Study Protocol

A multicentre prospective cohort study into the early management of acute pancreatitis in Great Britain and Ireland: PANC Study (Pancreatitis: A National Cohort Study)

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ABSTRACT

Introduction

Acute pancreatitis is a common, yet complex, emergency surgical presentation, with an incidence of approximately 56 cases per 100,000 people per year in the UK. The management of pancreatitis can vary significantly between different regions, hospitals or clinicians despite a number of national and international guidelines. Historic regional studies in Great Britain and Ireland have shown management to be suboptimal with regards to time to diagnosis, access to higher dependency care or CT for severe cases and time to definitive treatment of gallstones.

Aim

We aim to assess current variation in practice in the management of patients diagnosed with early acute pancreatitis. This will identify areas for future research need, and give the groundwork for a potential future model of ambulatory care in a select subgroup of patients.

Study design

Pancreatitis: A National Cohort Study (PANC Study) is a multicentre, prospective cohort audit which will be conducted through Great Britain and Ireland in Spring 2021. All patients ≥18 years, presenting with a diagnosis of acute pancreatitis by modified Atlanta classification, will be included during the 2-month collection period. Data will only be collected for the first 30-days from presentation. The data collected will include patient demographics, admission observations and investigations, aetiology, management and complications, and will be anonymised and uploaded onto an online platform for analysis.

Conclusions

Management of pancreatitis has not been previously assessed nationally in Great Britain and Ireland. Obtaining data on population characteristics, management choices and patient outcomes will allow for resource planning so that the service provision reflects local and national population needs.
Introduction

Acute pancreatitis is a common, yet complex, emergency surgical presentation with an incidence of approximately 56 cases per 100,000 people per year in the UK\(^{(1)}\). Most cases are mild and self-limiting and are managed under general surgical teams without input from a designated hepatopancreatobiliary (HPB) service. The practices around the management of pancreatitis can vary significantly between different regions, hospitals or clinicians. There have been a number of guidelines issued by several different international bodies over the last decade\(^{(1,2,3,4)}\). Due to the management of acute pancreatitis being primarily supportive, the criteria by which severity of pancreatitis is assessed have altered, with the focus shifting to the need for additional organ support rather than the degree of pancreatic necrosis.

Acute pancreatitis is by its nature, very complex. It is caused by a wide range of varied aetiologies, it affects patients in different ways causing mild symptoms in some or resulting in death in others. It has challenges with respect to fluid management, nutrition, the management of pancreatic necrosis, and frequently leads to organ failure and can require ITU support. Once recovered, patients need to have modifiable aetiologies such as gallstones managed, and may be at risk of developing (or exacerbating existing) diabetes or exocrine failure.

Variation in practice has not been assessed nationally in Great Britain and Ireland before. Previous regional or centre-based studies have shown that when compared to evidence-based guidelines, the management of acute pancreatitis is at times suboptimal in terms of the time taken to reach the diagnosis, access to or utilisation of high dependency care or dynamic CT in severe cases, ERCP availability and when applicable, time to cholecystectomy\(^{(5)}\).

A national multi-centre prospective audit to assess current practices is the first step in helping to guide resource planning to provide streamlined care and identifying areas in which care can be improved thereby reducing morbidity and mortality.
Current Guidelines

Guidelines to direct the best management of patients with acute pancreatitis have been published by several different groups. In 2005, UK specific guidelines were produced which outlined clear audit standards, but this guidance has not been updated for modern practice\(^6\). The NCEPOD report *Acute Pancreatitis: Treat the Cause* was released in 2016, and gave recommendations which included early cholecystectomy, establishment of pancreatitis networks and the use of early warning scores\(^7\). NICE produced their first guidance on acute pancreatitis 2018, and although it does give some broad recommendations, many areas such as pain management and timing of cholecystectomy have not been addressed\(^1\). Therefore, there is currently no single clear UK based set of recommendations, although many themes overlap between each publication.

In the international arena, the IAP/APA guidelines published in 2013 provide a stronger evidence base for their recommendations, and are much more in depth than those published in the UK\(^4\). We have therefore extracted a combination of audit standards from all four documents, and tried to find the common themes where possible, against which to assess current practice in Great Britain and Ireland (Table 1).
Aims

1. To describe variation in the management of early acute pancreatitis and deviation from evidence based standards in the 30 days following index admission.

2. Assess current networks in Great Britain and Ireland between tertiary centres and surrounding hospitals, and how this impacts on patient care.

