

FULL/LONG TITLE OF THE STUDY

Patient and staff experience of ambulatory emergency care on the Surgical Admissions Unit (SAU)

SHORT STUDY TITLE / ACRONYM

SAU Interview Study

PROTOCOL VERSION NUMBER AND DATE

Version 2.0 06.03.19

RESEARCH REFERENCE NUMBERS

IRAS Number: 232776

SPONSORS Number: 1718/01

This protocol has regard for the HRA guidance and order of content.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

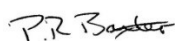
I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

Date:07/02/2019



Name (please print): Ms Pam Baxter

Position: Senior Research Governance Officer

Sponsor's representative, University of Exeter

Chief Investigator:

Signature:

Date:

...../...../.....

Name: (please print):

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KEY STUDY CONTACTS

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STUDY SUMMARY

Study Title	Patient and staff experience of ambulatory emergency care on the Surgical Admissions Unit (SAU)
Internal ref. no. (or short title)	SAU Interview Study
Study Design	Qualitative semi-structured interviews of patient and staff experience
Study Participants	<ol style="list-style-type: none"> 1. General surgical patients who have received ambulatory emergency care at the surgical assessment unit. 2. Staff involved in the care of these patients.
Planned Size of Sample (if applicable)	20 patients, 12-15 staff members: consultants, junior doctors, senior nurses and junior ward staff who provide care to patients undergoing ambulatory care
Follow up duration (if applicable)	N/A
Planned Study Period	September 2018 – September 2019
Research Question/Aim(s)	What are patients' experience of being managed in an ambulatory manner when they are referred to emergency general surgery? What are the opinions and attitudes of staff towards ambulatory emergency care in general surgery? What barriers would exist to expanding this service?

ROLE OF STUDY SPONSOR

The sponsor is University of Exeter as this research is being undertaken as part of a Masters by Research degree thesis. The sponsor is and has been involved in all stages of the study in particular the design and will oversee the conduct of the study. The research thesis containing the results of the study will be freely available publicly from the sponsor. The sponsor controls the final decision for all aspects of the study.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS**Study Steering Groups****Patient and public involvement group**

The overall design of this study and participant and potential participant information sheets and study literature has been discussed with members of the Royal Devon and Exeter hospital volunteer PPI group. Individuals that responded to a request for help with this research were consulted and changes were made to study documents including the introduction of a more detailed study information sheet as a result. Any changes made to the study as a result of e.g. low recruitment will be discussed with those volunteers.

The volunteer PPI group contact list is held by Jane Homan, Clinical Research Officer at the Royal Devon and Exeter Hospital, email: janehoman@nhs.net .

PROTOCOL CONTRIBUTORS

As described previously the sponsor is and has been involved in all stages of the study in particular the design and will oversee the conduct of the study with support from the educational supervisors. The research thesis containing the results of the study will be freely available publicly from the sponsor organisation the University of Exeter. The sponsor controls the final decision for all aspects of the study.

Data collection, data analysis and writing of the manuscript will be undertaken by Lisa Massey with input from Rob Bethune, Iain Lang and Jo Day as educational supervisors. Corrections to the manuscript may be suggested by the sponsor in their role.

As described previously individuals from the Royal Devon and Exeter volunteer PPI group have been involved in the design of the study, in particular the layout and wording of the information sheets. These are a mix of members of the public and previous service users.

