



***A qualitative study to determine the patient experience of  
the diagnosis of lower limb cellulitis***

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10.09.2018**

<b>Short title:</b>	Patient experience of the diagnosis of lower limb cellulitis
<b>IRAS Project ID:</b>	N/A
<b>Study Sponsor:</b>	University of Nottingham
<b>Sponsor reference:</b>	To be provided
<b>Funding Source:</b>	Funding from the Clare Wand Trust will be sought, providing a combined maximum of £2500. However, both funding sources require ethics approval before an application can be processed.

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## SYNOPSIS

Title	A qualitative study to determine the patient experience of the diagnosis of lower limb cellulitis
Short title	Patient experience of the diagnosis of lower limb cellulitis
Chief Investigator	Professor Kim S Thomas
Objectives	<ul style="list-style-type: none"> <li>• Explore the patient experience of challenges in the diagnosis of lower limb cellulitis</li> <li>• Explore the key features of cellulitis that prompts the patient to seek medical advice</li> <li>• Describe experiences where a diagnosis of cellulitis was correct, incorrect or delayed</li> <li>• Describe experiences of getting a diagnosis of cellulitis with different health care professionals</li> <li>• Inform the focus of a qualitative study on cellulitis diagnosis with health care professionals</li> </ul>
Study Configuration	Semi-structured interviews with cellulitis patients regarding lower limb cellulitis
Setting	Community
Number of participants	Approximately 15 through purposive sampling
Eligibility criteria	<p>Patients with recent episode of lower limb cellulitis in the last six months or have had recurrent cellulitis (two or more episodes of cellulitis of the same leg (occurring at least 1 month after initial diagnosis) within 2 years of the initial episode).</p> <p>Able to give verbal consent</p> <p>English speaking</p>
Description of interventions	Face-to-face and telephone interviews
Duration of study	November 2018 – February 2019. Each participant will take part in a face-to-face interview that will last 45-60 minutes.
Methods of analysis	Thematic inductive analysis

## ABBREVIATIONS

CI	Chief Investigator overall
CRF	Case Report Form
GCP	Good Clinical Practice
NHS	National Health Service
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
REC	Research Ethics Committee
R&D	Research and Development department
UoN	University of Nottingham
CEBD	Centre of Evidence Based Dermatology
RCGP	Royal College of General Practitioners
PATCH	Prophylactic Antibiotics for the Treatment of Cellulitis at Home

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## STUDY BACKGROUND INFORMATION AND RATIONALE

Cellulitis is an acute bacterial inflammation of the dermis and associated subcutaneous tissue, with 60% of cases affecting the lower limb <sup>1</sup>. The diagnosis of cellulitis can be challenging, with 31% of presentations of suspected lower limb cellulitis in the emergency department found to be other diagnoses <sup>2</sup>. Routine biochemical and haematology blood tests and blood cultures are not specific for cellulitis <sup>3</sup>. This results in avoidable hospital admissions and unnecessary antibiotic prescribing <sup>4</sup>. Definitive diagnostic criteria would also improve the validity of clinical research on cellulitis <sup>5</sup>, but there are no agreed diagnostic criteria for cellulitis.

Cellulitis cases commonly present to primary care services or the emergency department <sup>6</sup>. A recent cellulitis research priority setting partnership (PSP) ranked questions on 'diagnostic criteria' and identifying early signs and symptoms as important for future cellulitis research <sup>7</sup>.

A scoping review we conducted, showed 44 different pathologies misdiagnosed as cellulitis on initial presentation (in submission, British Journal of Dermatology). A systematic review we carried out, showed that there are no robustly developed and validated diagnostic tools or criteria for lower limb cellulitis (in submission, Journal of the American Academy of Dermatology). Despite eight potential tools having been explored so far: biochemical tests, imaging, predictive scoring and clinical features, they all provide limited clinical applicability and validity.

No previous studies have explored what patients believe are the main challenges when they present with an episode of suspected cellulitis to the health care professional.