3. To identify barriers to early discharge of patients with mild pancreatitis allowing for formulation of protocols favouring shorter hospital stay and ambulatory pathways.

4. To define the incidence of mild, moderately-severe and severe acute pancreatitis in the population of Great Britain and Ireland compared with that quoted in literature.
Method

Study approach

The study comprises two components: a Site Specific Survey and a prospective cohort study. Hospitals will be recruited using trainee-led research collaboratives, and national organisations such as ASGBI, AUGIS and PSGBI. All hospitals in Great Britain and Ireland providing emergency surgery services will be eligible to participate.

Study group

Each acute hospital within each registered hospital will require a consultant to act as Principal Investigator, preferably the lead for pancreatitis if there is one nominated. They will supervise a team of up to three trainees or allied health care professionals who will collect and submit data over the two month data collection period, and from the subsequent 30-day follow up from date of admission.

Teams will be asked to register all participants before the start of the data collection period, including their name (as they would wish to be published), email address and ORCID ID via a Google Docs form, which will include completion of the Site Specific Survey. If there is more than one acute hospital within a trust admitting patients with acute pancreatitis, all hospitals would be encouraged to register separately, with a separate Site Specific Survey; the Principal Investigator can be the same or different at different hospitals within the same trust.

Audit Standards

Audit standards have varied from the various organisations releasing guidance. The main points have been drawn out in Table 1, summerising which standards can be assessed by this study.
**Audit standards**

**Table 1. Audit standards utilised for the purpose of this study**

<table>
<thead>
<tr>
<th>Standard</th>
<th>Measure</th>
<th>Expectation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis ((^4))</td>
<td>Aetiology to be determined within 24 hours of admission [using detailed personal and family history, examination, laboratory serum tests and/or imaging]</td>
<td>80%</td>
</tr>
<tr>
<td></td>
<td>In patients considered to have ‘idiopathic’ acute pancreatitis further imaging should be performed within 8 weeks [EUS, sMRCP, CT]</td>
<td>No measured</td>
</tr>
<tr>
<td>Prediction of severity</td>
<td>Systemic inflammatory response syndrome (SIRS) is advised to predict severe acute pancreatitis at admission and persistent SIRS at 48 hours. (recorded on admission and at 48h)((^4))</td>
<td>Not measured</td>
</tr>
<tr>
<td></td>
<td>All patients should have physiological parameters recorded as part of their initial assessment (such as National Early Warning Score (NEWS))((^7))</td>
<td>100%</td>
</tr>
<tr>
<td>Imaging((^4))</td>
<td>Appropriate timing of CT: a) early in diagnostic uncertainty b) planned 96h after onset of symptoms</td>
<td>95%</td>
</tr>
<tr>
<td>Fluid therapy((^4))</td>
<td>Resuscitation performed with Hartmann’s solution (recommended for initial fluid resuscitation in acute pancreatitis)</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>Goal directed intravenous fluid therapy with 5-10ml/kg/h should be used initially until resuscitation goals are reached</td>
<td>Not measured</td>
</tr>
</tbody>
</table>
| **Assessment of response to fluid resuscitation** | 1) non-invasive clinical targets of heart rate <120/min, mean arterial pressure between 65-85 mmHg (8.7e11.3 kPa), and urinary output > 0.5-1ml/kg/h, 
2) invasive clinical targets of stroke volume variation, and intrathoracic blood volume determination, and 
3) biochemical targets of hematocrit 35-44%. (one or more of the above) | Not measured |
|---|---|---|
| **Intensive care**<sup>(4, 9)</sup> | A patient diagnosed with acute pancreatitis and one or more of the following parameters identified at admission as should be transferred immediately to an intensive care setting: 
(1) pulse <40 or >150 beats/min; 
(2) systolic arterial pressure <80 mmHg (<10.7 kPa) or mean arterial pressure <60 mmHg (<8.0 kPa) or diastolic arterial pressure >120 mmHg (>16 kPa); 
(3) respiratory rate >35 breaths/min; 
(4) serum sodium <110 mmol/l or >170 mmol/l; 
(5) serum potassium <2.0 mmol/l or >7.0 mmol/l; 
(6) paO2 <50 mmHg (<6.7 kPa); 
(7) pH < 7.1 or >7.7; 
8) serum glucose >800 mg/dl or >44.4 mmol/L; 
(9) serum calcium > 15 mg/dl or >3.75 mmol/L; 
(10) anuria, or 
(11) coma<sup>(9)</sup> 
Furthermore, a patient with severe acute pancreatitis as defined by the revised Atlanta Classification should be treated in an intensive care setting.<sup>8</sup> | 100% |
<p>| <strong>Management in, or referral to, a specialist centre is necessary for patients with severe acute pancreatitis and for those who may need interventional radiologic, endoscopic, or surgical intervention.</strong> | 95% |
| <strong>Preventing infectious complications</strong>&lt;sup&gt;(1,4,9)&lt;/sup&gt; | Intravenous antibiotic prophylaxis is not recommended for the prevention of infectious complications in acute pancreatitis. | 100% |</p>
<table>
<thead>
<tr>
<th>Nutritional support(^{(4)})</th>
<th>Oral feeding in predicted mild pancreatitis can be restarted once abdominal pain is decreasing and inflammatory markers are improving. (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Enteral tube feeding should be the primary therapy in patients with predicted severe acute pancreatitis who require nutritional support within 72hrs.(^{(4)}) (95%)</td>
</tr>
<tr>
<td></td>
<td>Parenteral nutrition can be administered in acute pancreatitis as second-line therapy if nasojejunal tube feeding is not tolerated and nutritional support is required. (95%)</td>
</tr>
<tr>
<td>Biliary tract management(^{(4)})</td>
<td>Urgent ERCP (&lt;24 hrs) is required in patients with acute cholangitis. (\text{Not measured})</td>
</tr>
<tr>
<td></td>
<td>ERCP is probably indicated in biliary pancreatitis with common bile duct obstruction.</td>
</tr>
<tr>
<td></td>
<td>ERCP is not indicated in predicted mild biliary pancreatitis without cholangitis.</td>
</tr>
<tr>
<td>Timing of cholecystectomy (or endoscopic sphincterotomy)(^{(4)})</td>
<td>Cholecystectomy during index admission for mild biliary pancreatitis (80%)</td>
</tr>
<tr>
<td></td>
<td>Delayed cholecystectomy for patients with peripancreatic collections - at 6 weeks (\text{Not measured})</td>
</tr>
<tr>
<td>Analgesia(^{(9,10)})</td>
<td>Potential benefit of NSAID use beyond pain control(^{(7)}) and seemingly underutilisation as suggested by NCEPOD(^{(8)})</td>
</tr>
<tr>
<td></td>
<td>Use of opioids - theoretical risks of exacerbation of pancreatitis by morphine, which can increase pressure in the sphincter of Oddi, but little evidence that this is clinically significant(^{(9)}) Referral to acute pain team if received analgesia considered inadequate by patient(^{(9)})</td>
</tr>
</tbody>
</table>
Local registration with audit department and Caldicott guardian

