



Medical Sciences Division

Chief Investigator: Dr. Margaret Glogowska

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PARTICIPANT INFORMATION SHEET

Unmet needs in cellulitis diagnosis and treatment: Understanding healthcare professionals' knowledge and experiences

Researchers from the Nuffield Department of Primary Care Health Sciences would like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If anything is unclear, or if you would like more information, please ask us.

What is the purpose of the study?

Cellulitis is a bacterial infection of the skin, which is treated with antibiotics. There are a number of other conditions which can present in a similar way to cellulitis, and it can be difficult to distinguish theses clinically, resulting in patients being given antibiotics when they don't really have an infection. We are interested in the role that diagnostic technologies may play in improving the diagnosis and management of cellulitis. In this study we aim to interview healthcare professionals (HCPs) with experience of caring for patients with cellulitis in community- and/or hospital-based settings to explore their knowledge and experiences of the challenges relating to the diagnosis and treatment of cellulitis. Our aim is to support development of new tests for cellulitis by establishing where in the patient journey tests would be helpful and what their ideal characteristics would be.

Why have I been invited?

We want to explore the experiences and perceptions of HCPs who have experience caring for patients with cellulitis in community- and/or hospital-based settings (e.g. district nurses, practice nurses, emergency nurse practitioners, GPs, and Consultants in Acute & General, Dermatology, Infectious Diseases, Microbiology and Surgical specialties). Broadly we would like your opinion on:

- Which stage/s of diagnosis and/or management are particularly challenging and why
- What you perceive to be the key aspects of an ideal diagnostic which could differentiate cellulitis from other conditions with a similar clinical presentation

Inclusion/Exclusion Criteria

HCPs must have current or previous experience of cellulitis diagnosis and care pathways. They must also be willing and able to give informed consent for participation in the study and take part in an audio-recorded interview that is conducted in English.

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What will happen if I decide to take part?

- If you are interested in taking part or have any questions, let us know by email or telephone
 using the contact details listed.
- You will be able to arrange a time for an interview according to your preference (telephone or via MS Teams), and at your convenience.
- At the online or telephone interview, we will ensure that you have read and understood the
 participant information leaflet, and have had an opportunity to have all your questions and
 concerns addressed.
- We will also ensure that you are willing to give your consent for the interview to proceed.
- Your verbal informed consent to participate in the study will be obtained by the researcher prior to the interview, and documented using a standardised informed consent form. A copy of this consent form will be emailed to you for your records, and the original stored securely by the research team.
- The member of the research team will then interview you about the diagnosis of cellulitis.
 - o The interview will be audio recorded and transcribed.
 - o It will take up to 60 minutes of your time.

What are the possible benefits and disadvantages of taking part?

- Being interviewed will involve you giving up some of your time.
- Although you might not benefit directly from the study, many people find offering feedback a
 positive experience. The information gained may prove to be of benefit to HCPs and patients
 in the future.

Will I be reimbursed for taking part?

Participants will be offered a £40 gift voucher in recognition of the time required to participate in the study. You will also receive a certificate of participation for Continuing Professional Development purposes.

Do I have to take part?

No. You can ask questions about the research before deciding whether to take part. If you do agree to take part, you may withdraw yourself from the study at any time by advising us of this decision. This will not have any adverse consequence and you will not need to provide a reason.

What will happen if I don't want to carry on with the study?

If you withdraw, your interview will only be included in the study if the audio recording has already been transcribed and de-identified at that point.

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What happens to the data provided?

The information you provide during the study is the <u>research data</u>. Any research data from which you can be identified (name, age, work setting, the original audio recording) is known as <u>personal</u> data.

<u>Personal data</u> will be stored on a password protected computer in the Nuffield Department of Primary Care Health Sciences (NDPCHS). Contact information (e.g. name, telephone number) will be stored only until the final interview has been completed. Audio recordings will be securely transferred to an approved transcription company, which guarantees that information in the transcripts will remain confidential. On return to the researcher, the transcripts will be checked against the audio recordings and any identifying information will be removed from the transcripts. Audio-recordings will be retained in case of queries arising in analysis about interpretation and deleted once analysis and publication of results are complete.

Other data relating to you (years of experience and workplace setting) will be labelled with an identifier. The identifier key will be stored separately and securely on a password-protected computer in the NDPCHS. This will not include your name or contact details. This will be deleted once the final interview has been completed.

<u>Research data</u> (including consent forms, interview notes, and transcripts) will be stored for 10 years after publication or public release of the work of the research. The research team and transcriber will have access to the research data. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the research.

We would like your permission to use direct quotes anonymously in any research outputs, and to use anonymised data in future studies / to share data with other researchers (e.g. in online databases).

Any information that could identify you will be removed or changed before information is shared with other researchers or results are made public.

If a participant reveals practice not in line with good clinical practice/NICE guidelines, the research team (which includes qualified clinicians) will discuss and decide on the best route forward. If the interviewer has any concerns about practice that may be putting patients at risk, they would follow local Trust protocol for reporting this.

What will happen to the results of this study?

We plan to publish the study findings through journal articles, reports, presentations and conference papers. You will be able to access them on the National Institute for Health Research (NIHR)

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Medtech and In vitro diagnostics Co-operatives (MIC) website. You will not be able to be identified in any written or verbal reports from the study.

Who is organising and funding the study?

The study is being organised by researchers at the University of Oxford, in collaboration with researchers at Brighton & Sussex Medical School. The study is funded by the NIHR Community Healthcare Medtech and In Vitro Diagnostics Co-operative.

Who has reviewed the study?

This study has been reviewed by, and received ethics clearance through, a subcommittee of the University of Oxford Central University Research Ethics Committee (Reference number R83117/RE001).

What if there is a problem?

If you have a concerns about any aspect of this study, please contact Dr Margaret Glogowska on +44 (0)1865 617872, and she will do her best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with.

If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Medical Sciences Interdivisional Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, OX3 7GB.

Further information and contact details:

Dr Katy Baple or Dr Elizabeth Cross Clinical Research Fellows

University Hospitals Sussex NHS Foundation Trust

Clinical Research Facility, Sussex House, 1 Abbey Road, Kemptown, Brighton, BN2 1ES

Email: uhsussex.cellulitis@nhs.net

Thank you for your time and consideration.