



The PANORAMA Study

oPtimising post-dischArge care
pathways after acute paNcreatitis:
evaluatiOn of health seRvice
utilisAtion, outcoMes (PANORAMA)

This protocol has regard for the HRA guidance

Version Number: *1.1*

Version Date: *11-May-2026*

1 PROTOCOL DEVELOPMENT

Protocol amendments				
The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.				
Amendment number	Date of amendment	Protocol version number	Type of amendment	Summary of amendment

2 PROTOCOL SIGN OFF

Chief Investigator (CI) signature page	
I, the Chief Investigator, confirm that I have read and agree with the following protocol, and that I will conduct the study in compliance with the version of this protocol approved by the REC and any other responsible organisations. I agree to ensure that the information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor. I also confirm that I will make the findings of the study publicly 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 stated in this and any subsequent approved protocol will be explained.	
Study name:	The PANORAMA Study
Protocol version number:	Version:
Protocol version date:	11-May-2026
CI name:	Mr Matthew Lee
Signature and date:	 _____ 11-May-2026

Sponsor Statement

By signing the IRAS form for this study, University of Birmingham, acting as sponsor, confirm approval of this protocol.

Compliance statement

This protocol describes the PANORAMA study only. The protocol should not be used as a guide for the treatment of patients not taking part in the PANORAMA study.

The study will be conducted in compliance with the approved protocol, the UK Policy Framework for Health and Social Care Research, Data Protection Act 2018 and the Principles of Good Clinical Practice (GCP) as set out in the UK Statutory Instrument (2004/1031) and Mental Capacity Act 2005, and subsequent amendments thereof. Every care has been taken in the drafting of this protocol, but future amendments may be necessary, which will receive the required approvals prior to implementation.

Principal Investigator (PI) signature page

As Principal Investigator, I confirm that the following protocol has been agreed and accepted, and that I will conduct the study in compliance with the approved protocol where this does not compromise participant safety.

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

Study name:	The PANORAMA Study
Protocol version number:	Version: __ __
Protocol version date:	__ __ / __ __ / __ __ __ __
PI name:	
Name of Site:	
Signature and date:	_____ __ __ / __ __ / __ __ __ __

3 ADMINISTRATIVE INFORMATION

Reference Numbers	
Sponsor number	RG_25-105
ISRCTN reference number	< ISRCTN reference number >
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CPMS reference number	<CPMS number>

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The Funder of the study has had no role in the study design, data collection, data analysis or data interpretation.	

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PANORAMA Oversight Committee	
Chair: XXXX	Details of position

4 ABBREVIATIONS

Abbreviation	Term
AE	Adverse Event
AP	Acute Pancreatitis
BiCOPS	Birmingham Centre for Observational Prospective Studies
DCF	Data Collection Form
CI	Chief Investigator
GCP	Good Clinical Practice
HRA	Health Research Authority
ICF	Informed Consent Form
ISF	Investigator Site File
ISRCTN	International Standard Registered Clinical/sociAl sTudy Number
NHS	National Health Service
PAG	Patient Advisory Group
PI	Principal Investigator
PIS	Participant Information Sheet
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMF	Study Master File
SMG	Study Management Group
UoB	University of Birmingham

5 STUDY SUMMARY

Title:	The PANORAMA Study - oPtimising post-dischArge care pathways after acute paNcreatitis: evaluatiOn of health seRvice utilisAtion, outcoMes (PANORAMA)
Study Design	A mixed-method study including qualitative interviews, a prospective cohort study, and an implementation workshop.
Objectives:	• Develop conceptual framework for a 'gold-standard' post-hospital discharge pathway (WP1) • Explore patient experience of post-hospital discharge care (WP2) • Explore clinician approaches to post-discharge care (WP3) • Describe real-world pathways experienced by patients after hospital discharge (WP4) • Identify groups at highest risk of use of health care services (WP2&4) • Co-produce interventions for post-discharge care pathways (WP5)
Population:	• Patients, or their carers, treated for acute pancreatitis (AP) • UK based clinicians and policy makers with a role in acute pancreatitis care
Sample size	WP1: 80 participants WP2: 20-30 participants WP3: 20-30 participants WP4: 1017 participants WP5: 20-30 participants
Outcome measures	WP4: Health resource utilisation for 6 months following hospital discharge after AP Onset of anxiety or depression following AP assessed using PHQ-9 and GAD-7 Healthcare costs related to AP Quality of life scaling after AP measured using EQ-5D-5L
Study Duration:	30 months
Subject Participation Duration:	WP1: 15 minutes WP2: 1 hour WP3: 1 hour WP4: 6 months WP5: 6 hours
Funding:	Funded by the NIHR Health Services and Delivery Research Funding Stream.

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7 BACKGROUND AND RATIONALE

There is no good evidence on the post-discharge management of patients treated for acute pancreatitis (AP). Specifically, there is no guidance on who needs to be followed up early or routinely, what needs to be assessed during outpatient follow-up, and what information patients need after discharge. This leads to variation in practice, and possibly increased healthcare utilisation post-discharge. There is a need to understand variation and need in this aspect of care. This would help us to improve and standardise patient follow-up after AP.

The research questions addressed in PANORAMA will help us to develop pathways and strategies to support patients following AP.

7.1 Background

The pancreas is an abdominal organ with a role in digestion of food and control of blood glucose. This can become inflamed, known as acute pancreatitis (AP), which affects ~40,000 individuals each year in the UK[1], and carries healthcare costs of approximately \$2 billion globally[2]. AP can range in severity; mild cases may present with symptoms like pain and nausea, while severe cases can result in organ failure, critical care admission, and death in 2.3% cases[3]. Patients are treated with supportive measures unless significant complications arise, and in some cases may be managed through virtual-ward pathways. Once pain subsides & other AP related issues are resolved, patients are discharged from acute secondary care support.

Recovery after an episode of acute pancreatitis can be slow, impacting quality of life. Around 8% of patients are re-admitted within 30 days of discharge (~ 3,000 readmissions each year). Of these, around 1/3 require no intervention, and the remaining 2/3 either have recurrence of AP, or have developed complications[3]. Overall, 1/3 of the whole AP population will develop pancreatic insufficiency (inability to digest food) following discharge[4]. This manifests as loss of appetite and weight loss. Type 3c diabetes can occur in 25% of patients after destruction of endocrine tissue during inflammation[5]. We also know that people can experience mental health problems after AP, with up to 1 in 3 experiencing anxiety or depression related to the condition[6, 7]. Therefore, patients with AP are at high-risk of developing multimorbidity, further reducing patient quality of life and increasing healthcare costs[8].

Around half of cases of AP are caused by gallstones[6]. This has well defined pathways to deal with the underlying cause, and so early intervention with cholecystectomy or endoscopic biliary clearance may be needed[9]. Another common cause of AP is alcohol use. This represents a significant challenge, as alcohol use is associated with recurrent episodes of AP, as well as predisposing to the risk of Chronic Pancreatitis[10]. It is recognised that alcohol use is particularly associated with socioeconomic status; with physical and mental health impacts greatest in those from more deprived groups, and people from ethnic minorities[11]. Health literacy, particularly the ability to self-manage or seek help for health problems correlates with socioeconomic group, and can also be impaired in people with chronic health conditions[12]. This means that patients may seek help from unvalidated or unreliable sources,

or not at all. This has implications for post-discharge care in a population at risk of complications after an acute event.

There is no standardised follow-up after discharge from hospital for patients with AP[12]. With appropriate strategies, it may be possible to reduce excess readmissions, and implement ambulatory approaches across secondary or primary care, towards an integrated approach. AP can lead to long-term conditions including diabetes mellitus, depression, and chronic pain, which if not detected early can have a serious impact on quality of life and health, and lead to increased health service use[3, 13]. Stratifying patients at risk of significant healthcare use may lead to benefits from structured follow-up, reducing overall healthcare use, improving management of long-term conditions and quality of life for patients.

7.2 Study rationale

This project will address two priorities from the James Lind Alliance Priority Setting Partnership (JLA PSP)[14]:

- **5:** How can people with AP be helped to manage their condition post-diagnosis?
- **10:** What are the psychological (mental & emotional) impacts of AP?

Both issues relate to what happens after hospital discharge. There is an estimated burden of ~3000 unplanned readmissions each year[14], as well as delays in recognition and management of new long-term conditions such as diabetes, pancreatic insufficiency, and mental health conditions. Our PPI contributors highlighted this is a major issue for patients.

The NIHR prioritises prevention of ill health, and ensuring that services meet individual needs[15]. People with this condition are likely to have multiple long-term conditions[16] or be from underrepresented groups (i.e. non-white, socioeconomically deprived, non-English speaking)[17], including those with excess alcohol use (1 in 5 presentations)[16], both of which feature in the NIHR key priority document.