It will be the responsibility of the local research collaborative to obtain approval and register the study as a clinical audit or service evaluation. Permission must be obtained from the trust Caldicott guardian to allow transfer of the anonymised data out of the trust. Once study approval is obtained the hospital can be registered via Google Docs form (which includes the Site Specific Survey), and this will allow the generation of individual REDCap (Research Electronic Data Capture) logins for individual collaborators. The form can be found https://tinyurl.com/PANCSurvey

Research ethics approval is not required for this study and this has been confirmed by the use of the online National Research Ethics Service (NRES) decision tool (http://www.hra-decisiontools.org.uk/research/). Inclusion in this study will not have any effect upon an individual patient’s clinical pathway.

Site Specific Survey

This will be completed once for each participating site. The survey will assess local provisions of care and access to tertiary hepatopancreatobiliary (HPB) services. It will include factors such as hospital capacity, volume of referrals and availability of diagnostic and therapeutic modalities. For detailed information see Appendix 1. Appendix 2 states the definitions required to complete the site resource survey. This will need to be completed as part of the registration process for the study.

Prospective cohort study

All patients with the diagnosis of acute pancreatitis (as per the revised Atlanta criteria) admitted within a two month study period will be included. Data will be uploaded to the REDCap online platform hosted by University College London. The data collected will include patient demographics, admission observations and investigations, aetiology, management and discharge from hospital. A full list of data points can be found in Appendix 3. All data uploaded will be anonymised. No dates will be recorded for patients as this can be classed as an identifier in some trusts. Each participating centre will hold a spreadsheet
linking study identifiers to Hospital or NHS numbers to aid with follow up, future data queries and preventing duplication of records.

**Eligible patients**

Inclusion criteria:

- All patients over the age of 18 years of age admitted with acute pancreatitis as defined by meeting two or more of the following criteria:
  - abdominal pain suggestive of pancreatitis,
  - serum amylase or lipase level greater than three times the upper normal value or
  - characteristic imaging findings

Exclusion criteria:

- Patients transferred from another trust after their initial acute presentation

**Data collection**

Data collection will be undertaken using the online Research Electronic Data Capture (REDCap) platform. Patients presenting to emergency departments and surgical assessment units will be screened on a daily basis by the local teams. Eligible patients will be identified using the aforementioned inclusion criteria and followed up for 30 days from admission. The data collected will include patient demographics, history, assessment on admission and within the first 48 hours, investigations, aetiology, management, discharge from hospital and follow-up plans (Appendix 3). Clarification of the exact data points to be collected is available in Appendix 4.
Data management

Only anonymised data will be uploaded. Each participating centre will hold a spreadsheet linking study identifiers to Hospital or NHS numbers to aid with follow up and future data queries. It is the responsibility of the local collaborative group to ensure all patient identifiable data is held in accordance with local data protection guidance and is password protected. Collaborators will be asked to complete electronic record for each patient in a timely manner using source documents.

Data validation

Following completion of data collection, only data sets with >95% completeness will be accepted for analysis. Fulfilling this criteria will be required for authorship. Local Principal Investigators will identify an independent assessor for their site to validate the data; this person will review 10% of submitting patient files and 25% of data points within these submissions and they will be acknowledged for this work in future manuscripts. The overall responsibility for data completeness and accuracy will rest with the Principal Investigator for that institution.

Data analysis

The data analysis will be undertaken by the PANC Study Group. Once initial analysis has been undertaken and published, other parties can approach the study group to apply for access to the data for further analysis.
Proposed Study timeline

The proposed recruitment period will be the 1st March 2021 until the 30st April 2021, with information recorded on each patient over the 30 days following their initial admission. The planned last day for data lock on the database is the 30th June 2021.
Authorship

All collaborators will be acknowledged according to their input to the study. All collaborators who fulfil their responsibilities as described above will be recognised on any resulting publications as citable co-authors on PubMed. Manuscript preparation following data analysis will be undertaken by a writing committee. As explained, units that fail to submit data, or whose data is incomplete, or does not meet the standards of data accuracy will be excluded from the authorship list.

Dissemination

Local teams will retain access to their own data to facilitate local quality improvement. Results of the study will be reported at national and international scientific meetings, submitted to peer-reviewed publications and lead to national quality improvement initiatives.

Appendices

Appendix 1: Site specific survey
Appendix 2: Definitions and clarifications for site specific survey
Appendix 3: Data collection sheet
Appendix 4: Definitions and clarifications for site specific survey
Appendix 5: Acronyms and their definitions
Appendix 6: Rockwood Clinical Frailty Score
Appendix 1.

**Site Specific Survey**

**Hospital information**

1. Hospital name: _____________________

2. Trust name: _______________________

3. Type of hospital:
   - ○ Pancreatic resectional unit
   - ○ Other acute hospital
   - ○ Other

4. Number of ITU beds in hospital: ________

5. How many consultants cover the general on call rota? ________

6. How many of these consultants perform cholecystectomies as part of their practice? (Either elective or emergency): ________

7. Organisation of emergency general surgical services (select all that apply):
   - ○ No UGI or HPB services at this site
   - ○ Mixed General Surgical take
   - ○ Streamed surgical take

8. At your hospital do you have (tick all that apply):
   - ○ Dedicated UGI specialist on call (which would include pancreatitis patients)
   - ○ Dedicated separate pancreas specialist on call
   - ○ Neither

9. Can your hospital perform intraoperative imaging on patients undergoing an acute/urgent cholecystectomy if required (select multiple if required)?
   - ○ No
   - ○ Laparoscopic ultrasound: Routinely
   - ○ Laparoscopic ultrasound: Selectively
   - ○ Laparoscopic ultrasound: Rarely
   - ○ On table cholangiogram: Routinely
   - ○ On table cholangiogram: Selectively
   - ○ On table cholangiogram: With difficulty
   - ○ On table cholangiogram: Rarely
10. Does your hospital have ambulatory care facilities?
   ○ No
   ○ Monday to Friday (limited booked appointments)
   ○ Monday to Friday (triage all patient presenting during day)
   ○ 7 day service
   ○ Other ______________________

11. Do you use NEWS2 routinely in your hospital on acute surgical admissions?
   ○ Yes
   ○ No
   ○ Similar system but not NEWS2. Please specify ________________

Biochemical markers:
12. Which biochemical marker do you routinely use to diagnose pancreatitis? (tick all that apply)
   ○ Amylase
   ○ Lipase

13. Do you have access to (tick all that apply):
   ○ Amylase
   ○ Lipase
   ○ Urinary amylase

Radiological access:
14. Ultrasound access:
   ○ No access
   ○ Normally same day
   ○ Normally next day
   ○ Longer

   Weekend availability: (tick all that apply)
   ○ Routine access to USS Saturday
   ○ Routine access to USS Sunday

15. MRCP:
   ○ Routinely performed as inpatient
   ○ Outpatient only
   ○ No access

16. Do you have access to secretin MRCP (sMRCP)?
   ○ Yes
   ○ Occasionally but often difficulties in supply
   ○ No
17. CT 24-hour access?
   ○ Yes
   ○ No

18. EUS
   ○ Yes, at this trust, can be performed as an inpatient
   ○ Yes, at this trust, outpatient only
   ○ Yes, but at another trust
   ○ We do not access this service

19. Is your site recruiting to Sunflower RCT (use of pre-operative MRCP in cholecystectomy patients)
   ○ Yes
   ○ No
   ○ Plan for March - April 2021, but not currently open to recruitment.

**Definitive treatment pathways:**
20. Most common pathway from laparoscopic cholecystectomy
   ○ Emergency list
   ○ Dedicated same admission biliary list
   ○ Dedicated urgent (within 2 weeks) elective cholecystectomy list
   ○ Routine outpatient list
   ○ Number of dedicated urgent half day lists a week: ______

21. ERCP, inpatient access?
   ○ Yes, number of lists a week: ______
   ○ No

**Assessment of severity:**
22. Does your unit expect a formalised severity assessment for acute pancreatitis
   ○ Yes
   ○ No
   ○ Varies between clinicians

23. Which measures are normally used (tick all that apply)
   ○ Glasgow
   ○ APACHE II
   ○ Ranson
   ○ 48 hour CRP
   ○ Other (please specify): _______________________

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Management of complicated pancreatitis:

24. Interventional radiology access:
   ○ None
   ○ 9am - 5pm
   ○ Limited out of hours service
   ○ 24/7 on call service

25. Endoscopic treatments (EUS guided drainage/ luminal apposing metal stents):
   ○ No access
   ○ Good access through another trust
   ○ Done in house

26. Surgical treatments (tick all available at your trust):
   ○ Videoscopic assisted retroperitoneal debridement (VARD)
   ○ Transgastric necrosectomy
   ○ Laparoscopic necrosectomy
   ○ Open necrosectomy
   ○ None available at our hospital

Referral pathways:

27. Once admitted, are patients with acute pancreatitis most commonly
   ○ Kept under the admitting team
   ○ Referred to local specialist team in complex cases
   ○ Referred to local specialist team in all cases
   ○ Selective take, so admitted under specialists straight away

28. Is there a named lead for pancreatitis at the hospital?:
   ○ Yes
   ○ No
   ○ NA

29. Is there a nurse specialist available for support?:
   ○ Yes, at our hospital
   ○ Yes, access advice from another trust
   ○ No

30. If not a specialist centre, please state your local referral centre:
   ○ __________________
   ○ Unclear
   ○ NA
31. If not a specialist centre, how do you access the regional service?
   ○ Very rarely access regional services
   ○ Ad hoc pathway
   ○ Clear criteria for referral - please state: ________________________

32. Is there access to a pancreatitis MDT?:
   ○ Local
   ○ Regional
   ○ No

Patient information:
33. Do you have an information sheet available on acute pancreatitis?
   ○ Yes
   ○ No
   ○ In development

34. Is the information sheet routinely given to all admitted with acute pancreatitis?
   ○ Yes
   ○ No
   ○ Ad hoc
   ○ N/A

Normal practice for patients with first episode of presumed ‘idiopathic’ pancreatitis:
35. Follow up after discharge?
   ○ Yes
   ○ No
   ○ Ad hoc

36. Routine further investigations until cause identified (please tick all that apply)
   ○ Triglycerides
   ○ Calcium
   ○ IgG4
   ○ Repeat USS
   ○ MRCP
   ○ EUS
   ○ CT scan

37. Are you aware of any surgeons in your trust who undertake cholecystectomy in patients with idiopathic pancreatitis?
   ○ No
   ○ Yes after first episode and would consider without EUS
   ○ Yes after first episode, but only after EUS to exclude other causes
   ○ Yes after multiple episodes and would consider without EUS
   ○ Yes after multiple episodes, but only after EUS to exclude other causes
Definitions and clarifications for Site Specific Survey

Please note most questions are specifically about the hospital you are completing for, and not the trust.

1. Formal name from specific hospital.

2. Formal name from specific trust.

3. A pancreatic resectional unit is classed as any hospital undertaking elective pancreatic cancer resections as part of their routine work load.

4. Total number of ITU beds routinely available on site.

5. Number of different consultants: Does not need to equate to full time equivalents (FTE).

6. Number of different consultants: Does not need to equate to full time equivalents (FTE).

7. No UGI or HPB services at this site: General surgical take made up of purely colorectal consultants (or other generalists) with no input from UGI or HPB specialised consultants (either benign or resectional).

   Mixed General Surgical take: All patients admitted are placed under either UGI/HPB or colorectal. This is dependent on who is on call that day and is not affected by the underlying diagnosis.

   Streamed surgical take: Patients are directed to the appropriate subspecialty at the point of admission.

8. Dedicated UGI specialist on call (which would include pancreatitis patients): UGI specialist who would either have the patient admitted under them directly, or would be available for advice in difficult cases.

   Dedicated separate pancreas specialist on call: Pancreas specialist available to discuss difficult patients at the trust.

   Neither: No specialist advice available at the trust.
9. **Laparoscopic ultrasound**: Used to assess for the presence of bile duct stones intraoperatively.

   **Routinely**: Patients undergo this intraoperative bile duct imaging regardless of indication by the majority of surgeons performing laparoscopic cholecystectomy.

   **Selectively**: Patients undergo this intraoperative bile duct imaging dependent on indication and preoperative test results by the majority of surgeons performing laparoscopic cholecystectomy.

   **Rarely**: Patients can undergo this intraoperative bile duct imaging at this hospital but it is not a part of routine practice (only done in exceptional cases, or by a small percentage of surgeons).

10. **Ambulatory care**: Defined as ‘the investigation, care and treatment of patients for whom in the absence of an Ambulatory service, admission would have been the default option’.

11. NEWS2 Score

12. Please confirm these responses with the lead surgeon at your trust.

13. Choose whichever is the routinely ordered blood marker to assess for pancreatitis for patients admitted with abdominal pain.

14. Please tick all that are orderable through your local biochemistry laboratory.

15. Please indicate when you would expect a USS to be performed, if the request was made by midday.

   For weekend USS please indicate if there is normally capacity to perform USS on inpatients on Saturday and Sunday without having to call a radiologist from home to do so in exceptional circumstances.

16. Please indicate whether you would routinely expect MRCPs to be triaged and performed on the same admission (in general within 48hrs) for patients awaiting cholecystectomy.

17. If required, do you have access to sMRCP at your hospital. If you are unsure please check with radiology for the appropriate response.

18. **CT 24-hour access**: Do you have routine access to CT out of hours without having to call in staff from home in exceptional circumstances to perform this.
19. Please give the answer that best describes your service.

20. The Sunflower Study: A randomised controlled trial to establish the clinical and cost effectiveness of expectant management versus pre-operative imaging with magnetic resonance cholangio-pancreaticogram (MRCP) in patients with symptomatic gallstones undergoing laparoscopic cholecystectomy at low or moderate risk of common bile duct stones: https://sunflowerstudy.blogs.bristol.ac.uk

21. Emergency list: NCEPOD list, normally shared with other specialities
   
   Dedicated same admission biliary list: List for either urgent emergencies or specifically for biliary patients, run separately to the main NCEPOD emergency list
   
   Dedicated urgent (within 2 weeks) elective laparoscopic cholecystectomy list: List with specific access allowed to enable rapid booking of urgent cases
   
   Routine outpatient list: No difference in lists accessed to routine outpatients

22. ERCP, inpatient access?: Would you expect the majority of your ERCP requests to be actioned as an inpatient within the next 7 days of inpatient stay?

