**Study Title:**  Digital alerting to improve sepsis detection and patient outcomes in NHS Trusts: a qualitative study (DiAlS Qual).

**Internal Reference Number / Short title:** Digital alerts for sepsis: a qualitative study (DiAlS Qual).

**Ethics Ref:** Insert

**IRAS Project ID:** 313699

**Date and Version No:** Version2, 26th September 2022

|  |  |
| --- | --- |
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| **Sponsor:** | University of Oxford  Research Governance, Ethics & Assurance Team, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB. |
| **Funder:** | NIHR HS&DR |
| **Chief Investigator Signature:** |  |

The investigators declare that they have no conflicts of interest.

**Confidentiality Statement**

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, HRA unless authorised to do so.

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# KEY STUDY CONTACTS

|  |  |
| --- | --- |
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| **Sponsor** | University of Oxford  Research Governance, Ethics & Assurance Team, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB.  [ctrg@admin.ox.ac.uk](mailto:ctrg@admin.ox.ac.uk)  01865 289885 |
| **Funder(s)** | National Institute for Health Research Health and Social Care Delivery Research (NIHR HS&DR) |

# LAY SUMMARY

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 high or low temperature and fast breathing rate are used to create a score showing the possibility of sepsis. Electronic Health Records (EHR) 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 digital alert. Different hospitals have used different methods to create a score and use different types of digital alerts. This research wants to find out what hospital doctors and nurses think about digital 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 digital alerts. Understanding how these digital alerts are used and how they affect patient care can help us to see how they could be used better so patients can benefit.

# SYNOPSIS

|  |  |
| --- | --- |
| Study Title | Digital alerting to improve sepsis detection and patient outcomes in NHS Trusts: a qualitative study (DiAlS Qual). |
| Internal ref. no. / short title | Digital alerts for sepsis: a qualitative study (DiAlS Qual). |
| Sponsor | University of Oxford  Research Governance, Ethics & Assurance Team, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB. |
| Funder | National Institute for Health Research Health and Social Care Delivery Research (NIHR HS&DR). |
| Study Design, including methodology | Qualitative study including observation of healthcare professionals working in hospitals, one-on-one interviews with healthcare professionals and focus groups or interviews with patients/family members. |
| Study Participants, including sampling strategy | Hospital healthcare professionals who use, or help implement, deteriorating patient/sepsis alerts in NHS trusts.  Patients recruited from NHS trusts, who have previously had sepsis or family members of patients who have had sepsis. |
| Sample Size | Approximately 30 healthcare professionals  Approximately 20 patients/family members, 3-4 focus groups each with around 6 patients. |
| Planned Study Period | The project will run from August 2022 to August 2023.  Healthcare professionals will take part in one interview and/or be involved in observations at work on up to 4 occasions over a maximum period of 6 months.  Patients/family members will take part in one focus group or one interview and will not be followed up. |
| Planned Recruitment period | August 2022 – June 2023 |
| Aim and Objectives | |
| Primary | Aim: To explore the views and experiences of healthcare professionals and patients/family members on use of sepsis/deteriorating patient alert systems in hospitals. |
| Secondary | Objectives:  1. To understand how healthcare professionals use sepsis alerts and how alerts influence their decision making.  2. To observe healthcare professionals use of sepsis alerts during routine hospital shifts.  3. To identify barriers and facilitators to the implementation and use of digital sepsis alerts in NHS hospital settings.  4. To explore patients’ and family members’ views of sepsis alert systems and management of sepsis in hospitals. |

# ABBREVIATIONS

|  |  |
| --- | --- |
| CI | Chief Investigator |
| RGEA | Research Governance, Ethics & Assurance Team |
| HCP | Healthcare Professional |
| HRA | Health Research Authority |
| ICF | Informed Consent Form |
| NHS | National Health Service |
| PIL | Participant/ Patient Information Leaflet |
| R&D | NHS Trust R&D Department |
| REC | Research Ethics Committee |
| SOP | Standard Operating Procedure |
| EHR | Electronic Health Records |

# BACKGROUND AND RATIONALE

Sepsis is a common cause of serious illness and death with an estimated 123,000 cases and 46,000 deaths in the UK each year.1 Similarly, high levels of sepsis have been reported internationally2,3 and sepsis is recognised by World Health Organisation as a global health priority.4 Many countries have nationwide sepsis action plans and all UK hospitals have set targets to rapidly diagnose and treat patients with sepsis. Timely appropriately targeted intravenous antibiotics have been shown to be effective in improving outcomes for patients, with a 4% increase in odds of mortality for every hour’s delay in administration of intravenous antibiotics.5–7

The need for rapid treatment has led to the development of clinical criteria and ‘screening tools’ have been proposed to identify patients with sepsis. These include Sequential (Sepsis related) Organ Failure assessment, Systemic Inflammatory Response Syndrome (SIRS) criteria8 and in England the National Early Warning Score (NEWS), which was developed by the Royal College of Physicians.9  In December 2017, an updated version of NEWS, NEWS2 was published, which is recommended by NICE and the Royal College of Physicians as the most effective screening tool for sepsis in the UK.10,11 Available tools are based on current observations which clinicians are able to take and quickly calculate a score but there is a paucity of evidence as to which tool to use and their effect on patient outcomes.

Potential pathways for the effectiveness of alerts when clinical deterioration is due to sepsis are likely to include an increase in the proportion of patients receiving intravenous antibiotics in one hour,12 and other ‘sepsis six’ measures.13 Improved communication and changes in dialogue between healthcare teams has been suggested as an important pathway for improvements in clinical outcomes.14 In addition, the introduction of sepsis alerts is often accompanied by treatment plans as well as education and training activities. Little is known about the contribution of these and other potential mediators on the effectiveness of alerts.

Previous qualitative research with healthcare professionals has highlighted problems in identification and management of sepsis including limits in professionals’ capacity to identify sepsis, difficulties in handover of patients and errors in communication.15-19 These studies highlight both the requirement for healthcare professionals to feel confident in their assessment of patients and for clinical and organisations structures to work efficiently to provide optimal patient care. Previous qualitative research with patients has reported on patients’ decisions to seek help with symptoms, experiences of hospitalisation and how patients have managed life after surviving sepsis.20-22 Additional studies with caregivers have described the burden on those caring for sepsis survivors and their role in advocating for their loved ones.22,23 Another study has looked at the words patients and call handlers use to describe symptoms of sepsis when patients seek help.24 These topics can help to inform how patients and clinicians could use and potentially benefit from the use of digital alerts in hospitals.

This study is part of a wider programme of work seeking to determine the effectiveness of the introduction of digital alerts to improve outcomes of patients with sepsis. This component of the work seeks to explore healthcare professionals’ and patients’/family members’ views and experiences of deteriorating patient/sepsis alert systems in hospitals. This work will be undertaken within at least some of the NHS Trusts involved in the wider programme of work (Royal Berkshire NHS Foundation Trust, Oxford University Hospitals NHS Foundation Trust, University College London Hospitals NHS Foundation Trust, Imperial College Healthcare NHS Trust, Chelsea and Westminster Hospital NHS Foundation Trust and Cardiff & Vale University Health Board) and potentially additional Trusts if required.

This is a qualitative study which includes three methods of data collection; observation of healthcare professionals working in hospitals, one-on-one interviews with healthcare professionals and interviews/focus groups with patients/family members.

Healthcare professionals will include doctors, nurses and other professionals who use, or help implement, deteriorating patient/sepsis alerts in NHS hospital trusts. Patients/family members will include patients recruited from NHS trusts and community settings, who have previously had sepsis or are family members of patients who have had sepsis.

Interviews and focus groups will include topics which may be upsetting for some patients/family members or healthcare professionals. All participants will be made aware of sources of support available to them through the NHS and other relevant organisations (see below section 13.3). Patients and family members will have the option of taking part in a focus group or an individual interview depending on what they feel comfortable with.

# AIM / RESEARCH QUESTIONS / OBJECTIVES

|  |
| --- |
| **Aim / Research Questions / Objectives** |
| Aim:  To explore the views and experiences of healthcare professionals and patients/family members on the use of deteriorating patient/sepsis alert systems in hospitals. |
| Objectives:   1. To understand how healthcare professionals use sepsis alerts and how alerts influence their decision making. 2. To observe healthcare professionals use of sepsis alerts during routine hospital shifts. 3. To identify barriers and facilitators to the implementation and use of digital sepsis alerts in NHS hospital settings. 4. To explore patients’ and family members’ views of sepsis alert systems and management of sepsis in hospitals. |

# STUDY DESIGN

## Methodology

This study takes a critical realist approach using interviews, observations, and focus groups to understand the use and implementation of deteriorating patient/sepsis alerting systems in NHS hospital trusts. This will enable us to answer the aim and objectives of the research by asking stakeholders their views and experiences of sepsis alerts and observing use of alerts during routine clinical practice. Speaking to healthcare professionals, patients and family members will allow us to consider how sepsis alerts impact clinical decision making, patient experience and the actors involved.25 Unstructured observations will allow us to identify any influences on clinician decision making and sepsis alert use which healthcare professionals and patients may not be fully aware of and have shown to be useful in sepsis research previously.26

## Sampling Strategy

### 7.2.1 Healthcare Professionals

We will conduct interviews with a range of healthcare professionals recruited from NHS trusts. We will use a combination of purposive and convenience sampling. We will use our existing networks within each Trust and ask appropriate contacts to identify eligible healthcare professionals who can be invited to the study. For potential participants who express interest we will ask their job role, years of experience, expertise in sepsis/infection (if any) and experience of using (digital) alerts for sepsis (if any). If we get several expressions of interest for interviews, we will use this information to select participants to give a maximum variation sample in terms of job role, experience and expertise related to sepsis/digital alerts. A maximum variation sample will help us to identify a range of stakeholder who should provide insights into a variety of facilitators and barriers to healthcare professionals using digital alerts for sepsis.

### 7.2.2 Patients and Family Members

We will conduct focus groups (or interviews where required) with patients and family members recruited from NHS trusts and through community channels. We will select patients and family members to give variation in age and sex and to capture breadth of experience with sepsis where possible. We will prioritise including patients over family members but will include family members specifically where patients are not able to give a full account of their experience of sepsis/hospital care. Again, a maximum variation sample, where possible, will help us identify patients with a range of experiences which should provide diversity in views on digital alerts for sepsis and sepsis management in hospitals.

## Methods of Data Collection

### 7.3.1 Healthcare Professionals

Semi-structured interviews with healthcare professionals will be carried out in person, where possible, or remotely using telephone or video-conferencing software (Microsoft Teams). In person interviews with healthcare professionals will be carried out at their place of work. Questions will ask healthcare professionals about their experiences of managing patients with sepsis and their experiences of using (digital) alerts and other screening tools for sepsis.

Unstructured observations of clinical practice will be undertaken within wards/departments of NHS hospital trusts. We seek to observe clinical practice on different days of the week and times of day to identify whether sepsis digital alerts are used differently by healthcare professionals in different roles. HCPs will be observed at work on up to 10 occasions over a maximum period of 6 months. We envision two scenarios for the observations. Scenario 1 – Clinical Team observations. The researcher will sit in a specific department/unit (e.g., Emergency Department, Emergency Assessment Unit, Surgical Emergency Unit) as to be able to see the computers screens and observe when and how often a sepsis alert fires, how the clinical team responds to the alert, and note the clinical practices around this. Scenario 2 – One-to-one observations/shadowing. The researcher will shadow one HCP, most likely a sepsis nurse working across a Trust, following them from when they are notified of a sepsis alert in a department to when they move around to interact with other HCPs as a result of an alert. The researcher will interact with the shadowed HCP, asking questions about their practices, both during and after they have addressed each case. The researcher will not observe or interact with patients. The researcher will also not interact in any way with Trust computers, patient EHRs, or the digital alerts. No audio-recording will occur, only paper-and-pencil notes taken by the researcher.

### 7.3.2 Patients and Family Members

Focus groups and interviews with patients will follow a semi-structured design to ensure that key questions are asked to all participants but to allow flexibility for follow up questions. Interviews and focus groups will be carried out remotely using telephone or Microsoft Teams as patients may be clinically vulnerable and therefore shielding. Participants will be encouraged to talk about any topics which are of importance to them in relation to the research aims. Patients and family members will be asked about their previous experience of management of sepsis in hospital settings and their views on the use of digital alerts for sepsis.

Interview and focus group questions will be piloted prior to recruitment to ensure questions are understandable and that the interview/focus group duration does not exceed the proposed maximum time. Interviews are expected to last between 45 and 60 minutes but may be longer where a participant wishes to provide more information and is happy to continue. Focus groups are expected to last between 1-2 hours and, if lasting longer than an hour, will include a short break. Focus groups will include small groups (around 6 participants) to enable everyone to have sufficient time to share their views and discuss the topic.

Interviews and focus groups will be audio-recorded using a stand-alone audio-recorder (i.e. not using a recording function in any video-conferencing software). Audio-recordings will be transferred onto the University IT network immediately after the interview/focus group, labelled with an anonymous identifier and stored in a folder with access restricted to the research team only. The audio-recordings will be transcribed verbatim or detailed notes will be made based on the recordings.

## Methods of Data Analysis

Data from interviews, focus groups and field notes from observations will be analysed inductively using thematic analysis.27,28 Each dataset will initially be analysed separately although interviews and observations may be combined later. Thematic analysis allows the research team to take a pragmatic approach to data collection, remaining grounded in the data but ensuring that the analysis answers the research objectives. Similarities and differences between transcripts will be assessed using a constant comparison approach.29 Codes will be compared with one another to create categories, grouping similar codes together. All categories will be clearly defined to ensure that only related data are coded to that category. Thematic frameworks will be developed to represent each dataset as required.

## Study Sequence and Duration

Healthcare professionals will take part in one interview and/or be observed at work on up to 10 occasions over a maximum period of 6 months.

Patients/family members will take part in one focus group or interview and will not be followed up.

# PARTICIPANT IDENTIFICATION

## 8.1 Study Participants

Participants will include hospital healthcare professionals and patients/family members in the UK.

The sample size will depend on saturation28,29, i.e. no new themes are identified in data from later interviews/focus groups, however it is estimated that around 30 healthcare professionals and 20 patients/family members will participate.

Analysis of data from the interviews and the focus groups will occur concurrently to data collection, where possible, to inform future sampling and data collection.

## 8.2 Inclusion Criteria

### 8.2.1 Healthcare Professionals

* Participant is willing and able to give informed consent for participation in the study.
* Any gender aged 18 years or above (no upper age limit).
* Fluent in English (or able to participate in an interview with other measures in place, e.g. interpreter).
* Currently working as a healthcare professional (e.g. doctor, nurse) in an NHS hospital trust.

### 8.2.2 Patients and Family Member

* Participant is willing and able to give informed consent for participation in the study.
* Any gender aged 18 years or above (no upper age limit).
* Fluent in English (or able to participate in an interview with other measures in place, e.g. interpreter).
* Member of the public who has previously been diagnosed with sepsis and treated in hospital or family member/carer of someone who has previously had sepsis.

## 8.3 Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

* Healthcare professional has less than 3 months experience working in relevant role. This is estimated to be a reasonable amount of time for them to have good experience of identifying patients with sepsis and/or using sepsis alert systems.

# STUDY ACTIVITIES

## 9.1 Recruitment

The study is multicentre, involving recruitment of participants from several NHS hospital trusts and from community settings.

### 9.1.1 Healthcare Professionals

We will use our existing networks within Trusts, to identify suitable contacts and ask them to identify eligible healthcare professionals. We will ask contacts to invite any individuals to the study by email and will ask them to send emails out to relevant group email lists within the trust, where applicable, to advertise the study.

### 9.1.2 Patients and Family Members

We will ask contacts in NHS trusts to advertise the study to eligible patients. This will involve staff sharing study adverts with eligible patients either in person or by email. A template email will be provided for NHS staff so that they can use it to circulate the study advert. This will include advertising the study to any existing patient groups linked to trusts (e.g., an ‘ICU survivors’ group present in one Trust). Those inviting patients will be part of the existing care team who already have access to patient details. Patient details will not be shared outside of the existing care team prior to patients contacting the research team. We will also advertise the study in hospital waiting areas and wards where relevant. We will also seek to recruit patients and family members through community channels. This will include advertising the study through relevant organisations, (e.g., UK Sepsis Trust), on social media websites (e.g., Twitter, Facebook) and though research participation websites (e.g., www.bepartofresearch.nihr.ac.uk).

Potential participants will be asked to contact the research team if they are interested in joining the study.

## 9.2 Informed Consent

Written versions of the PIL and ICF will be provided to participants in advance of an interview, focus group or observation. Potential participants will be allowed as much time as they wish to consider the information, and the opportunity to question the Investigator or other independent parties to decide whether they will participate in the study. The researcher will ask if the participant has any questions or would like to clarify any aspect of the PIL or consent. It will be clearly stated that the participant is free to withdraw from the study up until the point when their data have been included in the analysis without prejudice to future care, and with no obligation to give the reason for withdrawal.

Informed consent will be taken at the start of interviews, either verbally if an interview is carried out remotely or taken as written consent for interviews carried out in person. Informed consent for focus groups will be taken prior to virtual focus groups, where each participant will be telephoned and asked to give verbal consent. Written informed consent for shadowing of a HCP will be taken at the start of the observation session. A written record of verbal consent will be made by the interviewer. The researcher will sign and date written consent forms and the written records of verbal consent and will securely email a copy to the participant. The Outlook 365 PROTECT function for encrypting will be used and the subject of the email will indicate CONFIDENTIAL. In all cases, attachments will be encrypted, and password protected at a document level. Password will be shared separately. All records of consent will be retained electronically on the University of Oxford computer network. We will amend default folder permissions (full control, modify, read only) as appropriate and password protect sensitive files at document level. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Prior to starting the Clinical Team observations in wards or departments, we will contact the ward manager/head of department so that they can notify in advance by email all members of staff, across all shifts, that during the upcoming 6 months a researcher will occasionally be onsite and to confirm that no member of staff has opted out of research. To this end, a template email will be shared with the ward manager/head of department to be sent to staff. In the email, a brief description of the study and of what the observations would entail is offered. A PIS will be attached to the email and provide additional, detail information to all staff members. If a staff member opts out the observations, observations will not be conducted when that staff member is on duty, or another ward/department/trust will be identified in lieu.

The person who obtained the consent must be suitably qualified and experienced and have been authorised to do so by the Principal Investigator.

## 9.3 Screening and Eligibility Assessment

A member of the research team will assess potential participants eligibility to take part in the research when they receive expressions of interest in response to emails and study adverts and when potential participants are identified by NHS trusts. Each participant must satisfy all the approved relevant inclusion and exclusion criteria of the protocol.

## 9.4 Subsequent Visits

Participants will take part in one interview or focus group. Health care professionals taking part in an interview may also be observed at work but they will not be required to undertake any further study activities besides the original interview.

## 9.5 Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study without giving a reason up until the point when their data have been included in the analysis. Any data collected from that participant up to point of withdrawal will still be included in analysis. Participants who withdraw will not be replaced once recruitment has ended.

The Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

• Ineligibility (arising during the interview)

• Withdrawal of Consent

The reason for withdrawal by researcher (and by participant, if this information is volunteered) will be recorded in a study file.

## 9.6 Definition of End of Study

The end of study is the time at which point all study data will have been collected.

# ANALYSIS

## Description of Analytical Methods

Data from interviews, focus groups and field notes from observations will be analysed inductively using thematic analysis.27,28 Thematic analysis allows the research team to take a pragmatic approach to data collection, remaining grounded in the data but ensuring that the analysis answers the research objectives. NVivo 12 software will be used to assist with the organisation and coding of data. We will support the rigour and trustworthiness of the analysis by triangulating healthcare professional and patient data to get a fuller understanding of how sepsis is managed in hospitals. We will assess the transferability of findings by comparing findings across the several Trusts taking part in the research and will describe the context of each Trust in detail to help establish what is common and different in findings between contexts. Confirmability will be established by making clear records of processes involved in data analysis and ensuring that findings can be tracked back to the original source(s).