Our PPI work has highlighted variation and shows the need for consistency following hospital discharge. Patients want advice and support around diet, return to normal activities, and what to do when they are concerned about further episodes of AP. Patients have reported dietary support ranging from no advice to dietitian input. Some patients have access to a specialist nurse who can facilitate urgent planned assessment of abdominal pain, or act as an access point for other post-AP symptoms. This is an example of patient-initiated follow-up, compared to clinician defined follow-up, which might include one outpatient attendance at a variable timepoint post-discharge. This variation shows that patients in different areas might receive vastly different care after discharge, with resulting impacts on their recovery, self-management, and may lead to unplanned healthcare use. This will add to the \$2 billion annual cost of AP admissions[18].

There are four strands of evidence to consider:

- *The PANC study:* A 2023 national audit reviewed 2,500 admissions with AP across 110 hospitals. It found that one in four had been previously admitted with AP. Within the 30 days

after discharge, 3.3% of patients were readmitted for a reason unrelated to AP, 3.6% for a recurrence of AP, and 2.3% with a complication of AP. [18]. These figures relate to a follow-up of only 30-days; it is likely that longer-term readmission rates will be even higher. Readmissions classified as 'unrelated' may be due to mild symptoms mistakenly attributed by patients to AP, or anxiety about a recurrent episode of acute illness. A survey of 111 hospital sites showed variation in planned follow up, with 73 stating they regularly planned follow-up. In patient-level data, only 1 centre reported following up all patients, and centres typically followed up <50% of patients.

- *Published studies of lived experience after AP:* There is a relative paucity of data on the lived experience and support needs of patients following AP. Qualitative studies from China suggest anxiety, fear, and uncertainty about disease recurrence dominated post AP experience[7, 19] [20].
- *Systematic review of guidelines:* A systematic review of clinical guidelines has mapped recommendations to different parts of the treatment pathway[21]. This review included 20 guidelines, of which only one provided recommendation for post-discharge support in patients with alcohol-induced acute pancreatitis. They identified the need for counselling and smoking cessation services, but this guideline was from the USA[22]. See Figure 1 for graphical summary.
- *Systematic review of readmissions after AP:* This systematic review found rates of readmission after AP due to gallstones ranged from 4-37%, and AP due to alcohol was 2-60%[23]. Readmissions for those with severe or necrotising AP ranged from 20-75%. The estimated median cost of a readmission for AP was \$18,000 per admission. These values are taken largely as secondary outcomes from trials around early cholecystectomy or deploying enhanced recovery in AP. The trials were typically set in the US.

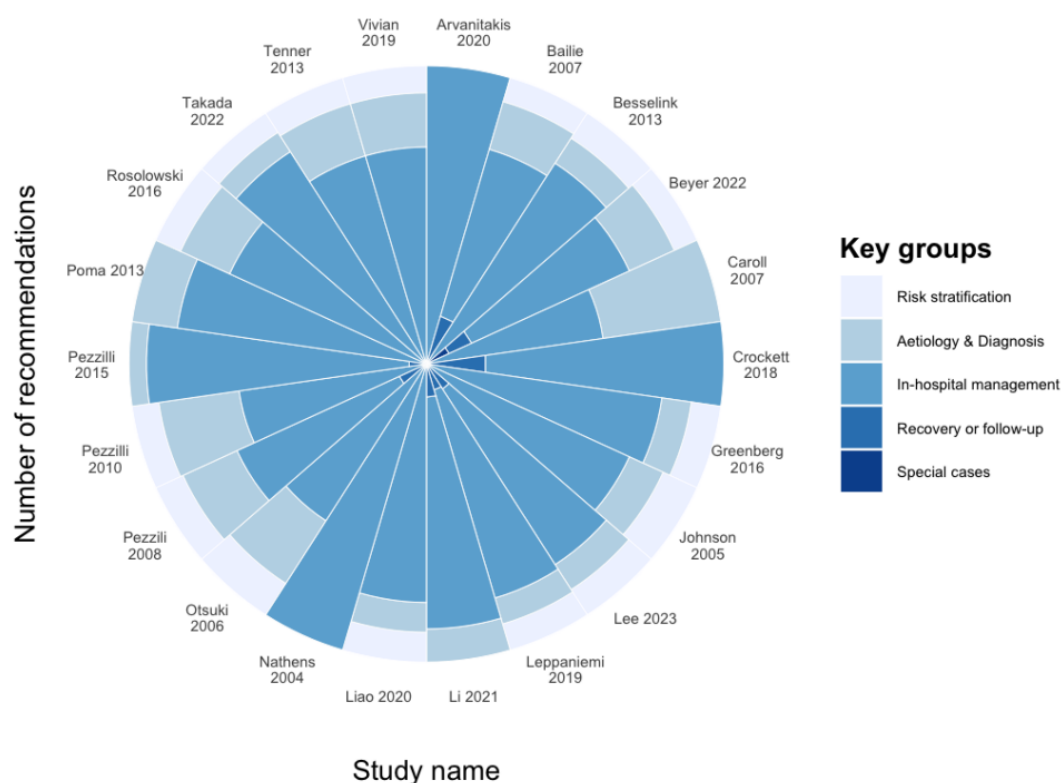


Figure 1: Mapping of guideline content demonstrating paucity of post-discharge care recommendations

Taken together, the evidence clearly demonstrates a paucity of consensus on post-discharge care and support. It also highlights the frequency of readmission and associated costs. This confirms the need to strengthen the evidence base to improve recovery and avoid unnecessary health care utilisation.

7.3 Justification for participant population

PANORAMA is designed to include those with relevant experience of AP, or those providing care to people with AP within the NHS. This ensures that experience and findings are directly relevant to the health system.

7.4 Justification for design

To understand the challenges around post-discharge care, a mixed and multimethod study is required. This will allow us to use qualitative and quantitative data to understand the challenges in current care and identify opportunities for future improvement.

8 AIMS AND OBJECTIVES

Research Question: What care is offered to and accessed by people with AP after discharge and what are the opportunities to improve this?

Objectives

1. Develop conceptual framework for a 'gold-standard' post-hospital discharge pathway (WP1)
2. Explore patient experience of post-hospital discharge care (WP2)
3. Explore clinician approaches to post-discharge care (WP3)

4. Describe real-world pathways experienced by patients after hospital discharge (WP4)
5. Identify groups at highest risk of use of health care services (WP2&4)
6. Co-produce interventions for post-discharge care pathways (WP5)

Secondary Objectives

1. How does post-discharge follow up vary after acute pancreatitis.
2. How do different post discharge pathways influence recovery, healthcare associated costs, and health service utilisation

9 STUDY DESIGN AND SETTING

Study design

A UK-based mixed and multi method investigation of post-discharge care pathways and outcomes. It is made up of five work packages (WP):

WP1: A survey of key stakeholders to identify characteristics of a 'good' follow-up service after AP

WP2: Semi-structured interviews with people who have experienced AP in preceding six months

WP3: Semi-structured interviews with clinicians who provide care for people with AP

WP4: Cohort study of post-discharge health service use following discharge after an episode of AP

WP5: An implementation workshop including all stakeholders to propose changes to pathways

10 Work package 1: How to define a ‘good’ follow-up pathway

10.1 Overview

We will undertake a short survey of stakeholders to identify the key features and characteristics that define a ‘good’ follow-up pathway for patients with AP.

10.2 Study population

People who have experienced AP and their carers/relatives, clinicians who provide care for people after AP in secondary care (e.g. surgeons, gastroenterologists, specialist nurses), and primary care physicians. All must have experience of AP care in the NHS.

10.2.1 Inclusion criteria

Patients	Experience of adult acute pancreatitis care in the NHS as patient
	Adults ≥ 16 years of age
Carers	Experience of caring for a patient who received acute pancreatitis care in the NHS
	Adults ≥ 16 years of age
Clinicians	Experience of providing NHS care to patients with acute pancreatitis in primary or secondary care settings
	Adults ≥ 16 years of age

10.2.2 Exclusion criteria

All Unable to complete the survey in English

10.3 Recruitment & consent

10.3.3 Overview

The study will be advertised to potential participants in the following ways:

- Online through social media (Linkedin)
- Mailshots through relevant charities (e.g. GUTS!UK) and NIHR ‘Be Part of Research’ network.
- Recruitment of hospital specialists through existing research networks and specialty association promotions
- Promotion to GPs by engagement with NIHR RRDN primary care networks, as well as integrated care boards, local medical committees, and relevant societies.

Through these channels, potential participants will be invited to participate in the study and signposted to the dedicated study website to self-enrol.

10.3.4 Recruitment Process

Mailshots and social media posts will include a short summary of the aims and objectives of PANORAMA and invite potential participants to follow a link to complete the survey.

After clicking the link, potential participants will be presented with a webpage which explains:

- the purpose of the study
- how the data collected will be used
- who has approved the study
- contact details for the research team
- It will highlight that consent to participate will be implied by completion of the survey
- A link to the privacy policy will be provided

Should they wish to proceed, the potential participant must check a box to confirm understanding and then proceed to complete the survey.