23. Does your unit expect a formalised severity assessment for acute pancreatitis:
   Expectation defined as ‘it would be asked to be done by the consultant’ if not provided on the admission clerking

24. Glasgow:
   
   APACHE II: https://www.mdcalc.com/apache-ii-score
   
   Ranson: https://www.mdcalc.com/ransons-criteria-pancreatitis-mortality

25. Interventional radiology access
   
   No: No access at the hospital and patient would always need to be transferred
   
   9am - 5pm: Access at the hospital during normal working hours during the week
   
   Limited out of hours service: Informal arrangement and you get out of hours access if the right person is free to help
   
   24/7 on call service: Dedicated full time oncall at your hospital

26. Endoscopic treatment
   
   None: No access at the hospital and the patient would always need to be transferred
   
   Good access through another trust: Established link from your hospital to another where these patients can be transferred for endoscopic treatment
   
   Done in house: Dedicated access at your trust.
27. Please tick all that are available in your hospital.

   **Videoscopic assisted retroperitoneal debridement:** A minimally invasive surgical option for pancreatic necrosis, usually offered when patients have not responded to conservative or percutaneous treatment options.

   **Transgastric necrosectomy:** An endoscopic method of removing pancreatic necrosis via the stomach.

   **Open necrosectomy:** A more invasive, open operation for removing pancreatic necrosis

   **None available at your hospital:** Patients would require transfer to another hospital for surgical treatment.

28. **Kept under the admitting team:** Acute pancreatitis will be admitted under the consultant on-call, irrespective of their specialty.

   **Referred to local specialist team in complex cases:** Acute pancreatitis may be referred for take over of care to the UGI local team in more complex cases.

   **Referred to local specialist team in all cases:** Acute pancreatitis will always be referred for take over of care to the local UGI team.

   **Selective take:** Admitted under the UGI straight away. See question 7.

29. **Named lead for pancreatitis:** A specifically named person who is a dedicated point of contact for all queries regarding pancreatitis advice, care and management.

26. **Nurse specialist:** A nurse dedicated to pancreatitis for support and serves as an expert in evidence based nursing practice. This is different to an emergency or UGI nurse specialist who does not have a specific named role in the management of complex pancreatitis patients.

27. **Local referral centre:** The named hospital that you would contact for advice regarding care, management or to transfer the patient for more specialist care. If you do not have a clear link with one hospital you would contact please indicate ‘unclear’.

   **NA:** You site is the tertiary referral centre.

28. **Regional service:** Often tertiary centre specialised in individual services for pancreatitis.

   **Ad hoc pathway:** No formalised pathway is set, but a specific hospital or group of people can be contacted if help regarding a pancreatic patient is required.

   **Clear criteria for referral:** Please state all criteria that are in place for access to your regional service (e.g. failed conservative management or ongoing patient deterioration).
29. **Pancreatitis MDT:** A multidisciplinary team meeting is a meeting amongst experts in pancreatitis treatment and management that will occur at regular intervals of time (e.g. every fortnight). Please state whether yours is **local** (in your hospital), **regional** (within the region and discussed elsewhere) or **not available**.

30. **Information sheet:** A patient information sheet or leaflet that has been made specifically for patients presenting with acute pancreatitis in your hospital.  
   **Yes:** Information sheet available (and can be accessed e.g. on the trust intranet)  
   **No:** No information sheet available.  
   **In development:** Plans in place for a dedicated information sheet to be made.

31. Is the information sheet routinely given to all patients admitted with acute pancreatitis?  
   **Yes:** Distributed to all patients with acute pancreatitis routinely.  
   **No:** Available as an information sheet but not routinely distributed.  
   **Ad hoc:** Distributed to patients depending on which consultant/junior doctor is working.  
   **N/A:** No information sheet available for distribution.

32. **Idiopathic:** Cause of pancreatitis unknown.  
   **Yes:** Dedicated follow up in place for idiopathic pancreatitis.  
   **No:** No dedicated follow up for idiopathic pancreatitis.  
   **Ad hoc:** Patient dependent. No specific service in place, but some idiopathic pancreatitis patients are followed up.

33. **Routine further investigations:** Please tick all that your hospital would routinely perform in cases of idiopathic pancreatitis.
# Data collection sheet

**Appendix 3.**

## PANC Study Protocol v.1

<table>
<thead>
<tr>
<th>REDCap ID:</th>
<th>Two of three of these criteria needed to be included</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Classical history of acute pancreatitis</td>
</tr>
<tr>
<td></td>
<td>Amylase or lipase &gt;3x upper limit of normal</td>
</tr>
<tr>
<td></td>
<td>Imaging compatible with acute pancreatitis</td>
</tr>
</tbody>
</table>

### DEMOGRAPHICS

<table>
<thead>
<tr>
<th>1. Sex</th>
<th>M</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Age</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### HISTORY

