



SPRUSD
Setting Priorities &
Reducing Uncertainties
for people with Skin
Disease



The University of
Nottingham

Nottingham University Hospitals
NHS Trust



**Identifying and prioritising important research
questions for the treatment of eczema – a
collaborative partnership between patients, carers,
clinicians and researchers**

Study protocol

Version 1 (06 April 2011)

Ethics ref:

R&D ref:

UK CRC portfolio ID:

Contact details:

Tessa Clarke

UK Dermatology Clinical Trials Network, Senior Trials Development Manager

Centre of Evidence Based Dermatology

University of Nottingham

King's Meadow Campus

Lenton Lane

Nottingham NG7 2NR

Tel: +44 (0)115 846 8622

Fax: +44 (0)115 846 8618

Email: Tessa.Clarke@Nottingham.ac.uk

Background to the Eczema Priority Setting Partnership

The James Lind Alliance (JLA) is a project which is funded jointly by the National Institute of Health Research and the Medical Research Council. 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”.

The Centre of Evidence Based Dermatology (CEBD) at the University of Nottingham (UoN) in collaboration with the JLA will undertake this prioritisation exercise to identify uncertainties about treatments for eczema and to prioritise them for future research. This study is part of a wider research programme called ‘Setting Priorities and Reducing Uncertainties for People with Skin Disease’ (SPRUSD), which is funded by the National Institute for Health Research.

The current Eczema Priority Setting Partnership (PSP) is the second JLA exercise to have been conducted as part of the SPRUSD research programme. A similar exercise was conducted in 2009/10 looking at treatments for vitiligo.

Management of the Eczema PSP

The Eczema PSP will be led and managed a Steering Group. The Steering Group includes representation of patient groups, clinicians and researchers (The James Lind Alliance and Centre of Evidence based Dermatology). Researchers are represented on the Steering Group in order to facilitate delivery of the project. However, they will not formally participate in the prioritisation exercise itself. This is to ensure that the final prioritised research questions are those agreed by patients and clinicians only, in line with the JLA mission.

Aims and objectives of the Eczema PSP

The aim of the Eczema PSP is to identify the unanswered questions about eczema treatment from patient and clinical perspectives and then to prioritise

those that patients and clinicians agree are the most important. The objectives of the Eczema PSP are to:

- work with patients and clinicians to identify uncertainties about the effects of eczema treatments
- to agree a prioritised list of those uncertainties, for research purposes
- to publicise the results of the PSP and the 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 eczema
- carers of people who have had eczema
- medical doctors, nurses and professionals allied to medicine with clinical experience of eczema.

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 participate equally to the process. A list of possible stakeholders for the Eczema PSP will be identified 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.

Exclusion criteria

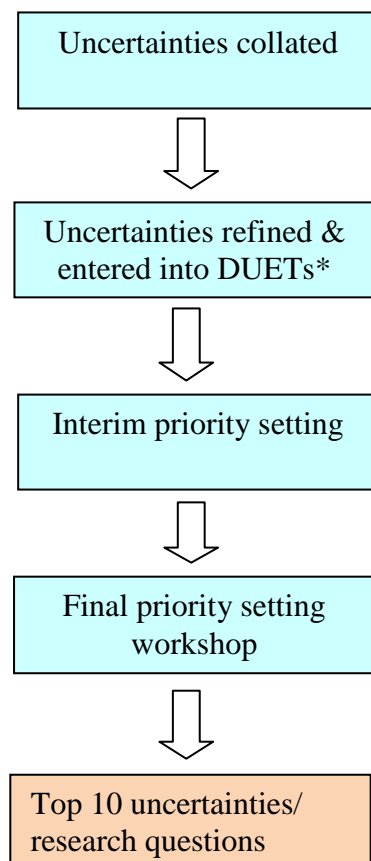
Some organisations may be judged by the JLA or the steering group to have conflicts of interest. These may be perceived to adversely affect those organisations' views, causing unacceptable bias. As this is likely to affect the ultimate findings of the PSP, those organisations will not be invited to participate. It is possible, however, that interested parties may participate in a

purely observational capacity when the steering group considers it may be helpful.

METHODS

The Eczema PSP will follow the methodology outlined in the JLA Guidebook (<http://www.jlaguidebook.org>). The methods used will be an adaption of the traditional JLA working method to seek to overcome some of the lessons learned from the previous vitiligo PSP whilst remaining true to the ethos of transparency, accountability and inclusivity.

Figure 1: Diagram of the JLA prioritisation process



* DUETS – Database of Uncertainties about the Effects of Treatments

The prioritisation exercise will take place in the following stages:

1. Identification and invitation of potential partners

The first stage involves initiating the research through consultation with relevant organisations, in particular those that can advocate and represent people with eczema; individuals with eczema (and their parents/carers); and clinicians with an interest in eczema. 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 eczema PSP and may be invited to attend and participate in an initial stakeholder meeting.