The webpage will be hosted on REDCap (Research Electronic Data Capture) a software platform designed specifically for building and managing online surveys and databases for research. The REDCap software is hosted on servers at the University of Birmingham.

If the study does not reach sample size through the above recruitment strategy, we will engage with relevant groups to maximise recruitment. This will use the online promotion material and will be supported by a member of the research team attending a relevant meeting e.g. GP practice meeting, specialty group meeting or a patient charity meeting, to briefly present the study, demonstrate how to access the survey and ask for completion.

10.3.5 NIHR Be Part of Research

The purpose of the Be Part of Research Volunteer Service (BPORVS) is to allow members of the public to become volunteers by creating an account, specifying the areas of research that they are interested in and give consent to be contacted by the Be Part of Research team. Those who consent will receive information about BPORVS, in particular to alert them to specific BPORVS registered studies that they may be interested in based on their volunteered details and study specific eligibility criteria, using an online self-registration service. The register is open to those that live in the UK, are over 18 and have an email address.

At the time of registration, volunteers are made aware that they are not signing up to take part in a specific health study when they join this register and that they will only be signposted to studies that have NIHR funding or are listed on the NIHR RDN Portfolio. If the volunteer is interested in the study there will be a link in the email to take them to the study team (e.g. website, pre-screener) where they

will move into the study team's screening process and consenting process if they take part in the study.

The Be Part of Research Volunteer Service is funded by the Department of Health and Social Care and delivered by the National Institute for Health and Care Research (NIHR) in conjunction with Public Health Agency, Research & Development, Northern Ireland, NHS Scotland and Health and Care Research Wales. Further information on the Be Part of Research Volunteer Service is available here: <https://bepartofresearch.nihr.ac.uk/volunteer-service/researchers>

10.4 Consent

Completion of the survey on REDCap will imply consent. This will be outlined on the REDCap landing page and potential participants will be required to acknowledge they understand before they can complete the survey.

10.5 Study Schedule

Participants in WP1 will be asked to complete a single online survey.

The survey consists of three questions:

- Basic demographics including stakeholder group and region of residence or practice.
- A free text box to answer the question 'What things would make a follow up pathway for acute pancreatitis a 'good' pathway?'
- An option to supply their email address if they wish to hear more about future work package participation or to hear about results of the study.

Following submission of the form, no further actions are required.

10.6 Sample size

We will aim to secure at least 20 completed responses from each stakeholder group, with an upper limit of 40 responses per group. This is a flexible target based on the number of participants required to generate rich and meaningful data[24] alongside what is considered to be feasible given the timeframe of WP1.

10.7 Analysis

Qualitative content analysis using a thematic approach, as described by Braun & Clarke[25], will be used to analyse the free text comments from the survey data. Analysis will be conducted by two researchers and supported by the wider team. We will develop a matrix that focuses upon characteristics of a 'good' post-discharge pathway. This may include aspects related to 'timeliness/access', 'prevention of complications', and 'mental health support'.

11 Work package 2: Participant interviews

11.1 Overview

This WP will use semi-structured interviews to explore the experiences of participants following discharge from hospital following AP.

11.2 Study population

Adult patients, and carers of AP patients, (aged 16 years or older) (n = 20-30) with a hospital admission for AP, who have been discharged from acute inpatient or virtual ward care no more recently than three months, and no longer than six months ago.

Participants will have conversational standard of English..

11.2.1 Inclusion criteria - patient

- 16 years of age or older
- Hospital admission for acute pancreatitis within the NHS
- Discharged from acute inpatient or virtual ward care between three and six months previously

11.2.2 Inclusion criteria – carer

- 16 years of age or older
- Carer for a patient with a hospital admission for acute pancreatitis within the NHS
- Carer for a patient discharged from acute inpatient or virtual ward care between three and six months previously

11.2.3 Exclusion criteria - patient

- Received primary care outside NHS setting

11.2.4 Exclusion criteria – carer

- Carer for a patient who received primary care outside NHS setting

11.3 Identification

Potential participants will be drawn from the following areas:

- The NIHR 'Be Part of research' database: allowing patients to express interest in participation.
- Social media (Facebook, LinkedIn) and in patient interest groups and charity email list.
- Those who have registered an interest from Work Package 1.

Potential participants from social media and 'Be part of research' will be presented with information through a REC approved digital flyer or through a standard highlight from the 'Be part of research' team. Both will include a QR code and url link, which will lead to a short summary of the study, a link to download the PIS, and a link to a short video summarising the study.

Participants will be asked to review the supplied documents as they consider taking part. If they wish to proceed, they can click next to access the expression of interest (EOI) form. The EOI form will ask participants to confirm their age, ethnic group, region of the country where they reside, and what the cause of their pancreatitis was (if known). This will allow us to ensure a range of experiences are included in the study. Potential participants will be asked to provide contact details for the central research team (email and telephone).

The central research team will contact people who have registered their interest based on an approach to maximise sampling across collected descriptors (sex, ethnicity, aetiology, region). When no further interviews are required, those who have expressed an interest in participating but not been selected will be informed, with the reminder that they may still participate in Work Package 5, if they have registered their interest for that.

11.4 Consent

Potential participants will be contacted by the qualitative researcher who is a member of the central research team to confirm interest in participation, and to answer any questions they might have about the study. If they express a desire to proceed, they will be provided with a link to complete an electronic consent form. Following completion of this, an interview can be arranged.

11.5 Study Schedule

Interviews will be conducted by a qualitative researcher based at the University of Newcastle. This researcher is not a clinician and has no prior relationship with participants.

A virtual or telephone interview will be arranged at a mutually convenient time, occurring between three and six months post discharge after AP. The meeting will be recorded and transcribed. Interviews will typically last 30 minutes to 1 hour.

The interview schedule will be informed by previously published systematic reviews and qualitative work and will draw from WP1. This will be reviewed by the research team including lay co-investigators.

11.6 Statistical considerations

A sample size of 20-30 total participants is expected to be adequate for thematic saturation[24].

11.7 Analysis of outcomes

All interviews will be audio-recorded, transcribed and data entered into NVivo software for qualitative analysis. The data will be analysed using a thematic approach. Thematic analysis is a generic approach to data analysis, widely used in qualitative research. It enables data sources to be analysed in terms of principal concepts or themes. We will follow the process proposed by Braun & Clarke[25]. This follows several key steps:

- 1) **Transcription.** Verbatim transcription of the audio recording of an interview is standard practice. This transcription may be undertaken by the investigator who conducted the interview or by

a researcher from their team. In some cases, this may be contracted to an outside service. The researchers would then read the transcripts to familiarise themselves with the content of interviews, and to begin to consider

2) **Familiarisation** with the interview. Review of the interview transcript along with the audio recording and field notes allows the researcher to immerse themselves in the content of the interview, and to understand contextual content.

3) **Coding**. The research assesses the transcript line by line and codes any content within a phrase which might be important to any aspects of the research question.

4) **Developing a working analytical framework**. After coding 3-5 transcripts, the research team meets to discuss and agree on a framework structure. This involves identification of overarching (superordinate) themes, and sub- (subordinate) themes which address specific aspects of a theme. This also allows the researchers to compare themes and labels identified, allowing them to be harmonised for future transcript analysis.

5) **Application of analytic framework**. The refined analytic framework is then applied to the already coded transcripts, and to the remaining transcripts in a study. It is possible that new ideas will emerge as subsequent transcripts are analysed. New themes will be discussed by the research team and the analytical framework further refined.

6) **Populating the framework matrix**. The framework matrix is a summary table where each row represents a case, and each column represents a theme. The matrix is populated with appropriately coded text for each case and theme. This may be achieved using specialised computer software. We will also consider the expressed desires within Bradshaw's taxonomy of needs, categorising them into normative, felt, expressed, or comparative[26].

7) **Interpreting data**. The research team reviews the matrix to provide a narrative of the phenomenon under investigation.

Interviews will be coded by two reviewers ensuring robust assessment. This will be reviewed by the wider research team to understand the ideas being presented.

12 Work package 3: Clinician interviews

12.1 Overview

We will undertake semi-structured interviews with clinicians to explore how follow-up is delivered. Interviews will explore current pathways and what they aim to achieve at each planned contact, as well as advice given at discharge. Interviews will also explore potential changes to post discharge pathways, why these could be made and how they might be implemented.

12.2 Study population

Participants will be NHS clinicians with responsibilities for the care of patients with AP. This includes surgeons, gastroenterologists, general practitioners, and specialist nurses.

12.2.1 Inclusion criteria

- 16 years of age or older
- Experience of providing care for acute pancreatitis patients within an NHS setting

12.3 Identification and registration

Participants will be recruited from WP4 participating sites, through social media recruitment (Linkedin, Facebook), from PANORAMA WP1, and through mailing lists of relevant specialty associations. We will aim to have a mix of specialist and general surgeons, as well as representation from gastroenterologists and nurses. We will ensure representation from primary care through engagement with general practitioners and primary care networks, as this group is often the first contact for ongoing concerns.