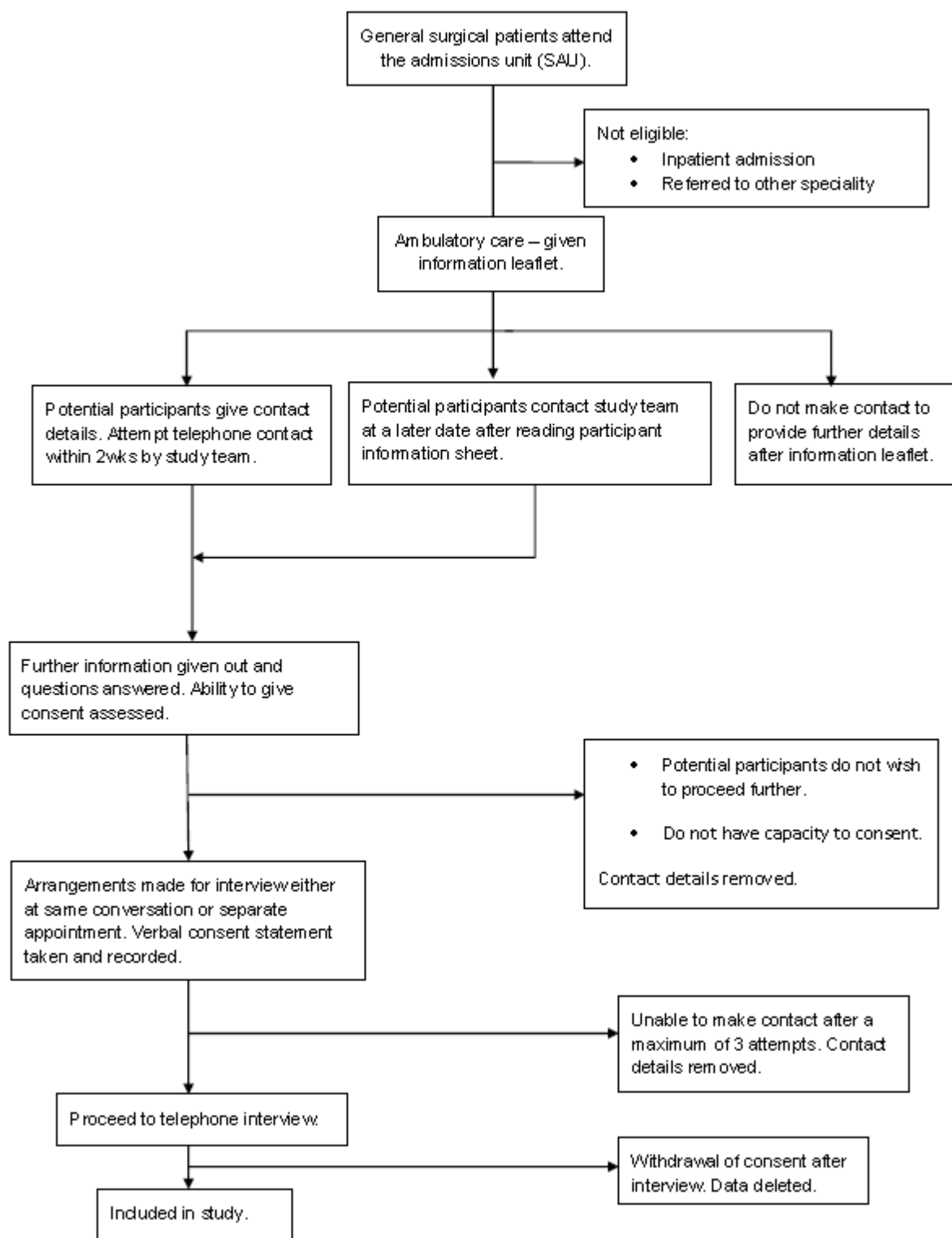
KEY WORDS:

Emergency general surgery

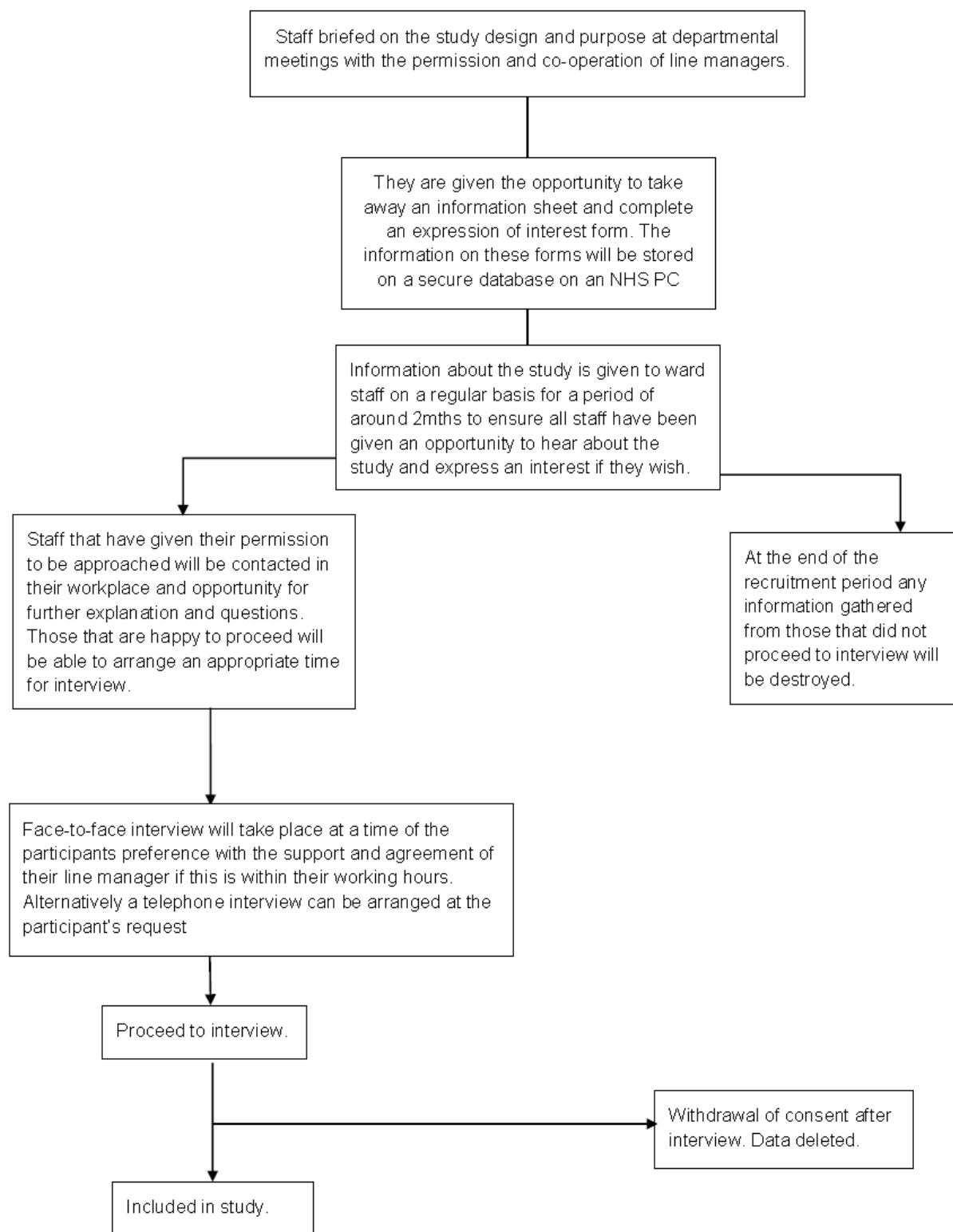
Ambulatory care

Patient experience

STUDY FLOW CHART FOR PATIENT INTERVIEWS



STUDY FLOW CHART FOR STAFF INTERVIEWS



STUDY PROTOCOL

Patient **and staff** experience of ambulatory emergency care on the Surgical Admissions Unit (SAU)

1 BACKGROUND

Abdominal pain is a common reason for people to attend hospital as an emergency. It makes up a considerable proportion of the patients being admitted under the care of general surgeons. Other common reasons for people attending include infections such as abscesses and problems following previous surgery.

A Surgical Assessment Unit (SAU) is an ambulatory area with a waiting room and assessment cubicles. It is staffed by a triage nurse or healthcare assistant and doctors from the surgical team. Patients can be assessed and have investigations including blood tests and radiology procedures including x-rays, ultrasound and CT. After assessment they are either admitted to the ward, discharged home or have their care continued in an ambulatory manner returning in the next few days for further or repeat assessment.

Previously patients were either discharged or admitted for observation, investigation and treatment such as intravenous antibiotics. Many of these patients could be managed safely in a "day case" manner. This pathway allows for re-attendance should it be required.

Emergency ambulatory care is well-established in medicine for conditions such as suspected deep vein thrombosis (DVT) and transient ischaemic attack (TIA) but has not yet been widely adopted in surgery.[1] There is uncertainty surrounding the best way of looking after these patients as the diagnosis is often uncertain and it can be difficult to judge which patients require admission.

Pilot studies have shown that up to 30% of emergency general surgical patients could be managed in this way.[2] These studies also report a high patient satisfaction score but do not inform us what works, why and for whom. These would be important considerations for organisations looking to expand their emergency general surgical ambulatory service.

This study aims to expand upon previous work in this area[3] by conducting semi-structured interviews with patients who have experienced emergency general surgical ambulatory care **and the staff who deliver this care**. We hope to identify themes that influence patient experience of emergency ambulatory care and whether this might vary depending on patient factors such as age, social support/responsibilities and attending condition.

The attitudes and experience of staff who deliver this care will help to understand better some aspects of patient experience and also the way in which ambulatory emergency care has been implemented. We are interested in speaking to staff who are the "decision-makers" for selecting patients for ambulatory care (senior doctors and nurses) and also those who deliver this care (junior doctors and ward support staff including junior nurses, health care assistants, ward receptionists). We are interested in staff perception of patient experience and their attitudes towards the implementation and possible expansion of emergency care.

The topic guide for the staff interviews have been informed by the Consolidated Framework for Implementation Research (CFIR).[4] This will bring a structured approach to understanding the way in which ambulatory emergency care has been implemented in this department.

2 RATIONALE

Emergency ambulatory general surgical care is a new area that is set to expand in the next few years.[1] There will be economic implications to this expansion. Reduction in inpatient stays will reduce healthcare costs but pilot studies have used additional resources such as a separate consultant allocated to the assessment unit and dedicated imaging slots.

Patient experience is an important factor in the quality of the care delivered and will influence how people interact and engage with the service. Within this study we are interested in discovering what factors in the delivery of this care are important for the patient experience, and how this varies amongst patients. This will allow individual clinicians to make better-informed decisions about which patients may not be suitable for ambulatory care, or may need support to enable it to be delivered in a way that works for them. It will also inform organisations looking to expand their ambulatory services about which components of the service are important from a perspective of patient experience.

Our literature review within this field identified that the experiences and attitudes of staff delivering this care may have an effect upon the success of any change in the delivery of this type of care. Examining this in further detail was initially beyond the scope of this study due to time constraints but there has arisen opportunity to devote more time to this project with the expansion of the researcher's degree from MbyRes to MD. We therefore decided to expand our study to include interviews with staff to explore the rationale for their attitudes to this type of care.