Stakeholder organisations which have decided to participate in the PSP will be asked to complete a declaration of interests, including disclosing relationships with the pharmaceutical industry. Organisations will be excluded from participating if they are considered to have conflicts of interest that may affect their views (Buckley, 2007).

2. Identifying and collating treatment uncertainties

The consultation and collation stage consists of collecting uncertainties, about the effects of treatments for eczema, from people with eczema (and their parents) and clinicians with an interest in eczema. Surveys were chosen as the data collection method because there is no potential for interview bias (Grey, 2004) or interview effects (Aldridge and Levine, 2001). Furthermore because the researcher does not have to be present whilst the survey is completed, the sample can be drawn from a wide geographical area (Aldridge and Levine, 2001). For practical and ethical reasons, the parents of children with eczema, will be asked to complete a survey on their child's behalf.

The uncertainties will be gathered through the self-completion survey which has been designed to capture the participant's uncertainty about the effects of treatments for eczema. The participants will be asked to submit a maximum of 5 uncertainties within 4 – 6 weeks of the start date, by email or post. A draft

copy of the survey to be used is appended (Appendix 2), and an on-line version of this form will be provided in order to facilitate data collection.

Within this study, most individuals will be recruited after they have volunteered to take part in response to an advert. Articles will be placed in newsletters and on websites targeting the population of interest. Individuals with eczema who are in contact with the CEBD and the JLA will be directly contacted, informed of the study and asked if they would like to participate. The Centre of Evidence Based Dermatology currently holds a database of over 700 individuals who have expressed an interest in hearing about eczema research, and these people will also be sent a copy of the survey. These sampling methods have been chosen in order to recruit as larger sample as possible from the population of interest.

The information sheet and survey text has been designed to be easy to understand and provide all the relevant information. Completing the survey will be considered consenting to participate in the research and allowing the uncertainties provided to be published on UK Database of Uncertainties about the Effects of Treatments (DUETs).

Where appropriate other methods may used to elicit the treatment uncertainties . This may include, but will not be limited to, methods such as membership meetings, email consultation, internet message boards and group discussions.

3. Interim priority setting

The consultation process will produce “raw” unanswered questions about diagnosis and the effects of treatments. The uncertainties gathered from the surveys will be assembled and refined and any similar uncertainties will be combined, where appropriate (Buckley, 2007).

An examination as to what extent these uncertainties have, or have not, been answered by previous research will be done by searching existing sources of information about treatment uncertainties for patients and clinicians. The

sources of information used will include, but may not be limited to, question-answering services for patients, NHS Evidence – skin disorders, carers and clinicians; research recommendations in systematic reviews and clinical guidelines; and an examination of existing treatment uncertainties already registered in the DUETs database.

Sometimes, uncertainties are expressed that can 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. These uncertainties will be sent to the National Eczema Society and may be sent to other relevant stakeholders such as the British Association of Dermatologists and NHS Choices so that these issues can be incorporated into the development of their patient information resources.

The interim prioritisation, to proceed from a long list of uncertainties to a shorter list (approximately 20-50), will be carried out using a combination of workshops and further survey. The exact details of this process will be decided by the Eczema PSP Steering Group. The top ranking/most frequent uncertainties and/or research questions will be taken through to the final priority setting stage.

Uncertainties which are not adequately addressed by previous research and not taken through to the final prioritisation stage will be collated and uploaded onto the eczema section within the UK DUETs. This is a key component of the JLA process.

4. Final priority setting

The aim of the final stage of the priority setting process is to prioritise the identified uncertainties and/or specific research questions relating to the treatment or management of eczema. This will be carried out by members of the steering group and the wider partnership that represents patients and clinicians.

The final stage of the priority setting will be conducted using workshops, group discussions and plenary sessions. The methods used for this prioritisation process will be determined by the Eczema PSP Steering Group. 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.

Findings and research

It is anticipated that the findings of the eczema 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.

Publicity

As well as alerting funders, partners and steering group members are encouraged to publish the findings of the eczema PSP using both internal and external communication mechanisms. The JLA will 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.

Timelines

March – May 2011	June –July 2011	Aug – Dec 2011	Jan - March 2012
<ul style="list-style-type: none"> • Convene SG • Establish website 	<ul style="list-style-type: none"> • Conduct survey to collect uncertainties 	<ul style="list-style-type: none"> • Collate responses • Run workshops to rank and prioritise “topics” and define research questions 	<ul style="list-style-type: none"> • Submit PSP priorities and research topics to funders • Publish results

Signatures

The undersigned agree to follow the eczema Priority Setting Protocol.

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Chief Investigator *Date*

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Organisation

References

Aldridge, A. & Levine., K. (2001). *Surveying the social world: principles and practice in survey research*. Buckingham: Open University Press

Buckley, B., Grant, AM., Firkins, L., Green, AC., & Frankau (2007). Working together to identify research questions. *Continence UK*, 1: 76-81.

Grey, DE. (2004). *Doing research in the real world*. London: Sage Publications