Purposive sampling will be undertaken to ensure representation of key specialties, and specialist interest of those caring for this patient group (surgeons, gastroenterologists, specialist nurses), along with a geographic spread.

Potential participants identified through social media will be presented with information through a media post which invites participation. This will include a URL link and a QR code, which will lead to a short summary of the study, and a link to download the PIS. Participants will be asked to review the supplied documents as they consider taking part. If they wish to proceed, they can click next to access the EOI form. In this, we will ask participants to confirm their clinical role (surgeon, gastroenterologist, primary care physician, specialist nurse), and region of practice. They will also be asked for email and/or telephone contact details.

A qualitative researcher from the central research team will contact people who have registered their interest based on an approach to maximise sampling across collected descriptors. When no further interviews are required, those who have expressed an interest in participating but not been selected will be informed, with the reminder that they may still participate in Work Package 5, if they have registered their interest for that.

12.4 Consent

Potential participants will be contacted by a central qualitative researcher to confirm interest in participation and to answer any questions they might have about the study. If they express a desire to proceed, they will be provided with a link to complete an electronic consent form. Following completion of this, an interview can be arranged.

12.5 Study Schedule and follow-up

Semi-structured interviews will be conducted by qualitative researchers. The semi-structured interviews schedule will be informed by existing research[25], and with input from patients and clinical experts. Interviews will focus on post-discharge advice, and healthcare needs following discharge. To promote recruitment, health care practitioners will be offered telephone or virtual interviews as per their preference. In line with research practice, no further interviews will be conducted when saturation is reached. One interview will be conducted for each participant. Interviews typically last 30 minutes to 1 hour.

12.6 Sample size

Given the heterogeneity of the sample, we anticipate that a sample of up to 30 participants will be required to achieve saturation[27]. We will monitor recruitment, participants, and initial findings to ensure that we are capturing a broad range of experiences.

12.7 Analysis of outcomes

Analysis will be completed as for WP2, with a focus on clinician strategies for follow-up of AP. Strategies are likely to be driven by assumptions about disease and pathology and so will provide insights into the type of problems anticipated and their probable timing in the post-discharge course.

Interviews will be coded by two reviewers ensuring robust assessment. This will be reviewed by the wider research team to understand the ideas being presented.

13 Work package 4: Cohort study

13.1 Overview

In this work package, we will identify different modes of follow-up used for different patients, assess health resource utilisation in the 6 months following hospital discharge, and undertake modelling to identify the characteristics of those at highest risk of unplanned healthcare utilisation in this period. This will be supported by a health economic analysis.

13.2 Study population

13.2.1 Inclusion criteria

- Adult patients (aged 16 years and above)
- Have a diagnosis of acute pancreatitis of any severity.
- Due for discharge from an NHS secondary care setting within the study data collection window

NB: There are no limits on participation based on aetiology.

13.2.2 Exclusion criteria

- Patients unable to provide consent themselves or who lack capacity*:

**Proxy PROM completion for this population is not fully validated and may lead to unreliable results.*

13.3 Inclusivity considerations

Efforts have been made around inclusivity, specifically:

First language:

- We will provide materials to support recruitment in English plus two other languages and provide translated versions of PROMs.
- Videos will also support people who are unable to fluently read English, regardless of spoken language.

13.3.3 Avoiding exclusion at follow-up

We will ensure a range of methods are used to complete follow-up PROMS. This includes the use of text messages and email to trigger PROM completion online, as well as postal completion. This reflects the fact that the majority of people in the UK have access to one or all of these communication methods.

13.4 Identification

Patients will be approached for participation prior to discharge from hospital, or prior to transfer to a virtual/ambulatory ward. The initial approach is by their clinical team who will ask permission to share details with the research team. If they agree, the research team will provide them with written participant information sheet (PIS) and an option for a short animation explaining the study. These

materials will be provided in English plus two additional languages based on the overall profile of participating sites. There will also be REC approved posters in clinical areas to support patient awareness. Eligibility will be confirmed by the research team.

Potential participants will be provided with sufficient time to consider participation, then written informed consent will be requested. If the participant then expresses an interest in participating in the study, they will be asked to sign and date the latest version of the ICF. The PI or delegate will then sign and date the ICF. A copy of the ICF will be given to the participant, a copy will be filed in the medical notes and the original placed in the Investigator Site File (ISF).

Once an electronic entry is created in the study database, the participant's study registration number will be entered on the ICF maintained in the ISF. Details of the informed consent discussions will be recorded in the participant's medical notes for WP4. This will include date of discussion, the name of the study, summary of discussion, version number of the PIS given to participant, version number of ICF signed and date consent received.

13.5 Participant Registration

Registration will be via a secure online system (REDCap) hosted by the University of Birmingham's Centre for Prospective and Observational Studies (BiCOPS). REDCap is a secure, web-based application designed to support data capture for research studies[28, 29].

Unique log-in usernames will be provided to research team members using the REDCap database and who have been delegated the role of registering participants into the study as detailed on the PANORAMA Site Signature and Delegation Log.

These unique log-in details must not be shared with other staff and in no circumstances should staff at sites access the system using another person's login details.

13.6 Registration process

After eligibility for registration has been confirmed and informed consent has been provided and documented, the participant can be registered to the study using the PANORAMA REDCap system.

During the online registration process, eligibility must be confirmed and participant contact details for follow-up must be entered. A Registration Number will be given once all questions have been answered.

The local research team should add the participant to the PANORAMA Participant Recruitment and Identification Log which links participants with their PANORAMA Study Number. PIs must maintain this document securely and it must not be submitted to the Study Office. The PANORAMA Participant Recruitment and Identification Log should be held in strict confidence.

13.7 Informing the participant's GP of study enrolment

Once the patient has consented for entry into PANORAMA WP4, their GP should be notified that they are in the PANORAMA Study, using the PANORAMA Study GP Letter.

13.8 Study Schedule and follow-up

Following consent, baseline assessments will be completed on the day of hospital discharge by the local research team. Age, sex, ethnicity, & co-morbidities, prior mental health diagnosis, and alcohol use (using AUDIT-C[33]) will be captured. Details relevant to hospital admission including aetiology of AP, primary or recurrent pancreatitis, occurrence of complications (necrosis, pseudocyst, etc) and length of hospital stay will all be recorded. Finally, PROM data addressing general quality of life (EQ-5D-5L), and assessing for anxiety and depression (GAD-7/PHQ-9), will be collected.

Further assessments of PROMS (EQ-5D-5L/GAD-7/PHQ-9/PEI-Q) will be undertaken at day 7 & 28 (+/- 3 days) post discharge, and 3- and 6-months post discharge (+/- 7 days). A health service use questionnaire will also be completed at 28 days, 3 and 6 months post discharge. Follow up ends after the 6- month assessment. All post-discharge follow-ups are completed remotely and coordinated by the central research team. The table below shows timing of assessments. Notifications to complete assessments may be triggered by email, SMS, or mail/paper based. Digital reminders will be sent twice at 2-day intervals where responses are not completed at first reminder.

Table 1: Follow-up schedule. Assessments to left of thick line are done by local team. Those to the right are coordinated centrally.

	Baseline (Consent)	Day of discharge	Day 7 post discharge (+/-3 days)	Day 28 post discharge (+/- 3 days)	3 months post discharge (+/- 7 days)	6 months post- discharge (+/- 7 days)
Demographics	X					
Comorbidities	X					
AUDIT-C	X					
Prior mental-health diagnosis	X					
Aetiology	X					
Severity		X				
ITU admission during stay		X				
Interventional endoscopy during stay		X				
Radiological drainage during stay		X				
Timing of planned clinic		X				
Planned surgery		X				
Patient initiated follow-up		X				
GAD-7		X	X	X	X	X
PHQ-9		X	X	X	X	X
EQ-5D-5L		X	X	X	X	X
PEI-Q		X	X	X	X	X
Patient Survey of Health Care Utilisation				X	X	X

13.9 Study outcome measures

Primary endpoint assessment is six months following discharge from hospital after treatment of AP. Follow-up after discharge will be conducted centrally by the BiCOPS team using email or postal routes as preferred. Outcomes are assessed at 7 days, 28 days, 3 months, & 6 months post discharge:

- **Use of health services:** This will be captured through patient surveys at contact times.
- **Return to function:** Participants will be asked when they returned to work/normal activities
- **EQ-5D-5L:** A validated generic quality of life PROM[30].
- **PHQ-9:** A screening tool to detect depression in outpatients[31].
- **GAD-7:** A screening tool for anxiety[32].
- **PEI-Q:** A validated questionnaire to identify pancreatic exocrine insufficiency[33]

We will initially undertake assessment of health care utilisation using surveys at time points defined above. Health care utilisation will be defined as any contact with primary or secondary care in the period after discharge. This includes general practice, emergency department, outpatient, investigations, admissions for operations, commencement of new medication or referrals to specialist services.