We are not gathering data on clinical outcomes or undertaking an economic evaluation. These are also important factors to consider when expanding an ambulatory service but are outside the scope of this study methodology.

3 THEORETICAL FRAMEWORK

Data will be analysed using the method of thematic analysis. We have chosen this method because we are interested in individual themes that are important influences on the patient experience. These themes may be quite separate from one another and not related to an encompassing theory, which suits this method of analysis as opposed to e.g. a grounded theory method.[5]

4 RESEARCH QUESTION/AIM(S)

To explore general surgical patients' experiences of being managed in an ambulatory manner in the context of a surgical assessment unit (SAU).

To explore staff experience and attitudes of emergency ambulatory care in general surgery. The staff groups of interest are: senior doctors (consultants), senior nurses, junior doctors (all grades) and other ward staff including junior nurses, healthcare assistants and ward receptionists.

4.1 Objectives

To establish why this method of care works better for some people than for others.

To establish staff's beliefs about ambulatory care and its suitability for different patients.

To identify possible barriers to expansion of this method of care.

4.2 Outcome

To identify which groups of patients are most likely to be able to engage well with this method of care and for whom it would not be appropriate or may need more support. To identify parts of the process specific to ambulatory care that most affects patient experience.

To understand better staff's beliefs and experience about ambulatory care and how that impacts the way that they deliver this care.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

This is a qualitative study of patient experience. Data will be collected by semi-structured telephone interviews **(patients) and face-to-face or telephone interviews (staff).**

Interviews with patients

Participants will be recruited to the study by the clinical team by means of short verbal explanation and the provision of an information sheet. Potential participants will give their contact details to be passed to the study team or will make contact themselves at a later stage. They will then be contacted by the study team and given further information over the telephone. Those wishing to proceed will have arrangements made for a telephone interview. A recording of consent will be made prior to the start of the interview and will be stored as a separate audio file.

The interview schedule has been drawn up based on areas that have emerged from work in the past using patient diaries.[3] The PPI work done has included review of these questions for acceptability and ease of understanding and minor changes have been made to the wording of questions as a result. The prompts used are mainly to encourage explanations of why participants have answered the way they have.

The interviews will last 20-30mins and will be recorded using encrypted digital recording software. They will be conducted by the study co-ordinator. No potentially identifiable information will be recorded and participants will be advised not to divulge identifiable information prior to the interview. If this occurs inadvertently it will be deleted prior to transcription. These audio recordings will be given a unique identification number and then be transcribed into text documents using a paid professional transcription service within the UK. Once the transcription has been completed the recording will be deleted.

The transcribed data will be stored on a NHS server. It will be available for access to the study team by password protection and on request in an anonymised form by the University of Exeter sponsor if required for monitoring purposes. Once the study is complete it will be stored on the University of

Exeter Open Research repository for the period required for 5 years and securely deleted from the NHS server.

The transcribed data will be coded and then undergo thematic analysis using NVIVO software. Coding will be done by the principal investigator and a proportion of the data will be separately coded by the 2 senior members of the study team. Interim analysis will be conducted after each 5 patients and the interview schedule may undergo some change to explore in more detail areas of interest that emerge.

If groups are underrepresented in the interim analysis then there may be targeted recruitment to the underrepresented group. This may include the characteristics of patient age and presenting problem. All recruitment will be undertaken by the clinical team.

Participants will be informed at the point of recruitment that if they proceed to complete an interview that they will be given a £25 high street store “thank you” voucher. After completion of the interview details will be taken to allow it to be posted to an address of their choice. These address details will be written directly onto an envelope and will not be stored.

Interviews with staff

Staff participants will be recruited by the study team including by attending regular team meeting events (see staff study flow diagram p.viii). Potential participants will be given an information sheet to read and prior to interview will be asked to sign a consent form. A mutually convenient time to meet will be arranged at the initial meeting or through later discussions. Face-to-face interviews will be conducted from mutually agreed locations that may include a private room on the SAU, researchers’ office or participants’ office. If any participants prefer a telephone call then this will be offered as an alternative and telephone consent will be collected in the same manner as that described for patient participants.

The interviews will all be conducted from the Royal Devon and Exeter hospital using an encrypted digital recording device, will last around 20-30mins and data will be handled securely in the same way as patient interviews. Staff will be informed that although their name will not be used in any quotes that other staff may be able to guess their identity by their job role. Staff participants will be offered the opportunity to look at the research manuscript if there are any potentially sensitive or identifiable quotes included where possible.

Participants will be informed at the point of recruitment that if they proceed to complete an interview that they will be given a £25 high street store “thank you” voucher. This will be given to them by the researcher after completion of the interview.

6 STUDY SETTING

This is a single centre study based at the Royal Devon and Exeter Hospital. This hospital has a frequently-accessed surgical assessment unit but has not previously undertaken any other studies of ambulatory emergency care. It can therefore be considered to be a “typical” unit for a hospital of this size and suitable for this study.

