

Cellulitis Priority Setting Partnership

PROTOCOL 12th January 2016

1. Purpose of the PSP and background

The purpose of this protocol is to set out the aims, objectives and commitments of the Cellulitis Priority Setting Partnership (PSP) and the basic roles and responsibilities of the partners therein. It is recommended that the Protocol is reviewed by the Steering Group and updated on at least a quarterly basis.

The James Lind Alliance (JLA) is a non-profit making initiative, established in 2004. It brings patients, carers and clinicians together in Priority Setting Partnerships (PSPs). These partnerships identify and prioritise uncertainties, or 'unanswered questions', about the effects of treatments that they agree are the most important. The aim of this is to help ensure that those who fund health research are aware of what really matters to both patients and clinicians. The National Institute for Health Research (NIHR – www.nihr.ac.uk) funds the infrastructure of the JLA to oversee the processes for priority setting partnerships, based at the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), University of Southampton.

Cellulitis is an acute, painful and potentially serious infection of the skin and subcutaneous tissue. It is very common and is often managed in primary care. However, cellulitis also accounts for around 2-3% of hospital admissions. In 2013-14, around 70,000 people were admitted to hospital in England and Wales as a result of cellulitis.

There are numerous risk factors for cellulitis, including previous episode(s) of cellulitis; oedema (especially lymphoedema); skin disorders producing breaks in the skin; obesity; and diabetes. A significant number of patients will also have recurrent cellulitis. Cellulitis is a relatively under-researched topic area. The prevalence and associated complications of cellulitis warrant the need for further research into the diagnosis, treatment and prevention of this condition.

The Centre of Evidence Based Dermatology has experience of running other PSPs in the field of dermatology and found that they are an excellent way of stimulating interest in an under researched disease area, and help to develop collaborative links between different research groups with complimentary skills.

There are many uncertainties in the diagnosis, treatment and prevention of cellulitis – in part because it is a condition that is managed by many different specialities including general practice, emergency medicine, medical admissions in secondary care, tissue viability services and community nurses. As such, it is an ideal condition to focus on, and we hope that the PSP will act as a focus for renewed interest in this common and painful condition.

2. Aims and objectives of the Cellulitis PSP

The aim of the Cellulitis PSP is to identify the unanswered questions about cellulitis diagnosis, treatment and prevention from patient and clinical perspectives and then prioritise those that patients and clinicians agree are the most important.

The objectives of the Cellulitis PSP are to:

- work with patients and clinicians to identify uncertainties about the diagnosis, treatment and prevention of cellulitis
- to agree by consensus a prioritised list of those uncertainties, for research
- to publicise the results of the PSP and process
- to take the results to research commissioning bodies to be considered for funding.

3. The Steering Group

The Cellulitis PSP will be led and managed by the following:

Patient representative/s:

- Lymphoedema
 - Anita Wallace, Chair of Lymphoedema Support Network (LSN)
- Cellulitis
 - Julie Hooper, Cellulitis Patient Representative & Clinical Trial Co-ordinator at the University of Southampton
 - Barry Gamble, Cellulitis Patient Representative
 - Peter Smart, Cellulitis Patient Representative

Clinical representative/s:

- General Practitioner
 - Miriam Santer, GP & Associate Professor in Primary Care Research, University of Southampton
 - Nick Francis, GP & Clinical Reader, Cardiff University
- Dermatologist
 - Nick Levell, Dermatology Consultant, Norfolk and Norwich University Hospital
- Lymphoedema
 - Vaughan Keeley, Lymphoedema Specialist & Consultant in Palliative Medicine, Royal Derby Hospital
- Microbiology
 - Richard Brindle, Consultant Microbiologist, University Hospitals Bristol; University of Bristol & Public Health England
 - Member of the British Infection Association
- Nurse
 - Denise Hardy, Lymphoedema Nurse Specialist & LSNs Nurse Advisor

- Member of the British Lymphology Society

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

- The James Lind Alliance (JLA)
 - Leanne Metcalf
- The co-ordinating team at the Centre of Evidence Based Dermatology, University of Nottingham
 - Sadaf Akhtar, Research Fellow in Health Sciences
 - Sally Wilkes, Assistant Professor in Medical Statistics
 - Kim Thomas, Professor of Applied Dermatology Research
 - Shelley Dowey, UK Dermatology Clinical Trials Network Development Manager
 - Margaret McPhee, UK Dermatology Clinical Trials Network Co-ordinator

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

The Steering Group will agree the resources, including time and expertise that they will be able to contribute to each stage of the process. The JLA will advise on this.