13.10 Sample size

Following the good practice principles set out by Riley *et al.* for the development of a risk prediction model[34], assuming a 15% loss to follow-up, a minimum sample of 1017 is required to meet the criteria outlined below:

1. It will allow us to estimate the anticipated population outcome with 0.025 margin of error when the event rate is at 10%.
2. Targeting a small mean absolute prediction error rate of 0.035, with 10 predictive parameters.
3. Targeting a shrinkage factor of 0.9, with 10 predictive parameters.
4. Targeting small optimism of 0.025 in the apparent R² Nagelkerke with Cox-Snell of 0.15 and 10 predictive parameters.

13.11 Analysis of outcomes

Descriptive analysis will be performed to describe population outcomes including health service use. Regression models will be generated to explore factors associated with unplanned health service use, development of mental health conditions, and impaired return to normal activities. Latent group analysis will be carried out to explore potential groups that differ in risk category. Baseline characteristics explored will include aetiology and severity of pancreatitis, alcohol misuse, and presence of mental health condition at baseline.

GAD-7 & PHQ-9 have minimum clinically important differences of 4[35] and 5 points[36] respectively. We will assess whether participants cross these thresholds as part of the modelling, as this would indicate worsening mental health. These analyses will not be completed until the end of the cohort study. Where a participant is identified as having worsening mental health, by exceeding screen thresholds for either tool, this will trigger automated emails to be sent to the patient with details of available support and to the patient's GP to inform.

EQ-5D-5L responses will be converted to utility scores using the crosswalk algorithm as recommended by NICE[37] unless guidance on the most appropriate value set is updated before analysis is undertaken. Quality Adjusted Life Years (QALYs) will be calculated from the utility scores using the area under the curve approach.

Post-discharge costs and QALYs will be presented to better understand the economic impact by follow-up strategy. As differences in costs and health related utilities between patients may be driven by factors other than the assigned follow up, regression modelling will also be employed here to predict the costs and quality of life by strategy adjusted by relevant patient characteristics.

To obtain a total per-patient cost, resource use information will be combined with unit cost values. Information on unit cost values will be obtained from key UK national sources, such as the NHS reference costs[38], the Unit Costs of Health and Social Care[39], and the British National Formulary[40].

13.12 Safety considerations

GAD-7 and PHQ-9 scores will be calculated at the end of the study. Should a participant exceed the threshold suggesting they need further assessment, we will contact them using provided contact details to advise seeking further assessment from general practice or from primary care mental health services. If a participant indicates they have thought about harming themselves for at least half the time (option three or four in PHQ-9), separate emails will be automatically sent to the patient signposting sources of help and to their GP, advising need for further assessment. WP4 is otherwise low risk and does not require deviations from standard care, making this low-risk.

14 Work package 5: Implementation workshop

14.1 Overview

A one-day workshop to identify implementation opportunities for findings from the study.

14.1.4 Triangulation of research findings

WP1-4 will generate varied datasets, arising from different analytic techniques. We will triangulate data from these datasets using the following steps:

First, data will be sorted according to where content overlaps or deviates. We will assess the datasets for convergency and frequency of findings. We will also classify findings by topic using a classification of agreement, partial agreement, silence, and dissonance. This assessment will be compared between researchers conducting the assessment. Finally, the findings will be fed back to multidisciplinary members of the study management group, oversight group, and impact and implementation advisory group.

These steps will ensure a robust analysis and provide an understanding of data coverage and convergence or dissonance. This will form the basis of material to be presented at the implementation workshop.

14.2 Study population

Clinicians will be invited to participate, with eligibility as in WP3. General practitioners and service commissioners will also be eligible to participate. Patients with experience of AP and their carers will be eligible to participate. Those with a non-UK practice or with no relevant experience of AP will not be able to participate.

14.2.1 Inclusion criteria

Patients	Experience of adult acute pancreatitis care in the NHS as patient
	Adults ≥ 16 years of age
Carers	Experience of caring for a patient who received acute pancreatitis care in the NHS
	Adults ≥ 16 years of age
Clinicians & Service Providers	Experience of providing or commissioning NHS care for patients with acute pancreatitis in primary or secondary care settings
	Adults ≥ 16 years of age

14.2.2 Exclusion criteria

Patients	No relevant experience of adult acute pancreatitis care in the NHS as patient
	<16 years of age
Carers	No relevant experience of caring for a patient who received acute pancreatitis care in the NHS
	<16 years of age
Clinicians & Service Providers	No experience of providing or commissioning NHS care for patients with acute pancreatitis in primary or secondary care settings
	<16 years of age

14.3 Identification and registration

People who expressed an interest in participation in prior WP will receive an email invite to register for the workshop. As we aim to have balance between patients and other groups, we will ask people to indicate which of these groups they fall into on registration. We will invite the first 15 from each group to participate, providing the PIS and meeting information. Potential participants will be contacted again to address any questions they have about the study. Should they wish to proceed, they will be confirmed as attending and sent a link to complete a digital ICF.

Where potential participants decline or are unable to attend, we will invite the next person in order of expression of interest until we are quorate (minimum 20 participants).

14.4 Study Schedule and follow-up

This reflective focus group will be based around Rolfe's Co-reflective model 'What?, So What?, Now What?'. This has been used successfully in previous NIHR-funded studies on surgical conditions[41, 42]. The focus group will take place in a non-clinical location. It will run for 4-5 hours, depending on the type of information discussed.

(i) What: An overview of findings from the study will be presented to all participants over approximately one hour. The findings will be broken down into topics (i.e., unplanned service use, adaptations to diet, mental health impact). Participants will be asked to reflect on these findings and how they relate to each other.

(ii) So What: Participants will be split into groups reflecting on each of the domains. Each group will have a clinician facilitator, and a non-clinical member of the research team. The participants in breakout sessions will be balanced across different stakeholder groups to ensure voices from patients, clinicians, and commissioners, can be heard equally. Facilitators will ensure each stakeholder has an opportunity to speak. Participants will be given 30-45 minutes to discuss the impact or relevance of

findings on patient care, experience, and outcomes. These discussions will seek context for each point raised.

(iii) Now What: In the next phase, participants will be asked to propose interventions to support post-discharge care, specifying what, when, and for whom. For example, patient-initiated follow-up for 3 months for those at high risk of readmission.

Field notes will be made during the study to support discussion and consolidation of findings.

This approach will allow us to make clear recommendations for post-discharge care after AP. Recommendations may include those relevant to practice, and others relevant to research.

14.5 Statistical considerations

No formal sample size is mandated for this type of activity. Based upon previous experience, we believe a sample of 20-30 participants is required. We will aim for 50% of participants to be patients.

14.6 Analysis

Field notes will be transcribed into tables on each theme, using columns of 'what, so what, and now what'. Recommendations for pathway modifications will be assessed using the APEASE criteria (Acceptability, Practicability, Effectiveness, Affordability, Side-effects, Equity)[46]. In this, each intervention or pathway is considered across these domains, and rated as 'low risk', 'moderate risk', or 'high risk'.

15 PRINCIPLES OF CONSENT

It is the responsibility of the Principal Investigator (PI) to ensure written informed consent for each participant is obtained prior to enrolment in Work Package 4 of the PANORAMA Study. Consent can be delegated by the PI to other members of the local research team, if local practice allows and this responsibility has been documented in the PANORAMA site signature and delegation log.

The participant will acknowledge that they understand that their email address will be shared with the project management team at BiCOPS to facilitate distribution of PROMs.

Patients and carers self-consent to participate in Work Package 2 by completion of an online ICF, the link for which will be shared when they are selected for interview. Similarly, clinicians will self-consent into Work Package 3 as will all participants attending the workshop in Work Package 5.

Informed consent is a continuous and dynamic process and participants will be made aware from the beginning of their involvement in the study, that they can freely withdraw at any time. Continued consent will be assumed by the completion and return of the questionnaires at each time point. Participants are given details on how to withdraw from the study at any point in the PIS. If a participant decides that they do not wish to continue their participation in the PANORAMA Study, they may withdraw in one of two ways:

No study related follow-up: The participant does not wish to complete patient-reported study-specific follow-up (i.e. patient reported outcomes and QoL measures) but is willing for routinely collected data

to be used for inclusion in the study and, if applicable, using any central UK NHS bodies for long-term outcomes.

No further data collection: The participant is not willing to be followed up in any way for the purposes of the study AND does not wish for any further data to be collected (i.e., only data collected prior to withdrawal can be used in the study analysis)

No other parties outside of the study team will be informed of the participant's entry into the study unless otherwise stated in this protocol.

16 SAFETY CONSIDERATIONS

PANORAMA is based around standard care with no clinical intervention. For this reason, there are no safety considerations relating to interventions in the study. There is no anticipated risk of harm to either participants or investigators .

In WP4 patients are asked to complete Patient Health Questionnaire 9 on depression. If a patient indicates they have thought about harming themselves for at least half the time (option three or four in PHQ-9), separate emails will be automatically sent to the patient signposting sources of help and to their GP, advising need for further assessment and to trigger local safeguarding procedures.

In WP4, GAD-7 and PHQ-9 scores will be calculated at the end of a patient's follow-up period. Should a participant exceed the threshold suggesting they need further assessment, we will contact them using provided contact details to advise seeking further assessment from general practice or from primary care mental health services. A separate email will be sent to their GP advising the need for further assessment and to trigger local safeguarding procedures.

17 ASSESSMENT AND MANAGEMENT OF RISK

We do not anticipate that the study will involve significant risk or burden for participants. However, during the course of the interviews there is the potential for participants to discuss sensitive, emotive and upsetting issues. The relevant patient support charities will be signposted (eg GUTS!UK) by the qualitative researcher during the interviews. The interviews will be conducted in a sensitive manner and if participants become or appear distressed then the interview will be paused to ensure that the participant is able to continue and to check whether they are happy to continue. The qualitative researcher will have access to the CI and research team to discuss any issues that may arise from the interviews. If during the study participants are identified as being at risk of harm to themselves or others then local safeguarding procedures will be followed and their healthcare team will be informed, participants will be informed that confidentiality will need to be breached in order to do so.

Risk in WP4 will be as highlighted in the Safety Considerations (section 16) above.

18 ETHICAL AND REGULATORY CONSIDERATIONS

The study will be conducted in accordance with the UK Policy Framework for Health and Social Care Research and applicable UK Acts of Parliament and Statutory Instruments (and relevant subsequent amendments), which include Data Protection Act 2018 and the Principles of GCP as set out in the UK Statutory Instrument (2004/1031; and subsequent amendments).

It is the responsibility of the PI to ensure that all subsequent amendments gain the necessary local approval. This does not affect the individual clinicians' responsibility to take immediate action if thought necessary to protect the health and interest of individual participants.

18.1 Co-enrolment

Co-enrolment in other observational studies is permitted.

Possible inclusion in any interventional study should be discussed with the PANORAMA Study Office prior to inclusion.

18.2 Measures taken to avoid bias

The study has been designed to ensure representation of key stakeholders in WP1 & 5. Recruitment strategies for all WP have been designed to ensure people can access the study from different settings. Recruitment to WP4 will be across a broad geographic network, ensuring a range of people can participate. Efforts are being made to ensure that ability to read or speak English are not barriers in WP2 and 4 by development of materials in additional languages.

18.3 Research ethics committee (REC) and other regulatory review & reports

Before the start of the study, a favourable opinion will be sought from an NHS REC for the study protocol, informed consent forms and other relevant patient-facing documents.

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC and sponsor of the end of the study.
- An annual progress update will be submitted to the sponsor within 30 days of the anniversary date on which the study was approved, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC and sponsor, including the reasons for the premature termination.
- Within one year after of the end of the study being declared, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC and sponsor.

18.4 Regulatory review and compliance

Before any site can enrol patients into the study, the Chief Investigator will ensure that appropriate approvals each site are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study, the Chief Investigator, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

18.5 Amendments

The Chief Investigator will be responsible for making any final decisions on whether an amendment to the protocol is necessary and the sponsor will determine whether the amendment is substantial or non-substantial by following HRA guidance (<http://www.hra.nhs.uk/resources/after-you-apply/amendments/>). The Chief Investigator will be responsible for communicating protocol amendments to the REC and any other relevant regulatory agencies.

Protocol amendments will be recorded in Section 1 of this document.

18.6 Peer review

This study has undergone peer review as part of funding by the National Institute for Health and Care Research Health Service and Delivery Research Programme.

18.7 Patient & Public Involvement

This work has been stimulated by discussions with patient participants in the James Lind Alliance PSP on pancreatitis. We have worked with this group to understand the priorities and challenges they face post discharge. Two lay co-applicants are in the study management group. They will be involved in the development of patient facing materials, including the videos created for study recruitment. They will provide input into analysis at all stages, including patient interviews. We will support our co-applicants to present patient perspectives on findings at key stakeholder meetings. More widely, patients are at the heart of this piece of research. They can register an interest in hearing more about the study from WP1. This will help to engage a broad cross section of society as the study develops. As we progress to WP5, this group will be helpful to ensure we propose interventions with broad relevance and importance. We will ensure lay accessible summaries of research findings are available online, including in video format.

19 DATA HANDLING AND RECORD KEEPING

19.1 Source data

For WP1, source data is defined as the survey findings, entered directly into REDCap.

For WP2 & 3, source data is defined as interview recording and transcription of interviews.

For WP4, source data is defined as all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical study necessary for the reconstruction and evaluation of the study.

For WP5 field notes are the source data.

Source data within the PANORAMA study will be kept as part of the participants' medical notes generated and maintained at site.

Most of the follow-up within the PANORMA study is via patient-reported questionnaires; these are validated quality of life/patient reported outcome measures. This data is collected electronically and inputted directly by the participants onto the PANORMA REDCap database. The data inputted onto the PANORMA REDCap database forms the source data.

19.2 Data collection and management processes

WP1: Data collection is completed by participants onto a REDCap survey. Results will be transferred as free text into an NVivo project for analysis. This will be stored on the University of Birmingham servers.

WP2 & 3: Interviews will be audio-recorded via the relevant video conferencing software, or via an encrypted audio recorder for interviews carried out by telephone and stored in an encrypted format, with the naming convention using the unique identification number. University of Birmingham accounts will be used for any interviews taking place via Zoom or Teams. Interviews that take place via video conferencing software will be audio recorded only, no video will be recorded. University of Birmingham IT guidance will be followed for all audio recording. Audio recordings from both video conferencing or telephone interviews will be transferred to University of Birmingham servers within two hours of the interview, and will then be deleted from the original recorder. The recordings will be transcribed clean verbatim.

WP4: Baseline data collection will be completed by local research teams. Follow-up post discharge will be completed by patients following contact via email or other method to trigger survey completion. These contacts are at 7 days, 28 days, 3 months, and 6 months post-discharge.

WP5: Data collection will be in field notes collated by the research team. This will be anonymised but may contain verbatim quotes.

19.3 Clinical data

Clinical data will be entered into a bespoke REDCap database by those delegated that duty on the PANORAMA Study Delegation Log. It remains the responsibility of the local PI to ensure the accuracy of all data entered by their site and therefore access to the PANORAMA REDCap database will be restricted (via the use of individual logins) to those entering data and to the PI to ensure oversight.

The PANORAMA Study database employs conditional logic to ensure that only relevant questions are asked. A response is therefore mandatory for all questions. Data entry will be sanitised using automatic range checks on continuous variables and enforcement of temporal fidelity to the patient pathway. Manual checks detailed in the PANORMA Data Validation Plan will be undertaken on all records.

Sites will be instructed during site initiation on the correct procedure should source data be missing or otherwise unavailable. Queries and requests for missing clinical data will be raised using the inbuilt REDCap data resolution workflow (DRW), with the expectation of response within 30 days. If a satisfactory response is not received following 3 reminders, the matter will be escalated to the PI.

Full details of the automated and manual data accuracy checks performed will be specified in the Data Validation Plan

19.4 Patient reported outcomes

At the time of consent and entry into PANORAMA WP4, what the study involves will be discussed with each participant. It will be explained that completion of quality-of-life questionnaires will be requested at baseline and at 7 days, 28 days, 3 months, and six months post-discharge, and the methods of completion of the questionnaires discussed.

Patients will receive automated reminders, via the patient's preferred method of communication (SMS or email) to prompt them to complete validated questionnaires at the timepoints specified. Three reminders will be sent to any participant not completing the questionnaires one day after the initial request was made. After this time, unreturned forms will be regarded as missing and will not be requested again. Patient completed questionnaires will not be queried. Where patients have expressed a preference to complete questionnaires on paper, these will sent by the central research team via post with a freepost return envelope included.

19.5 Archiving

It is the responsibility of the PI to ensure all essential study documentation and source documents (e.g., signed ICFs, Investigator Site Files, participants' hospital notes,) at their site are securely retained for the contractual period. Archiving will be authorised by the BiCOPS project manager following submission of the end of study report. No documents should be destroyed without prior approval from the BiCOPS project management team.

The electronic SMF will be stored at BiCOPS for at least 3 years after the end of the study. Long-term offsite data archiving facilities will be considered for storage after this time; data will be stored securely and confidentially as detailed in Table 2.

20 QUALITY CONTROL AND QUALITY ASSURANCE

20.1 Site set-up and initiation

All PIs will be required to sign the necessary agreements and supply the BiCOPS project management team (on behalf of the Sponsor) a Site Signature and Delegation log and a current CV and GCP certificate. All members of the site research team are required to sign the Site Signature and Delegation Log, which details which tasks have been delegated to them by the PI. The Site Signature and Delegation Log should be kept up to date by the PI. It is the PI's responsibility to inform the Study Office of any changes in the site research team.