Potential patient participants will be approached by members of the clinical team after having their details screened from the existing admission list on the surgical assessment unit. They will be given a

brief description of the study and those that are interested are given an information sheet and the option to either give contact details (telephone number) immediately to the clinical team, or to contact the research team directly themselves. Those that give contact details will have these written on a paper form that will be stored securely in a locked drawer on the surgical assessment unit. They will later be collected by the study team and stored on an encrypted password-protected database that will be stored on an NHS computer in a locked research office.

The interview data will be collected on site at the Royal Devon and Exeter Hospital. The telephone interview with audio recordings will be carried out from a secure office on the NHS site. Audio files of the participant consent procedure and the interviews will be downloaded from the recording device onto a secure hard drive and will be allocated a unique participant ID number with the ID key kept in a separate location to pseudonymise the data. Prior to sending the data for transcription the interviews will be coded in a fully anonymised format to protect the data ready for transcription by a professional UK based transcription service. Once the transcription is complete the audio files will be securely destroyed by the transcription service and the researcher.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

Patients - Adult patients of any gender over the age of 18 undergoing emergency ambulatory care via the surgical assessment unit for a general surgical condition will be included. A good understanding of the English language will be required in order to understand the information provided and undertake a telephone based consent and interview process.

Staff – Staff employed in the SAU including consultants, junior doctors, senior nurses and other ward staff such as junior nurses, healthcare assistants and ward receptionists.

7.1.2 Exclusion criteria for patient participants

The following are exclusion criteria:

- Children under the age of 18
- Adults without capacity to consent as participants for the study
- Those who have primarily presented with a condition that is not within the remit of general surgeons
- Those who had their care continued as an inpatient immediately following their initial presentation.
- Unable to understand or speak English to the level required to understand the information sheet or conduct the interview

Exclusion criteria for staff participants:

- **Refusal or withdrawal of consent**
- **Staff who have not worked in ambulatory care (e.g. inpatient care experience only)**

7.2 Sampling

Patients - Sampling will occur any time the surgical assessment unit is open and receiving patients – generally between the hours of 08:00am-22:00pm and 7 days a week. It is possible that there will be targeted recruitment later in the study by the clinical team if certain groups are overrepresented using the random sampling technique.

Staff – We will aim to recruit 3-5 staff members from each of the following groups: consultants, junior doctors, senior nurses, ward support staff.

7.2.1 Size of sample

The sample size of 20 for patient participants has been estimated from other similar studies that use a similar technique of semi-structured interviews and thematic analysis. We believe this is a valid estimate as this is a single centre study looking at people attending the same unit with similar conditions. We will conduct interim analysis after each 5 patients to allow ongoing estimates of the number needed to reach thematic saturation.

We will aim to recruit 3-5 staff participants from each of the following staff groups: consultants, senior nurses, junior nurses, junior doctors and other ward staff including junior nurses, healthcare assistants and ward receptionists. This is considered to be a good subgroup size for this type of qualitative research. The overall size for the staff group is estimated to be 12-15 participants.

7.2.2 Sampling technique

Potential participants are identified from the admission list on the surgical assessment unit by the clinical team.

Patients will initially be approached at random but purposive sampling may be used later in the study if demographic groups e.g. by age are under-represented. This strategy has been used as we believe different groups may have different attitudes and difficulties with aspects of emergency ambulatory care. However, many patient characteristics are difficult to select for at the point of sampling so this will not be possible for most characteristics other than age.

Staff will be approached as a group at team meetings and be given the opportunity to register their interest with Expression of Interest forms to later be approached individually to arrange a time for interview. Regular updates on the progress of the study will be given to the ward team at existing daily briefings by the nurse-in-charge in conjunction with the researcher to allow those who had not previously heard about the study an opportunity to make contact for further information and to complete Expression of Interest forms.

7.3 Recruitment

7.3.1 Patient sample identification

Potential participants will be identified by the clinical team. There exists an admissions list on the surgical assessment unit that has basic patient details (name, date of birth and hospital number) and presenting problem listed. This is regularly consulted by the clinical team as part of their clinical work. Eligible patients will be given basic information about the study by the clinical team at the point at which they are being discharged from their ambulatory stay on the surgical admissions unit. Patients interested in finding out more about the study will be given an information sheet and given the option of either leaving their telephone number for the study team to make contact or contacting the study team themselves using contact information given on the information sheet.

Staff recruitment

General surgical senior and junior doctors that work on the SAU will be given information about the study at relevant departmental meetings during the study recruitment period. It is likely that there will be a changeover of junior staff during this time so it may be necessary to repeat this briefing. At these meetings potential participants will have access to Information Sheets and will be able to complete an Expression of Interest form if they wish. Those that have completed an Expression of Interest form will be contacted in a manner of their choosing to answer questions, confirm interest and arrange a date for interview if they are happy to proceed.