To inform analysis we will collect data on healthcare professionals’ sex, job role, years of experience in current role, and clinical expertise. We will collect data on patients’ and family members’ sex, age, nationality, ethnicity and comorbidities.

# DATA MANAGEMENT

## Access to Data

The Investigators listed on the title page will have direct access to the data. Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

## Data Recording and Record Keeping

Each interview and focus group will be audio recorded with participants’ permission. Recordings will be transcribed verbatim onto a Microsoft Word document. Audio recordings will be labelled with anonymous identifiers (IDs) and will be stored in a restricted-access folder on the University of Oxford computer network. Audio recordings will be deleted at the end of the study.

Transcription will be completed by an independent transcriptionist/transcription company who holds a contract with the University of Oxford. Transcripts will be labelled with anonymous IDs and any identifiable data (e.g., identifying the participant(s) or their place of work) will be removed from the transcripts.

Participant characteristics will be entered on a separate Microsoft Excel spreadsheet with unique participant IDs only. Observation field notes will be transcribed and stored as Word documents with unique site IDs and no mention of individual hospital staff so that Trusts cannot be identified. Participant characteristics, field notes and anonymised transcripts will be stored as Excel or Word documents a study folder with access restricted to the study team.

Transcripts and observations notes will be uploaded to NVivo 12 software to aid analysis.

Names and contact details of participants will be kept in a password-protected document until the end of the study and then deleted. Electronic copies of ICFs, which contain participants’ names, will be stored in password-protected files in a restricted-access study folder on the University of Oxford network and the Institute of Cancer Research network. Transcripts, field notes and ICFs will be stored securely for 5 years following the end of the study at the University of Oxford and the Institute of Cancer Research.

# QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, relevant regulations and standard operating procedures.

# ETHICAL AND REGULATORY CONSIDERATIONS

## Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

## Approvals

Following Sponsor approval the protocol, informed consent forms, participant information sheets, invitation letters/emails and any advertising material will be submitted to an appropriate Research Ethics Committee (REC), HRA (where required), and host institution(s) for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

## Other Ethical Considerations

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 raised with the research participant themselves, and the PI for the Trust.

If for any reason, patients and family members find the interview or focus groups discussions distressing, they will be able to choose to pause or stop the interview or focus group at any point. They can also choose not to answer certain questions. We can suggest some relevant charities or other services that the participant 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.

## Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required), host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties

## Transparency in Research

For interventional trials\* a statement of registration and undertaking to keep trial data up to date and results publicly available is required. Prior to the recruitment of the first participant, the trial will have been registered on a publicly accessible database.

## Participant Confidentiality

The study will comply with the UK General Data Protection Regulation (UK GDPR) and UK Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents (except the ICFs and the document with participant names and contact details which will be password-protected and deleted at the end of the study) and any electronic database(s). All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants’ personal data.

## Expenses and Benefits

Participation will be on a voluntary basis. All participants to interviews, focus groups and shadowing will be offered a £20 shopping voucher to thank them for their time.

# FINANCE AND INSURANCE

## Funding

This study is funded by the NIHR HS&DR. All study activities will be carried out within this funding.

## Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd’s of London PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by NIHR HS&DR. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

We will seek to report results of the study both in peer-reviewed academic publications and articles written for a lay audience, e.g. writing articles for The Conversation ([www.theconversation.com](http://www.theconversation.com)). We will seek input from patient and public representatives about potential additional dissemination activities.

# DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Ownership of IP generated by employees of the University vests in the University.  The University will ensure appropriate arrangements are in place as regards any new IP arising from the trial.

# ARCHIVING

All de-identified research data and (records of) consent forms will be stored for 5 years after the end of the study.

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# APPENDIX A: AMENDMENT HISTORY

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| **Amendment No.** | **Protocol Version No.** | **Date issued** | **Author(s) of changes** | **Details of Changes made** |
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