Prior to commencing recruitment, each recruiting site will undergo a process of site initiation, either a meeting or a teleconference, at which key members of the site research team are required to attend covering aspects of the study design, protocol procedures, collection and reporting of data and record keeping. Sites will be provided with an electronic ISF containing essential documentation, instructions, and other documentation required for the conduct of the study.

20.2 Local PI role

In WP4, PANORAMA anticipates that a surgeon will be the local Principal investigator, however any doctor, nurse or allied health professional who has appropriate GCP training and is able to accept the responsibilities of a PI at site is eligible for the role.

21 API SCHEME

PANORAMA will be registered for, and all sites will be encouraged to participate in the NIHR Associate Principal Investigator (API) Scheme. The national scheme is open to junior doctors, nurses and allied health professionals and aims to help them become the PIs of the future. <https://www.nihr.ac.uk/health-and-care-professionals/career-development/associate-principal-investigator-scheme.htm>

22 MONITORING

The central monitoring requirements for this study have been developed in conjunction with the study specific risk assessment.

The PANORAMA Study Office will check electronically received ICFs and data collection forms for compliance with the protocol, data consistency, missing data and timing at a frequency and intensity determined by the Data Management Plan. Sites will be notified of missing and potentially erroneous data via email with the expectation that issues be addressed through REDCap's data resolution workflow within 30 days.

The University of Birmingham clinical research compliance team (CRCT) may conduct study support visits in accordance with the UoB SOPs

23 AUDIT AND INSPECTION

The Investigator will permit study-related monitoring, audits, ethical review, and regulatory inspection(s) at their site and provide direct access to source data/documents. The investigator will comply with these visits and any required follow-up. Sites are also requested to notify the Study Office of any relevant inspections or local audits.

24 NOTIFICATION OF SERIOUS BREACHES

The sponsor is responsible for notifying the REC of any serious breach of the conditions and principles of GCP in connection with the study or of the protocol relating to the study. Sites are therefore requested to notify the PANORAMA Study Office of any suspected study-related serious breach of GCP and/or the study protocol as soon as they become aware of them using a deviation form to document the circumstance and nature of the breach. A member of the PANORAMA central research team at BiCOPS will review the submission in accordance with the deviation management plan.

Where the PANORAMA Study Office is investigating whether or not a serious breach has occurred, sites are also requested to co-operate with the Study Office in providing sufficient information to report the breach to the REC where required and in undertaking any corrective and/or preventive

action detailed in the CAPA. Sites may be suspended from further recruitment in the event of serious and persistent non-compliance with the protocol and/or GCP, and/or poor recruitment.

25 END OF STUDY DEFINITION

The end of study will be once all data has been captured, queries resolved and analysed from WP1-5.

The PANORAMA Study Office will notify the REC and the Sponsor within 90 days of the end of study.

The PANORAMA Study Office will provide the REC and the Sponsor with a summary report of the study.

26 STUDY ORGANISATIONAL STRUCTURE

26.1 Sponsor

The Sponsor for this study is the University of Birmingham

26.2 Coordinating centre

The study coordinating centre (Study Office) is located in the Birmingham Centre for Observational and Prospective Studies (BiCOPS), based at UoB.

26.3 Study Management Group

The Study Management Group (SMG) comprises individuals responsible for the day-to-day management of the study: the CI, BiCOPS director, and study manager. The role of the group is to monitor all aspects of the conduct and progress of the study, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the study itself. The SMG will meet at least bimonthly.

26.4 Oversight group

An independent oversight group will be appointed to provide independent oversight of the study. They will meet four-monthly during the study. Members are listed at the front of the protocol.

26.5 Impact and Implementation Board

In addition to the oversight committee, an impact and implementation board will be appointed to support translation of findings into clinical practice. Members are presented below:

Name & Role	Institution
Prof Natalie Blencowe, Professor of Surgery & Honorary Emergency General Surgeon. Surgical Specialty Lead for Emergency General Surgery	University of Bristol

Mr Samir Pathak, Consultant Pancreatic Surgeon and Surgical Specialty Lead for Pancreas surgery	Leeds Teaching Hospitals NHS Trust
Dr Barbara King, General Practice Acute Pathways ICB Lead	Birmingham and Solihull Integrated Care Board
Helen West, PPIE officer	Guts UK Charity, London

The committee will meet regularly during the study to discuss findings, and how these might be implemented into patient care.

27 FINANCE

The research costs of the study are funded by the NIHR HS&DR programme, awarded to Matthew Lee at the University of Birmingham. PANORAMA is an observational study involving no deviation from standard care pathways, therefore no excess treatment costs will be incurred.

28 DATA PROTECTION AND CONFIDENTIALITY

The University of Birmingham has policies designed to protect the security, accuracy, integrity and confidentiality of personal data, based on ISO 27001. The study will be registered with the Data Protection Officer at UoB and will hold data in accordance with the Data Protection Act 2018 (and subsequent amendments). Personal data categories that will be collected and analysed include name, date of birth, email address, health information and medical history. The PANORAMA Study Office has arrangements in place for the secure storage and processing of the study data which comply with UoB policies. These include:

- *Physical security measures.* Restricted access to the building, supervised onsite repairs and storages of back-up tapes/disks are stored in a fire-proof safe.
- *Access control and privilege management.* Access to the REDCap database is via individual, password protected accounts with two-factor authentication. Passwords are not stored as plain text but first salted and then hashed using a SHA-512 cryptographic hash function before being stored in the database table, each user account has its own unique salt value. Accounts are disabled after 5 failed login attempts and suspend after a specified period of inactivity. REDCap has an in-built audit trail that automatically logs user activity. Data transfer is a negotiated process between the sending and receiving servers, but will use the most secure version of SSL (secure shell layer) supported by both parties. At rest data is not encrypted, but is stored behind the University of Birmingham firewall.
- *System and Network security measures.* Routine and security updates to REDCap are assessed and implemented by UoB IT services, servers are behind the UoB site firewall. Audio recordings of interviews and transcripts will be held on the UoB Network.
- *Staff security measures.* The PANORAMA REDCap database will be developed and maintained by members of BiCOPS. As employees of the University of Birmingham they are required to follow local guidance on IT Security and Data Protection and attend annual training on Data

Protection and Information Governance. All BiCOPS employees complete GCP training biannually.

- All transcriptions will be anonymised with any identifying information about participants being removed. Transcription will be performed by an approved secretarial service, with a confidentiality agreement in place, and files will be encrypted before transfer. Recordings will be permanently deleted at the end of the study. If a study participant wishes to withdraw after they have been interviewed then their data will be kept and used in the analysis. Anyone who wishes to withdraw before the interview has taken place will have their data deleted. Prior to the start of the interview some background data for participants will be collected such as gender, ethnicity, which will be stored securely on RedCap.

In the case of specific issues and/or queries from the regulatory authorities, it will be necessary to have access to the complete study records. Representatives of the PANORAMA study team and sponsor may be required to have access to medical notes for quality assurance purposes, but participants should be reassured that their confidentiality will be respected at all times. The PANORAMA Study Office will maintain the confidentiality of all participant data and will not disclose information by which participants may be identified to any third party.

28.1 Data retention

In compliance with good clinical practice guidelines, the Chief Investigator will maintain all records and documents regarding the conduct of the study. Research data will be retained for 10 years or longer if necessary. The CI will act as data custodian. Relevant data and retention periods are presented in Table 2, below.

Table 2: Retained data and data retention periods for the datasets generated by PANORAMA

Work package	Data	Retention period
WP1	Survey responses	10 years
WP1	Email address	Until end of study
WP2	Self-register of interest (including email)	Until end of study
WP2	Interview recordings	10 years
WP2	Interview transcripts	10 years
WP3	Self-register of interest (including email)	Until end of study
WP3	Interview recordings	10 years
WP3	Interview transcripts	10 years

WP4	Cohort study data	10 years
WP4	Email/ contact details for participants	Until end of study
WP5	Self-register of interest (including email)	Until end of study
WP5	Field notes from meeting	10 years

29 FINANCIAL AND OTHER COMPETING INTERESTS

There are no financial or other competing interests related to the results of this study. Authors are similarly required to provide declarations at the time of submission to publishers.

30 INSURANCE AND INDEMNITY

The University of Birmingham has in place Clinical Trials indemnity coverage for UK sites for this study which provides cover to the University for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the study.

The risk of the study is no greater than the risk of the standard clinical care. Responsibility for the participants at sites remains with the organisation responsible for the clinical site and it is therefore indemnified through their normal arrangements.

With respect to the conduct of the study at site and other clinical care of the patients, responsibility for their care remains with the NHS organisation responsible for the Clinical Site and is therefore indemnified through the NHS Litigation Authority.

31 ACCESS TO FINAL DATASET

Requests for data generated during this study will be considered by BiCOPS. Data will typically be available after the primary publication of PANORAMA.

Only scientifically sound proposals from appropriately qualified research groups will be considered for data sharing. The request will be reviewed by BiCOPS in discussion with the CI and, where appropriate (or in absence of the CI) any of the following: the study sponsor or the SMG.

A formal Data Sharing Agreement (DSA) may be required between respective organisations once release of the data is approved and before data can be released. Data will be fully de-identified (anonymised).

32 PUBLICATION PLAN

A meeting will be held after the end of the study to allow discussion of the main results among the collaborators prior to publication. Results of the study will be submitted for publication in a peer reviewed journal. Manuscripts will be prepared by the SMG.

The success of the study depends on the collaboration of a large number of collaborators, for this reason the authorship will follow a corporate authorship policy. All investigators will be listed as collaborating authors under a single corporate author group; “The PANORAMA Collaborative Group”

Authors will be listed as per their involvement with each part of the study: there will be a writing group, study management group, and a list of collaborators. Collaborators will include site principal investigators, co-investigators and associate principal investigators, each grouped according to their role in the study.

In all publications, authors should acknowledge that the study was performed with the support of the NIHR HS&DR programme, and BiCOPS and credit the use of REDCap electronic data capture platform.

33 REFERENCE LIST

1. Context | pancreatitis | guidance | NICE
2. Forsmark CE, Vege SS, Wilcox CM (2016) Acute pancreatitis. *N Engl J Med* 375:1972–1981
3. PANC Study Collaborative (2023) PANC Study (Pancreatitis: A National Cohort Study): national cohort study examining the first 30 days from presentation of acute pancreatitis in the UK. *BJS Open* 7:. <https://doi.org/10.1093/bjsopen/zrad008>
4. Hollemans RA, Hallensleben NDL, Mager DJ, et al (2018) Pancreatic exocrine insufficiency following acute pancreatitis: Systematic review and study level meta-analysis. *Pancreatology* 18:253–262
5. Hart PA, Bellin MD, Andersen DK, et al (2016) Type 3c (pancreatogenic) diabetes mellitus secondary to chronic pancreatitis and pancreatic cancer. *Lancet Gastroenterol Hepatol* 1:226–237
6. Chen C, Zhou Y, Wang D, et al (2023) Anxiety, depression, and coping styles among patients with chronic pancreatitis in East China. *BMC Psychiatry* 23:. <https://doi.org/10.1186/s12888-023-04691-2>
7. Ma S, Yang X, He H, et al (2022) Psychological experience of inpatients with acute pancreatitis: a qualitative study. *BMJ Open* 12:e060107
8. Multiple Long-Term Conditions (Multimorbidity): a priority for global health research. <https://acmedsci.ac.uk/policy/policy-projects/multimorbidity>. Accessed 1 Oct 2024
9. da Costa DW, Bouwense SA, Schepers NJ, et al (2015) Same-admission versus interval cholecystectomy for mild gallstone pancreatitis (PONCHO): a multicentre randomised controlled trial. *Lancet* 386:1261–1268
10. Adeniran E, Yadav D, Pandol SJ, et al (2024) Intense and sustained alcohol consumption associated with acute pancreatitis warrants early intervention. *Gastro Hep Adv* 3:61–63
11. Fone DL, Farewell DM, White J, et al (2013) Socioeconomic patterning of excess alcohol consumption and binge drinking: a cross-sectional study of multilevel associations with neighbourhood deprivation. *BMJ Open* 3:e002337
12. Simpson RM, Knowles E, O’Cathain A (2020) Health literacy levels of British adults: a cross-sectional survey using two domains of the Health Literacy Questionnaire (HLQ). *BMC Public Health* 20:1819
13. Giorga A, Hughes M, Parker S, et al (2023) Quality of life after severe acute pancreatitis: systematic review. *BJS Open* 7:. <https://doi.org/10.1093/bjsopen/zrad067>
14. Mitra V, Munnelly S, Grammatikopoulos T, et al (2023) The top 10 research priorities for pancreatitis: findings from a James Lind Alliance priority setting partnership. *Lancet Gastroenterol Hepatol* 8:780–782
15. NIHR strategic framework for multiple long-term conditions (multimorbidity) MLTC-M research. <https://www.nihr.ac.uk/documents/nihr-strategic-framework-for-multiple-long-term-conditions-multimorbidity-mltc-m-research/24639>. Accessed 2 June 2024

16. Goodger R, Singaram K, Petrov MS (2021) Prevalence of chronic metabolic comorbidities in acute pancreatitis and its impact on early gastrointestinal symptoms during hospitalization: A prospective cohort study. *Biomed Hub* 6:111–117
17. Roberts SE, Akbari A, Thorne K, et al (2013) The incidence of acute pancreatitis: impact of social deprivation, alcohol consumption, seasonal and demographic factors. *Aliment Pharmacol Ther* 38:539–548
18. Forsmark CE, Swaroop Vege S, Wilcox CM (2016) Acute pancreatitis. *N Engl J Med* 375:1972–1981
19. Liu J, Zhang B (2020) The lived experience of inpatients with acute recurrent pancreatitis. *Gastroenterol Nurs* 43:249–257
20. Chen R, Wang Q, Wang D, et al (2023) Post-healing perceptions and experiences of alcohol withdrawal and life management in men with alcoholic pancreatitis: a qualitative study. *Front Psychol* 14:. <https://doi.org/10.3389/fpsyg.2023.1192835>
21. Kamarajah SK, Gopalan V, Khan Z, et al (2025) Gaps and uncertainties in the management of acute pancreatitis: a scoping review and quality assessment of clinical practice guidelines. *EClinicalMedicine* 103216
22. Forsmark CE, Baillie J (2007) AGA institute technical review on acute pancreatitis. *Gastroenterology* 132:2022–2044
23. Bogan BD, McGuire SP, Maatman TK (2022) Readmission in acute pancreatitis: Etiology, risk factors, and opportunities for improvement. *Surg Open Sci* 10:232–237
24. Hennink M, Kaiser BN (2022) Sample sizes for saturation in qualitative research: A systematic review of empirical tests. *Soc Sci Med* 292:114523
25. Braun V, Clarke V (2021) *Thematic analysis*. SAGE Publications, London, England
26. Bradshaw J (1972) *Problems and progress in medical care: essays on current research*. 7th series. In: McLachlan G (ed) Nuffield Provincial Hospital Trust
27. Saunders B, Sim J, Kingstone T, et al (2018) Saturation in qualitative research: exploring its conceptualization and operationalization. *Qual Quant* 52:1893–1907
28. Harris PA, Taylor R, Thielke R, et al (2009) Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 42:377–381
29. (2009) Research electronic data capture (REDCap)-A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 42:377–381
30. Herdman M, Gudex C, Lloyd A, et al (2011) Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 20:1727–1736
31. Arroll B, Goodyear-Smith F, Crengle S, et al (2010) Validation of PHQ-2 and PHQ-9 to screen for major depression in the primary care population. *Ann Fam Med* 8:348–353

32. Spitzer RL, Kroenke K, Williams JBW, Löwe B (2006) A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 166:1092–1097
33. (2017) Qualitative Assessment of the Symptoms and Impact of Pancreatic Exocrine Insufficiency (PEI) to Inform the Development of a Patient-Reported Outcome (PRO) Instrument. The patient. Pancreatology 10:182–190
34. Riley RD, Ensor J, Snell KIE, et al (2020) Calculating the sample size required for developing a clinical prediction model. BMJ 368:m441
35. Toussaint A, Hüsing P, Gumz A, et al (2020) Sensitivity to change and minimal clinically important difference of the 7-item Generalized Anxiety Disorder Questionnaire (GAD-7). J Affect Disord 265:395–401
36. Löwe B, Unützer J, Callahan CM, et al (2004) Monitoring depression treatment outcomes with the patient health questionnaire-9. Med Care 42:1194–1201
37. Introduction to health technology evaluation | NICE health technology evaluations: the manual | Guidance | NICE
38. England NHS NHS England » 2021/22 national cost collection data publication. <https://www.england.nhs.uk/publication/2021-22-national-cost-collection-data-publication/>. Accessed 1 Oct 2024
39. Jones KC, Weatherly H, Birch S, et al (2024) Unit Costs of health and Social Care 2023 manual. 113
40. BNF content published by NICE. <https://bnf.nice.org.uk/>. Accessed 1 Oct 2024
41. Coates E, Wickramasekera N, Barr A, et al (2022) Patient preferences and current practice for adults with steroid-resistant ulcerative colitis: POPSTER mixed-methods study. Health Technol Assess 26:1–118
42. Brown S, Hind D, Strong E, et al (2024) Treatment options for patients with pilonidal sinus disease: PITSTOP, a mixed-methods evaluation. Health Technol Assess 28:1–113