## STUDY OBJECTIVES AND PURPOSE

### PURPOSE

This study will help to identify the patient experience of challenges in the diagnosis of cellulitis. This initial qualitative work with patients will subsequently inform the design and conduct of a qualitative study covering related themes, from the perspective of healthcare professionals responsible for the care of patients with cellulitis.

Also, we will address the question 'early signs and symptoms of cellulitis that can help to ensure speedy treatment', which was a priority from the cellulitis research PSP.

### OBJECTIVES

#### Primary

- Explore the patient experience of challenges in the diagnosis of lower limb cellulitis

#### Secondary

- Explore the key features of cellulitis that prompts the patient to seek medical advice
- Describe experiences where a diagnosis of cellulitis was correct, incorrect or delayed
- Describe experiences of getting a diagnosis of cellulitis with different health care professionals
- Inform the focus of a qualitative study on cellulitis diagnosis with health care professionals



## **STUDY DESIGN**

### **STUDY CONFIGURATION**

Face-to-face or telephone interviews, lasting approximately 45-60 minutes will be conducted with people who have had experience of cellulitis of the leg. A purposive sample will be selected, with patients with a recent episode of suspected cellulitis in the last six months or recurrent cellulitis (defined as two or more episodes of cellulitis of the same leg (occurring at least 1 month after initial diagnosis) within 2 years of the initial episode).

Patients will be approached from a database of cellulitis patients held at the Centre of Evidence Based Dermatology (CEBD), who have previously been involved with cellulitis research and have consented to being approached for future cellulitis studies. Social media will also be used to identify possible participants.

### **STUDY MANAGEMENT**

The study will be managed from the central coordinating centre (CEBD, University of Nottingham).

The Chief Investigator (CI) has overall responsibility for the study and shall oversee all study management.

The data custodian will be the CI.

### **DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT**

**Study Duration:** Interviews will start in November 2018 and is expected to be completed by February 2019. The total duration will be four months.

**Participant Duration:** Each participant will take part in an interview that will last 45-60 minutes. No follow up interviews are planned. Participants will be offered the opportunity to receive a summary of the study findings. It is anticipated that up to 15 participants will be required, however more patients will be included if new themes emerge.

### **End of the Study**

The end of the study will be the last interview.

## **SELECTION AND WITHDRAWAL OF PARTICIPANTS**

### **Recruitment**

Participants will be recruited from pre-existing cellulitis research databases and through direct advertising through social media channels. The Lymphodema Network, who have supported previous cellulitis research at the CEBD, will be asked to advertise the study if recruitment is low.

MP will inform the participant of all aspects pertaining to participation in the study, either by e-mail or post, as soon as the participant has made initial contact. All the patients in the cellulitis research database speak English and therefore the consent forms and information sheets will not be available printed in other languages.

## **Eligibility criteria**

### **Inclusion criteria**

- Age >18 years
- All ethnicities
- Patients with suspected episode of cellulitis of the leg in the last six months or recurrent cellulitis (defined as two or more episodes of cellulitis of the same leg (occurring at least 1 month after initial diagnosis) within 2 years of the initial episode)
- Able to give informed consent
- Speak English language

### **Exclusion criteria**

- Non lower limb cellulitis

### **Expected duration of participant participation**

Study participants will be participating in the study for 45-60 minutes.

### **Participant Withdrawal**

Participants may be withdrawn from the study either at their own request or at the discretion of the investigator. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw, the data collected to date cannot be erased and may still be used in the final analysis.

