clinical Trials Network (UK DCTN) and the Society for Academic Primary Care (SAPC). The UK DCTN and SAPC have provided financial support for this PSP.

2. Initial stakeholder meeting (optional)[1]

Potential partners will be invited to an initial stakeholder meeting which will have several key objectives:

- to welcome and introduce potential members of the Acne 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 co-operation with the JLA.

Following the meeting, organisations which have decided to participate in the PSP will be asked to affiliate to the JLA and complete a declaration of interests, including disclosing any relationships with pharmaceutical or skin care companies.

3. Identification of treatment uncertainties – harvesting survey

A self-completion on-line survey will be used to identify uncertainties from people with acne, parents/guardians/partners, healthcare and other professionals involved in the delivery of medical or non-medical treatments for acne. 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. Because acne is such a common condition, we have set a minimum target of 600 responses to the survey.

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[1] The Steering Group decided at its first meeting that a launch meeting was not necessary.

The methods to be adopted to publicise the survey and encourage participation include but are not necessarily limited to:

a. Advertisements and links within stakeholder web sites
b. Identification of champion tweeters, Facebook and/or LinkedIn users with 200 or more followers
c. PSP members' personal networks
d. Patient and professional bloggers
e. Targeted mailshots
f. Newsletters distributed by stakeholders to members
g. Leaflets, postcards and posters for display in specialist treatment centres
h. Utilisation of research networks especially those of the National Institute of Health Research
i. Use of databases and informatics that can identify potential interested parties, use of texts to contact and encourage respondents

More specifically, we will invite patients in the Harrogate and District NHS Foundation Trust Database who are 16 years of age or above.

Acne is most prevalent during adolescence and early adulthood. Teenagers are a difficult group to motivate to take part in an exercise such as this and the Steering Group will draw on experts to advise how best to promote the exercise to them and encourage participation.

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, see section 10).

4. Collating, refining and verifying uncertainties

The JLA will participate in this process as Chair, to ensure accountability and transparency.

Submissions will be downloaded or manually entered into Excel. Those which are out of scope i.e. relate to prevention or delivery of care, are not recognised means of managing acne 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. This stage of priority setting is a crucial and demanding one. Rigorous processes will be developed in consultation with the UK DUETs Database Editor to ensure it is accomplished in a logical and efficient manner.

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 submitted that can 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. A separate record of these 'answerable questions' will be kept. If deemed necessary by the Steering Group, they will be brought to the attention of UK organisations that produce and disseminate acne treatment guidelines/ recommendations.

5. 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).

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.

6. Priority setting workshop

The aim of this penultimate stage of the priority setting exercise is to prioritise through consensus the most popular uncertainties relating to the management of acne. This will be carried out by eligible members of the Steering Group and the wider partnership that represents people with acne 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 acne and care providers. However, it is recognised that differences between the groups may not be reconcilable. If this should occur, the SG will consider how best to address the problem.

The number of participants in the priority setting and translational workshops (see below) will be limited to 40. Attendees who have not already done so, will be asked to complete a declaration of interests, including disclosure of relationships with for-profit organisations.

7. Translation workshop(s) to develop research questions

The Steering Group will convene one or more translation workshops to which acne researchers and representatives of partner organisations will be invited to attend.

Invitations will also be sent to selected care professionals and people with acne who have contributed positively to the Acne 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 acne, 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 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.

8. Entry into DUETS

Uncertainties in standard format that have not been adequately addressed by previous research will be collated and entered into an acne section within the UK DUETs (www.library.nhs.uk/duets). This is a key component of the JLA process. Entry into DUETs can begin as soon as the Steering Group has agreed the long list of uncertainties.

9. Publication and dissemination

The findings of the Acne 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 Acne Academy site (www.acneacademy.org). 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. 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.

The priorities identified by the Acne PSP will be reported to funding and research agenda setting organisations such as the NIHR HTA Programme and the MRC, as well as major research funding charities.

A timeline for the Acne PSP can be found in Appendix 1.

VIII. Additional research elements within this protocol

Whilst the basic processes for the conduct of a priority setting exercise are fixed, there is scope and sometimes a need for adaptation and modification to meet the varying challenges that different patient-provider communities present.

It is recognised that a major challenge for this PSP is motivating teenagers whilst not focusing too much effort on them. It is also possible that difficulties engaging professionals may be encountered, as has been found by some other PSPs. Some completed PSPs have reported differences in the priorities of patients and treatment providers. A key question for those who conduct PSPs to address is how well ongoing or recently concluded clinical research studies relate to the uncertainties identified. These aspects provide the basis for additional research elements within the basic procedure of priority setting.

Specifically, the following supplementary analyses will be conducted:

1) comparison of the effectiveness of different mechanisms for promoting the PSP, especially to teenagers
2) comparison of response rates and types of question submitted by different categories of respondent[2], and exploration of the implications of any differences found.
3) comparison of the questions submitted with the topics addressed by acne RCTs and systematic reviews published in the last 5- 10 years or listed as ongoing.

These supplementary analyses will be conducted as time and resources permit. Where sufficiently rigorous, results will be submitted for publication in relevant journals.

Respondents to either survey will be invited to give permission for their demographics and contact details to be placed in a secure NHS database to form an acne registry; this will enable researchers to contact them about any future acne related research studies in which they might wish to participate.

IX. Signed by the Steering Group

The undersigned agree to follow the Acne Priority Setting Protocol.

Names: (1) ANNE EADY (2) ALISON LAYTON

Organisation: Harrogate and District NHS Foundation Trust

Signature 1: *Date:* 05/03/2013

Signature 2: A.M Layton *Date:* 05/03/2013

Name: LESTER FIRKINS

Organisation: James Lind Alliance

Signature: Lester Firkins *Date:* 05/03/2013

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[2] Respondents will be categorised on the basis of the supplementary information provided on a voluntary basis.