Senior doctors will be given a choice of where they would like to perform the interview. A private room within the department will be available for booking but if consultants prefer to perform the interview from their private office this will be accommodated if possible. Junior doctors will be offered a booked private room within the surgical department or a private room booked near the SAU.

Ward staff will be given information about the study at departmental meetings and daily briefings as deemed appropriate by the Matron in charge of the ward. There will be the opportunity to take Information Sheets and complete Expression of Interest forms at this time and blank sheets and forms will be left on the ward as well. Staff completing Expression of Interest forms on the ward will be able to place them into an envelope within a drawer on the ward reception desk which the researcher will check regularly. Those that have completed an Expression of Interest form will be contacted in a manner of their choosing to answer questions, confirm interest and arrange a date for interview if they are happy to proceed.

A private room is available for booking in close proximity to the SAU that will be used for ward staff interviews. We have consulted the Matron in charge of SAU on the feasibility of facilitating staff interviews and it has been suggested that the best time would be before a shift starts or early on in their shift so we anticipate most interviews to take place between 0700-1100.

If any staff member wishes to take part but is unable to arrange time to do a face-to-face interview they will be offered the option of a telephone interview, the time of which will be scheduled in advance.

7.3.2 Consent

Potential participants who are interested in finding out more about the study will be given a **staff or patient** participant information sheet. This includes details of the study including the purpose of the study and method of data collection and details of how confidentiality will be ensured. They will be given the opportunity to ask for clarification and further questions at the first telephone contact meeting **(patients) or a follow-up discussion in their workplace or on email/telephone as preferred (staff).**

Patient consent

Capacity will be assessed at the initial telephone contact and again prior to the interview if this is scheduled for a separate conversation. This will be done by exploring with potential participants their understanding of the purpose and nature of the research, the potential benefits (which will likely be to others rather than them as an individual) and risks. This will include how the data will be handled and confidentiality ensured. We will also ask participants if they have discussed their decision to participate with others and establish whether there has been any element of coercion to take part. Individuals deemed not competent to consent will not proceed to recorded interview.

A statement of consent will be taken at the start of the telephone interview and stored as a separate file for patient participants. This will include the following statements:

- that they have read and understood the information sheet
- participation is voluntary and there will be a period immediately after the interview for up to 2wks when they can change their mind about participating
- they understand that their care will not be affected by the decision to participate
- interviews will be recorded and then transcribed using an external transcription service. This will not include any sensitive information and they should take care not to mention sensitive information including their name and address in the interview.
- direct quotes may be taken from their interview to be published in the final research but will not contain any potentially identifiable information
- if any concerns about the participants ongoing health arise during the interview we are obliged to disclose these to their GP, however the GP will not be routinely contacted as part of the research process

Staff consent

Staff will be given the opportunity to express interest in the study and complete an expression of interest form. They will then be contacted in a manner of their choosing for a follow-up discussion within 2 weeks when any questions about the study can be answered and interest confirmed. At this time arrangements will be made to complete an interview. This may require follow-up correspondence to secure an appropriate time and room booking. This period of time between initial information and interview will give staff time to consider the decision to take part.

Staff conducting a face-to-face interview will read and sign a copy of the staff consent form prior to the start of the interview. A copy of the consent form will be given to staff participants for their records.

8 ETHICAL AND REGULATORY CONSIDERATIONS

Patient participants

There is no intervention in this study and it will not affect any care that patients receive in the future. The main potential risks to the participant are considered to be potential distress from discussing upsetting episodes of care they received and risk to their confidentiality by the use of direct quotes.

This study does not aim to explore particularly sensitive or personal aspects of a patient's care. The interview schedule has been reviewed by volunteers interested in helping with research design to check that the questions are deemed to be acceptable. Despite this, it is not possible to predict what each individual may find upsetting and sensitive to discuss. Participants who become distressed during the interview will be given the option to halt or terminate the discussion. Some participants may wish to share their experience although they find it upsetting, because they believe it is important for the purpose of the research and will be given the opportunity to do this if they wish but will not be directly prompted to do so.

Participants will be made aware during the consent process that direct quotations from their interview may be used but that they will be de-identified and great care will be taken that they do not include any potentially identifiable personal information. Participants who inadvertently identify themselves during the interview will be reminded by the interviewer to avoid revealing identifiable information. In this event this section of the recording will be erased and the participant prompted to try to express their statement again without the identifiable information.

The potential benefits of this study are to foster a greater understanding amongst healthcare professionals of how patients experience emergency ambulatory general surgical care which may help them deliver this care in a way that is deemed more acceptable to patients. It may also help those planning an expansion in this service to identify those most likely to engage well with this method of care delivery. It is possible that these benefits may be seen by patients undergoing similar care again in the future but it is likely that this will be a small number of participants.

Telephone interview has been selected as the method of data collection for **patient participants** in this study as it is thought to be a method which minimises inconvenience and intrusion to the participants. The timing of the interviews is planned to be 1-2 weeks after the ambulatory attendance episode to give potential participants time to reflect on their experience and time to consider whether they would be willing to take part in the study and feel free from any sense of obligation to the staff who may have initially approached them regarding the study.

Staff participants

As with patient participants, staff participants will be made aware during the consent process that direct quotations from their interview may be used but that they will be de-identified and care will be taken that they do not include any potentially identifiable personal information. Participants who inadvertently identify themselves during the interview will be reminded by the interviewer to avoid revealing identifiable information. In this event this section of the recording will be erased and the participant prompted to try to express their statement again without the identifiable information.

It is recognised that due to the nature of team-working and the relatively small pool of staff eligible to be interviewed that staff accessing the research report in the future may be able to guess the identify of some of their colleagues. Participants will be counselled about this possibility during the consent process.

We recognise that staff participants may be fearful of consequences of being found to be critical of others during interview and the questions have been written to avoid asking participants questions inviting such answers.

The study is subject to NHS ethical review and HRA approval.

8.1 Assessment and management of risk

Patient participants

The interview questions have not been written to explore specifically the mental well-being of the participant but it is possible that participants may bring this up when discussing their experience at a time of ill-health. If the participant makes statements describing thoughts or intentions of self-harm then the interviewer will act on this as a safeguarding concern.

The **patient** participant will be asked if they have shared this information with any of their healthcare team, in particular their mental health team (if applicable) or GP. If not they will be encouraged to do so. The interviewer will then inform the participant that they are obliged to pass this information on to the participant's GP for them to arrange further support and care as needed. GP details will not be routinely collected but participants will be informed as part of the consent process that GP details will be obtained in these circumstances in order to act in the interest of patient safety.

Any issues that arise describing potential harm to others will need to be disclosed to the appropriate authority. This may include social service and the child safeguarding team at the Royal Devon and Exeter Hospital if the concerns relate to children. Any expression of intention to harm others will need to be disclosed to the police. The intention to disclose information will be declared to the participant unless it is thought this declaration risks endangering any other person.

Staff participants

The topic guides for staff participants have been written to avoid inviting or inciting staff to express overly critical opinions of their workplace or colleagues as we recognise that staff may be hesitant and fearful of doing this when their identity could be guessed. We are also not asking questions that probe into potentially distressing experiences they may have had at work but it is not possible to predict whether these will come out during some interviews. If staff become distressed during the interview they will be given the option to take a break or stop the interview.

Staff who have expressed concern about their working environment will be encouraged to speak to their line manager for further support. The researcher will also have available information on other sources of support for staff within the organisation and will offer these to participants. Those that have expressed health concerns during the course of the interview will be encouraged to visit their GP or seek medical care as appropriate. The researcher will not

disclose any details of the interview to anyone else within the organisation without the permission of the staff member.

Any patient safety concerns that arise during the course of the interviews will be discussed with Rob Bethune as Chief Investigator and supervisor. He will decide upon the appropriate action depending upon the nature of the concerns and use the trust's mechanism for reporting clinical incidents as appropriate. Staff will be informed that specific patient safety concerns will be escalated in this manner, though they will not be identified by name in this process without their consent.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Prior to the start of the study NHS Research Ethics Committee (REC) review will be sought via the Health Research Authority (HRA) and HRA Approval obtained. Any substantial amendments that require review will not be implemented until that review is in place and approved by the REC that approved the main study. The chief investigator is responsible for keeping all correspondence with the RECs, producing annual reports, notifying the REC at the end of the study and producing final reports.

Regulatory Review & Compliance

This is a single site study. All appropriate governance and compliance approvals will be gained prior to the start of the study and a copy of the approved study documents will be submitted to the site through the HRA Approval mechanism of Capacity and Capability Approval with the local site R&D Department.

Amendments

The chief investigator will make the decision to request an amendment. The sponsor's protocols for amendments will be adhered to and the sponsor will determine what constitutes a substantial or non-substantial amendment in line with the HRA Amendments processes. Following sponsor approval the amendment will be submitted for NHS REC approval following published HRA guidelines. This will include submitting a Notice of Substantial Amendment form in IRAS. Non-substantial Amendments will be approved by the Sponsor and submitted to the HRA Amendments team for Approval, as and when required.

History of amendments will be detailed within the protocol and previous versions of the protocol will be retained for reference.

8.3 Peer review

The proposal for the study has been internally peer-reviewed by experts in the field chosen by the sponsor that do not have any association with the study. Comments from this peer-review process were acted upon in the development of this protocol.

8.4 Patient & Public Involvement

A volunteer patient and public involvement in research (PPI) group associated with the Royal Devon and Exeter Hospital were involved in the design of the study including the acceptability of the interview schedule questions and the content, layout and readability of the study literature. This included detailed feedback from a small number of individuals who had had some experience of emergency surgical care.

8.5 Protocol compliance

Accidental protocol deviations will be documented and reported to the chief investigator and sponsor. There will follow a discussion amongst the study team about how future similar breaches can be avoided and an action plan documented.

8.6 Data protection and confidentiality

All investigators will comply with the requirements of the Data Protection Act 1998 and subsequent revisions prompted by the General Data Protection Regulations (25th May 2018) with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles and the University of Exeter's compliance requirements of the processing of data for research purposes as a task in the public interest.

All personal data collected during the course of the study will be either stored electronically on an encrypted, password-protected NHS computer hard drive or as paper files which will be stored in a locked drawer in a locked office with limited access. No NHS data will be transferred out of the NHS.

The participant interviews will be recording using a digital recording device by the principal investigator. Audio files of the participant consent procedure **(for those participants using telephone consent)** and the interviews will be downloaded from the recording device onto a secure hard drive and will be allocated a unique participant ID sequence with the ID key kept in a separate location as part of the pseudonymisation process. Prior to sending for transcription the interviews will be fully anonymised and the transcribed audio files will be securely destroyed once transcription is complete. This file will be stored in a secure password-protected encrypted file on an NHS server in a different location to the secure database containing the key.

A database linking the ID code to other information about the **patient** participants including sensitive data such as age, telephone number, presenting problem and distance from hospital will be stored separately in a secure password-protected encrypted file on an NHS server. **There will be a separate database for staff participants that will contain name, contact details and job title. These databases** will not be transferred elsewhere. **They** will be accessible only by the core members of the study team. **They** will be made available on request to the sponsor for the purposes of auditing or monitoring but will then have sensitive data such as telephone number removed. The sponsor will store the data on secure servers according to their protocols.

The de-identified study data will be transferred in an anonymised format to the University of Exeter Open Research repository and stored securely in an anonymised form by the sponsor for 5 years after the end of the study as per the sponsor's research data policy.

Lisa Massey will be the data custodian.

8.7 Indemnity

The sponsor (University of Exeter) is responsible for potential legal liability arising from the design and management of the research. Indemnity insurance is in place to cover this liability.

The NHS indemnity scheme will cover potential legal liability arising from the conduct of the research as this will be conducted on site at the Royal Devon and Exeter NHS Foundation Trust Hospital.

8.8 Access to the final study dataset

The full dataset will be accessible by the 4 named investigators only and on request by individuals nominated by the sponsor for the purpose of monitoring. No secondary analysis is planned for the dataset.

9 DISSEMINATION POLICY

9.1 Dissemination policy

The data arising from the study is owned by the investigators. On completion of the study the data will be analysed, tabulated and a final study report compiled. The Chief Investigator has ultimate responsibility for preparing this. The full study report and protocol will be accessible via the sponsor's server (Open Research Exeter) within 12mths of the completion of the study.

The study team have rights to publish the study data via peer-reviewed scientific journals, conference presentations and internal report.

The sponsor's role will be acknowledged within the publications. There is no funding body.

Participants who wish to know the results of the study will be able to access to a copy of the final study report by contacting the surgical assessment unit following the conclusion of the study and the compilation of the final study report.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Lisa Massey will write any publications with support from the other study team members who will review the manuscripts and both be named authors.

10. REFERENCES

1. Ireland, A.o.S.o.G.B.a., *Commissioning guide: Emergency general surgery (acute abdominal pain)*, N. accredited, Editor. 2014: Royal College of Surgeons of England.
2. Tierney GM, T.S., Hender J, Lund JN, *Pilot study of a new paradigm in the management of surgical emergencies using emergency surgery ambulatory care*. The Annals of The Royal College of Surgeons of England, 2014.

3. Caws, C., C. Lake, and K. Bilbe, *Improving the Patient Experience of the Ambulatory Care in the Surgical Assessment Unit*. 2017, The Foundation of Nursing Studies: FoNS Centre for Nursing Innovation.
4. *Consolidated Framework for Implementation Research*. Available from: <https://cfirguide.org>.
5. Braun, V. and V. Clarke, *What can "thematic analysis" offer health and wellbeing researchers?* International Journal of Qualitative Studies on Health and Well-Being, 2014. **9**.

11. APPENDICES

11.1 Appendix 1- Required documentation

CVS for Lisa Massey and Rob Bethune

Participant information sheet

Interview schedule

11.2 Appendix 2 – Schedule of Procedures

Procedures	Visits		
	Screening	First telephone contact	Interview
Participant information sheet given	x		
Further information given and questions answered		x	
Capacity assessed		x	x
Recorded consent			x
Interview			x

11.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	2.0	18/02/2019	Lisa Massey	<p>Mainly changes related to expansion of project to include staff interviews. These include:</p> <ol style="list-style-type: none"> 1. Changes to study summary including title. 2. Jo Day added as qualitative supervisor.

				<ol style="list-style-type: none">3. Additional information in study design and throughout the protocol about rationale and methods for staff interviews.4. References format changed.5. Wording changed to reflect the patient participants will be “offered” a copy of their consent form as early experiences have been that most participants do not wish to receive one.6. Addition of £25 thank you payment for future participants (patients and staff). This has been added to encourage a wider range of participants to take part.
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