### **Informed consent**

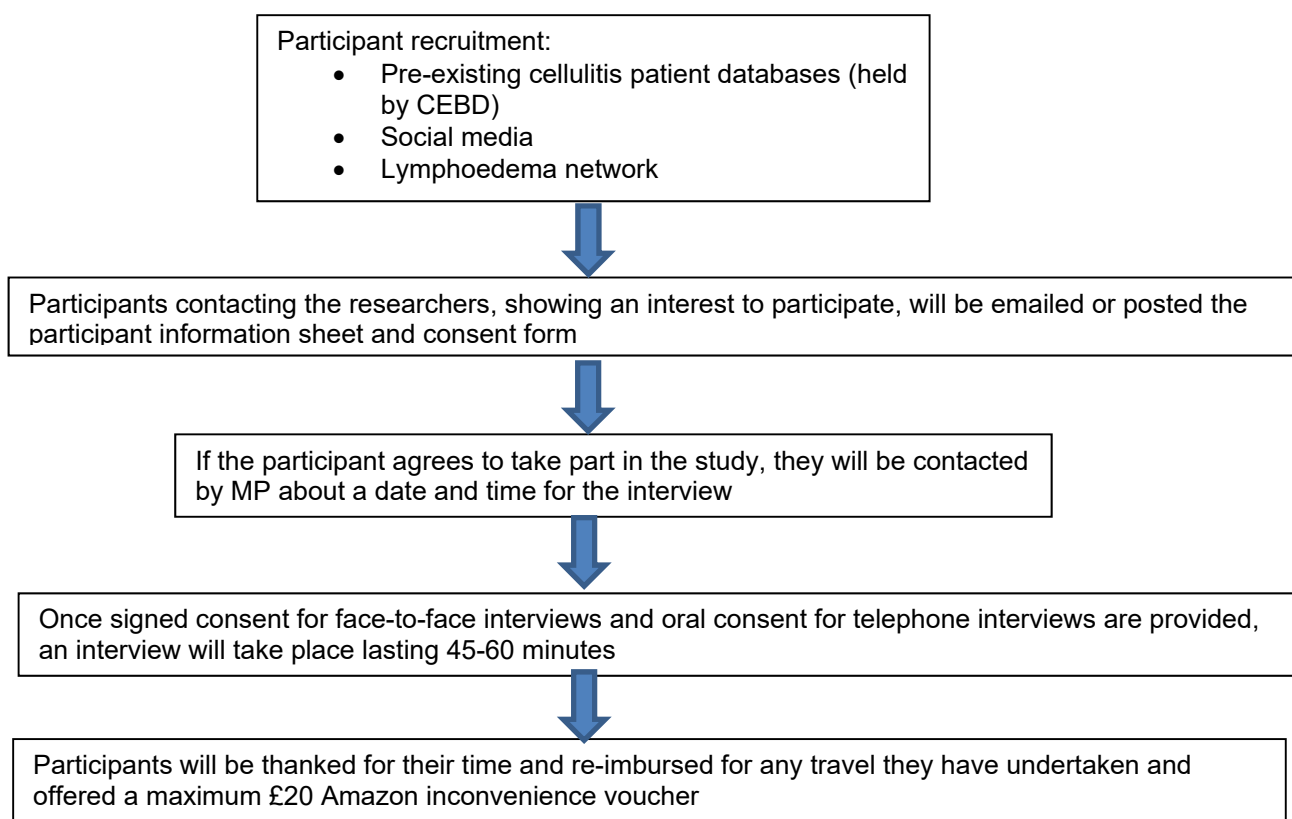
The Investigator will contact the patient by email or post before the interview to explain the details of the study and provide a Participant Information Sheet and Consent Form, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

For participants giving a face-to-face interview, the Consent Form will be signed and dated by the participant before the interview. For telephone interviews, oral consent will be gained. One copy of the Consent Form will be kept by the participant and one will be kept by the Investigator.

## STUDY REGIMEN

The individual steps that each participant will undertake are shown in Figure 1:

Figure 1: Study procedure



Interviews will take place at a place of convenience for the participant or by telephone. The interviews will be conducted by MP and recorded. A set series of questions will be used for the first two interviews, but may be adapted based on the findings of these interviews.

Patients will be asked to discuss a maximum of three separate episodes of cellulitis in the last six months or the last three episodes in recurrent cases.

### Compliance

We do not expect any compliance issues. However, if during the interview this becomes evident, then the participants will be asked to focus on the questions asked. If non-compliance persists, then the participant will be withdrawn from the study.

### Criteria for terminating the study

None.

## ANALYSES

### Methods

A semi-structured interview guide (see Appendix 1) has been developed around topic themes from existing literature and in our scoping review (see Box 1), however, this is flexible to allow unanticipated themes to emerge.

#### Box 1: Interview topic themes

Themes 1: Clinical features of suspected cellulitis

Themes 2: Experiences of diagnosis

All interviews will be audio-recorded and transcribed verbatim, with participant numbers assigned to avoid any personal identifiers.

All idiosyncratic features that add no meaning to the transcript will be removed. The cleaned transcripts will then be formatted for read-in compatibility with the data management software, password protected and stored on the secure server at the University of Nottingham.

The data transcripts will be organised using the qualitative software package QSR NVivo 12.

The data will then be handled following the six-step guide of thematic analysis <sup>8</sup>:

- 1) Become familiar with the data by reading and re-reading the data
- 2) Generate initial codes using line by line coding
- 3) Searching for themes by collating similar codes into broader preliminary themes
- 4) Review the themes by considering the validity and modifying each theme
- 5) Defining the themes by analysing the data in each theme
- 6) Producing the report of the study in a peer reviewed journal using direct participant quotes

The final themes generated will be commented on by the participants to check that it reflects the aims of the study, known as responder validation <sup>9</sup>.

### Data storage

Copies of the audio data files will be uploaded to a secure electronic platform to allow data transfer between the study team and the transcriber. Once the transcripts have been generated, uploaded to the platform, and retrieved by the study team, the audio files will be deleted from the platform. All raw audio data files and transcripts will be encrypted, password protected and stored on a secure server at the University of Nottingham.

### Sample size and justification

We approximate that fifteen participants will be included as a purposive sample. This number has been chosen because this is an exploratory study and it is feasible to include within the limits of study funding and time. All the patients in the included databases will be contacted to increase recruitment. We aim to include an equal number of men and women, with more participants over the age of 50 as we know that the incidence of cellulitis increases with age <sup>10</sup>. We also need to include participants who have had a first episode of cellulitis, as well recurrent cases, who may have a greater confidence in knowing when to seek help. Patients

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This protocol is confidential and the property of the University of Nottingham. No part of it may be transmitted, reproduced, published, or used by others persons without prior written authorisation from the University of Nottingham

from different ethnicities need to be sampled as different skin types may impact the ease of diagnosis. We also need to include patients who have been managed by the general practitioner, emergency care and dermatologists, to compare patient experiences with these different health care professionals who commonly diagnose cellulitis.

## **ADVERSE EVENTS**

The occurrence of an adverse event as a result of participation within this study is not expected and no adverse event data will be collected.

## **ETHICAL AND REGULATORY ASPECTS**

If confidential information, defined as information that may identify an individual or place, is shared during the interview, then this will be omitted from the saved copy of the transcript.

The researchers will not impart any medical judgements or opinions. However, if information is shared that may have affected patient safety, then this will be discussed with the CI and escalated as required.

## **ETHICS COMMITTEE AND REGULATORY APPROVALS**

The study will not be initiated before the protocol, consent forms and participant information sheets have received favourable opinion from the Faculty of Medicine and Health Sciences Ethics committee, University of Nottingham. Should a protocol amendment be made that requires ethics approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received favourable opinion from Ethics committee. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the Ethics committee are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the ethics committee will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice and the UK Department of Health Policy Framework for Health and Social Care, 2005.

## **INFORMED CONSENT AND PARTICIPANT INFORMATION**

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator and the participant shall both sign and date the Consent Form, for face-to face interviews, before the person can participate in the study. Oral consent will be taken for telephone interviews before participation.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study records.