4. The wider Partners

Organisations and individuals will be invited to be involved with the PSP as partners. Partners are groups or individuals who will commit to supporting the PSP by disseminating the PSP survey and helping the PSP to gather questions and uncertainties of practical clinical importance relating to the diagnosis, treatment and prevention of cellulitis. Partners represent the following groups:

- patients who have had or are currently suffering with cellulitis
- patients with lymphoedema
- carers of people who have had or are currently suffering with cellulitis or lymphoedema
- medical doctors, nurses and professionals allied to medicine with clinical experience of cellulitis.

It is important that all organisations which can reach and advocate for these groups should be invited to become involved in the PSP. The JLA Adviser will take responsibility for ensuring the various stakeholder groups are able to contribute equally to the process.

5. The methods the PSP will use

This section describes a schedule of proposed stages through which the PSP aims to fulfil its objectives. The process is iterative and dependent on the active participation and contribution of different groups. The methods adopted in any stage will be agreed through consultation between the Steering Group members, guided by the PSP's aims and objectives. More details can be found in the Guidebook section of the JLA website at www.jla.nihr.ac.uk where examples of the work of other JLA PSPs can also be seen.

Step 1: Identification and invitation of potential partners

Potential partner organisations will be identified through a process of peer knowledge and consultation, through the Steering Group members' networks. Potential partners will be contacted and informed of the establishment and aims of the Cellulitis PSP.

Potential partner organisations that have been identified so far are as follows:

- UK Dermatology Clinical Trials Network (UKDCTN)
- British Association of Dermatologists (BAD)
- Primary Care Dermatology Society
- British Society for Medical Dermatology
- Lymphoedema Support Network (LSN)
- British Lymphology Society
- Manual Lymphatic Drainage (MLD) UK
- Children's Lymphoedema Special Interest Group
- Leg Ulcer Forum
- Diabetes UK
- Royal College of General Practitioners
- Society for Academic Primary Care
- Royal College of Emergency Medicine
- British Infections Association
- Leg Clubs

Step 2: Identifying treatment uncertainties

Each partner will identify a method for soliciting from its members questions and uncertainties of practical clinical importance relating to the diagnosis, treatment and prevention of cellulitis. A period of 2 to 3 months 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 and internet message boards.

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

The starting point for identifying sources of uncertainties and research recommendations is NHS Evidence: www.evidence.nhs.uk.

Step 3: 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 the data management team into “collated indicative questions” which are clear, addressable by research and understandable to all. Similar or duplicate questions will be combined where appropriate.

Systematic reviews and guidelines will be identified and checked by the data management team 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.

Uncertainties which are not adequately addressed by previous research will be collated and recorded on a template supplied by the JLA) by the data management team. This will demonstrate the checking undertaken to make sure that the uncertainties have not already been answered. 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 submitted to the JLA for publication on its website on completion of the priority setting exercise, taking into account any changes made at the final workshop, in order to ensure that PSP results are publicly available.

Step 4: 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 diagnosis, treatment or prevention of cellulitis. 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 to be discussed at the final priority setting workshop (e.g. up to 30), may be carried out over email or online, whereby organisations consult their membership and choose and rank their top 10 most important uncertainties. There are examples of how other PSPs have achieved this at www.jla.nihr.ac.uk
- 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.
- The methods used for this prioritisation process will be determined by consultation with the partner organisations and with the advice of the JLA Adviser. 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.

6. Dissemination of findings and research

Findings and research

It is anticipated that the findings of the Cellulitis PSP will be reported to funding and research agenda setting organisations such as the NIHR and the major research funding charities. Steering Group members and partners are expected 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 Cellulitis PSP using both internal and external communication mechanisms. The Steering Group may capture and publicise the results through descriptive reports of the process itself in Plain English. 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.

7. Agreement of the Steering Group

Signed by the Steering Group

The undersigned agree to follow the Cellulitis Priority Setting Protocol.

[Insert name and organisation]

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Date:

[Insert name and organisation]

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Date:

[Insert name], The James Lind Alliance

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Date: