**Patient and Family Member Participant Information Sheet**

**DiALS QUAL Study**

We'd 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 there is anything that is not clear, or if* you *would like more information, please ask us.*

# What is the purpose of the study?

We are carrying out research to explore how hospital doctors and nurses could better use computer alerts to identify patients with sepsis.

Sepsis is a serious disease, most often caused by a bacterial infection, and can be treated with antibiotics. Identifying patients with sepsis as early as possible means treatment with antibiotics can be started earlier. To identify patients who may have sepsis, measurements such as temperature and breathing rate are used to create a score showing the possibility of sepsis. Patient electronic health records in hospitals contain the information needed to create a score and can alert a doctor or nurse that a patient may have sepsis.

Research has shown that more patients get antibiotics earlier because of hospitals using this type of computer-based digital alert. Different hospitals have used different methods to create a score and use different types of alerts.

This research wants to find out what hospital doctors and nurses think about alerts for sepsis and how they use them. We also want to find out what patients who have had sepsis think about hospitals using these alerts. Understanding how these alerts are used and how they affect patient care can help us to see how they could be used better so patients can benefit.

We will run online focus groups with patients who have had sepsis, and family members of patients who have had sepsis, to ask about their experiences of being treated in hospital and their views on hospital doctors and nurses using sepsis alerts. Participants will have the option of taking part in an online or telephone interview instead of a focus group.

# Why have I been invited?

* You have been invited because you have previously had sepsis OR because you are a family member of someone who has had sepsis and you are able to talk about the care they received in hospital.
* We are aiming to speak to around 20 people, around 15 who have had sepsis and up to 5 family members of people who have had sepsis.

# Do I have to take part?

* No, taking part is entirely voluntary. You can ask questions about the study before deciding whether or not to participate.
* Choosing not to take part will not affect your clinical care.

# What will happen to me if I decide to take part?

* If you decide to take part, you will be contacted by a researcher to confirm whether you would like to take part in a one-off focus group or interview. Once this is confirmed the focus group or interview will be arranged at a time which is convenient for you.
* If you choose a focus group, this will be run online using Microsoft Teams. It will include up to 6 people and will be run by one or two researchers. It will take 1-2 hours.
* If you choose an interview, it can be done online using Microsoft Teams or by telephone. It will take 45-60 minutes.
* Before the start the focus group or interview we will ask you to give consent to confirm that you understand what taking part in the study will involve and that your questions about the research have been answered.
* We will audio-record the focus group or interview with your permission. If a participant in a focus group or interview does not consent to being recorded we will not record the discussion and instead will make detailed field notes.
* The focus group discussion/interview will remain confidential.

# Are there any possible disadvantages or risks from taking part?

Taking part will involve talking about your experience, or your family members experience, of being ill with sepsis. We will be asking you, either as patient or family member, about the symptoms, how you accessed care and what happened with treatment in hospital. You may find it upsetting to recall these events.

If you take part in a focus group you will be talking about your experiences in front of a small group of people, both as patient and family member. In a focus group you will also hear about other people’s experiences of being ill with sepsis/being a family member of an ill person, they may have been more or less unwell than you/your family member affected by sepsis. Some people may have received better or worse care than you/your family member. Some people may have had sepsis more than once. You may also find hearing about their experiences distressing.

If you find discussions distressing, you can choose to pause or stop the interview or focus group at any point. We can suggest some relevant charities or other services that you can access for support if needed. This includes groups like the UK Sepsis Trust and local Patient Support Groups that may be hosted by NHS Trusts.

# What are the possible benefits of taking part?

* There will be no direct benefit to you from taking part in this study.
* Taking part will help us understand patient/family member’s views of how sepsis can be better identified in hospitals using sepsis alerts. This can help us provide recommendations for how hospitals use alerts and how they provide care for patients with sepsis.

# Will I be reimbursed for taking part?

* We will offer £20 in shopping vouchers as a thank you for your participation in either a focus group or an interview. This will be sent to you by email or post.
* You should not incur any expenses in taking part in this research.

# What will happen to my data?

UK Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is ‘a task in the public interest.’ The University of Oxford is the sponsor for this study, based in the United Kingdom, is the data controller and is responsible for looking after your information and using it properly.

The research data will be stored confidentially on the University of Oxford computer networks. The focus group or interview will be audio-recorded and/or we will take notes, meaning that the audio recording is optional. Both the audio recording and the notes will be stored in password protected computer files. The recording of your focus group or interview will be sent securely to an independent transcription company who will type up the recording within 7 days. Once they have completed and returned this work to the research team they will delete all copies of the data. The company has been assessed and approved for data security by the University of Oxford. Once the recording has been transcribed, the recording will be stored securely at the University of Oxford until the end of the study and then deleted. The transcript of the audio recording will be de-identified. To ensure confidentiality any written records or quotes from the recording will not include any names or other defining details that can identify participants.

Personal data will be stored securely in a locked cabinet at the University of Oxford or in password protected files on secure computers and university networks at the University of Oxford. Personal data will include your name, age, gender and ethnicity. This data will include participants’ completed consent form, basic demographics and contact details. The research team will have access to all research data. The transcription company will only have access to the audio recording of the focus group or interview (but will not know who the participants were). We will ask all participants for their permission to use direct quotes when presenting the study findings at conferences and in written reports and publications. All quotes will be de-identified, this means that anyone reading the quote will not know who you are.

We will be using information from you in order to undertake this study and will use the minimum personally-identifiable information possible. We will not keep identifiable information about you after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 5 years after the end of the study.

Responsible members of the University of Oxford, the Institute of Cancer Research – to which some investigators of this study are affiliated – and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at: <https://compliance.web.ox.ac.uk/individual-rights>

In the rare case that there may be a need to override agreements on confidentiality due to incidental findings that the researcher deems likely to result in serious or immediate harm to others (e.g., potential disclosure of unprofessional conduct or other ethical issues arising during data collection), this will be discussed with you and raised with the PI for the Trust.

# [What will happen if I don't want to carry on with the study?](http://hra-decisiontools.org.uk/consent/content-sheet-support.html#two)

* Taking part is voluntary. If you decide to take part, you can later change your mind, without giving a reason.
* Withdrawing from the study will not affect your clinical care.
* We will not use any data collected during your interview and your data will be deleted, if you decide to withdraw before your data are included in the study data analysis. Any data collected during a focus group will still be used. This is due to the nature of group discussions where it will not be possible to remove a single person’s comments

# What will happen to the results of this study?

* You will not be identified from any report or publication from this study placed in the public domain
* We intent to publish the results of this work in peer-reviewed scientific journals and results may be presented at scientific conferences but any quotes used, from focus groups or interviews, will be de-identified.
* If you would like to receive a copy of the final report at the end of the study please ask the research team using the details given at the end of the sheet.

# What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Dr Sarah Tonkin-Crine, 01865 289316 sarah.tonkin-crine@phc.ox.ac.uk or you may contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) office on 01865 616480, or the director of RGEA, email ctrg@admin.ox.ac.uk.

# How have patients and the public been involved in this study?

* Service users helped develop the research topic and what research questions should be asked.
* One of our patient contributors is a co-applicant who will continue to be involved in the study. She has helped us to develop questions to be used in interviews and focus groups.

# Who is organising and funding the study?

This work is being funded by the National Institute of Health Research through their Health Services & Delivery Research funding stream. The study is led by researchers at the Institute of Cancer Research and the University of Oxford.

# Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants’ interests. This study has been reviewed and given favourable opinion by HRA and HCRW Research Ethics Committee.

# Further information and contact details:

If you are interested in taking part or have any questions, please contact the research team on the details below. If you would like to receive a copy of the final report at the end of the study please also contact:

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*Thank you for reading this information*