## **RECORDS**

### **Case report form**

Each participant will be assigned a participant number. There will be one case report form (CRF), keeping a record of all :participant's name, date of birth and participant study number. This form will be stored in a secure file that only the researchers can access. In line with the UoN data storage procedures, data will be stored for at least 7 years.

This CRF will be treated as confidential documents and held securely in accordance with regulations. The CRF shall be restricted to those personnel approved by the CI and recorded as such in the study records.

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.

### **Source documents**

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, interview transcriptions and audio records. Only study staff shall have access to study documentation other than the regulatory requirements listed below.

### **Direct access to source data / documents**

All source documents shall be made available at all times for review by the CI, Sponsor's designee and inspection by relevant regulatory authorities.

## **DATA PROTECTION**

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the current UK General Data Protection regulation (GDPR). The CRF will only collect the minimum required information for the purposes of the study. The CRF will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and any relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method).

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

Any medical information provided will be kept confidential.

## **QUALITY ASSURANCE & AUDIT**

### **INSURANCE AND INDEMNITY**

Insurance and indemnity for clinical study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of

HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

### **STUDY CONDUCT**

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, timeliness of visits); accountability of study materials and equipment calibration logs.

### **STUDY DATA**

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation.

Study data and evidence of monitoring and systems audits will be made available for inspection by the ethics committee as required.

### **RECORD RETENTION AND ARCHIVING**

In compliance with the University of Nottingham Code of Research Conduct and Research Ethics, the CI will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the CI on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all anonymised audio recordings, study databases and associated meta-data encryption codes.

### **DISCONTINUATION OF THE STUDY BY THE SPONSOR**

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

### **STATEMENT OF CONFIDENTIALITY**

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

## **PUBLICATION AND DISSEMINATION POLICY**

The study results will be published in a peer reviewed academic journal and presented at conferences. All the participants will be sent the results.

Participants will not be identifiable in the dissemination of results.

## **USER AND PUBLIC INVOLVEMENT**

This study was developed from priorities in cellulitis research identified by patients at the cellulitis PSP. A patient with cellulitis, as a collaborator, has helped in the design of this protocol.

The results will also be discussed at the annual CEBD patient panel training day, where patients with various skin diseases will be present.

## **STUDY FINANCES**

### **Funding source**

Funding from the RCGP Practitioners allowance and from the Clare Wand Trust will be sought, providing a combined maximum of £2500. However, both funding sources require ethics approval before an application can be processed.

### **Participant stipends and payments**

Participants will be offered an Amazon inconvenience voucher of up to £20 to participate in the study. Travel expenses will be provided for participants to attend a face-to-face interview.



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## Appendix 1



### Interview schedule

We are hoping to find out your experience of the diagnosis of lower limb cellulitis. Any questions before we start?

#### **Can you tell me about when you were last told you may have cellulitis?**

Prompts:

- What did you notice?
- What made you go and seek medical advice?
- How long did you wait to seek help?
- Who did you see?
- Why did you see this person?
- What happened then?
- Were any tests done?
- What do you think went well?
- Was there anything that might have been more helpful?
- How was this similar to previous cases of cellulitis you have had?

#### **Can you tell me about any occasion when diagnosing your cellulitis was a problem?**

Prompts:

- What did you have on this occasion?
- At what point did you seek medical advice?
- What was diagnosed?
- Do you know why this was diagnosed?
- Did anything change from how you were?
- What did you do next?
- How long did you wait to seek advice again?
- What was done differently this time?
- Do you know what the final diagnosis was?

#### **We are interested in how different people diagnose cellulitis.**

Prompts:

- Who normally makes the diagnosis of your cellulitis?
- Are you confident that they will make the correct diagnosis?
- Would you see them again regarding cellulitis?
- Has your cellulitis ever been diagnosed by anybody else?
- If so, was there a difference in the approach that was used?
- What did they ask?
- What tests did they use?
- Has this changed who you would see in future?

That is all really useful, thank you. Is there anything that we haven't discussed that you would like to add?

Thank you so much