<table>
<thead>
<tr>
<th>3. Duration of symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Method of referral</td>
</tr>
<tr>
<td>5. Previous pancreatitis</td>
</tr>
<tr>
<td>6. BMI kg/m²</td>
</tr>
<tr>
<td>7. Smoker</td>
</tr>
<tr>
<td>8. Alcohol consumption</td>
</tr>
<tr>
<td>9. Diabetes</td>
</tr>
<tr>
<td>10. Charlson Comorbidity Index</td>
</tr>
<tr>
<td>11. Other factors</td>
</tr>
<tr>
<td>12. Frailty score</td>
</tr>
<tr>
<td>13. COVID status</td>
</tr>
</tbody>
</table>

### INITIAL ASSESSMENT

<table>
<thead>
<tr>
<th>14. NEWS2</th>
<th>22. Amylase/Lipase</th>
</tr>
</thead>
<tbody>
<tr>
<td>15. pH</td>
<td>23. Urea mmol/L</td>
</tr>
<tr>
<td>16. Lactate</td>
<td>24. Creatinine mmol/L</td>
</tr>
<tr>
<td>17. Arterial PaO₂</td>
<td>25. Glucose mmol/L</td>
</tr>
<tr>
<td>18. WCC T/L</td>
<td>26. CRP mg/dL</td>
</tr>
<tr>
<td>19. LDH u/L</td>
<td>27. Cort Ca²⁺ mmol/L</td>
</tr>
<tr>
<td>20. ALT u/L</td>
<td>28. Hematocrit</td>
</tr>
<tr>
<td>21. Bilirubin umol/L</td>
<td>Lipoaenic NA</td>
</tr>
<tr>
<td></td>
<td>29. Albumin g/L</td>
</tr>
</tbody>
</table>

### 30. Type of Fluid given in first 24 hrs

<table>
<thead>
<tr>
<th>Volume in 24hrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crystallloid: Hartmann's</td>
</tr>
<tr>
<td>Crystallloid: Other</td>
</tr>
<tr>
<td>Colloid (i.e. Albumin, Gelofusine)</td>
</tr>
<tr>
<td>Blood products</td>
</tr>
<tr>
<td>REDCap ID:</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td><strong>MANAGEMENT in first 48 hours</strong></td>
</tr>
<tr>
<td>31. Was pancreatitis diagnosed within 48h?</td>
</tr>
<tr>
<td>32. Highest NEWS2 in first 48hrs</td>
</tr>
<tr>
<td>33. Highest CRP in first 48hrs</td>
</tr>
<tr>
<td>34. Antibiotics within the first 48hrs?</td>
</tr>
<tr>
<td>35. Was a urinary catheter inserted?</td>
</tr>
<tr>
<td>Urine output?</td>
</tr>
<tr>
<td>36. Able to tolerate oral intake on admission?</td>
</tr>
<tr>
<td>37. Type of analgesia used (not all that apply)</td>
</tr>
<tr>
<td>38. Managed with only oral analgesia?</td>
</tr>
<tr>
<td><strong>IMAGING and INTERVENTION in the first 30 days</strong></td>
</tr>
<tr>
<td>39. Was an abdominal US performed?</td>
</tr>
<tr>
<td>Gallbladder stones found?</td>
</tr>
<tr>
<td>CBD stones found?</td>
</tr>
<tr>
<td>CED size?</td>
</tr>
<tr>
<td>40. Was a CT done?</td>
</tr>
<tr>
<td>Was the initial CT done for:</td>
</tr>
<tr>
<td>Findings:</td>
</tr>
<tr>
<td>Necrosis:</td>
</tr>
<tr>
<td>Peripancreatic fluid collections:</td>
</tr>
<tr>
<td>Did the CT affect management?</td>
</tr>
<tr>
<td>41. Was a second CT done?</td>
</tr>
<tr>
<td>Additional CTs can be added to RedCap</td>
</tr>
<tr>
<td>Findings:</td>
</tr>
<tr>
<td>Necrosis:</td>
</tr>
<tr>
<td>Peripancreatic fluid collections:</td>
</tr>
<tr>
<td>Did the CT affect management?</td>
</tr>
<tr>
<td>42. Interventional procedure? (IR or EUS)</td>
</tr>
<tr>
<td>If yes, was it:</td>
</tr>
<tr>
<td>43. Necrosectomy performed?</td>
</tr>
<tr>
<td>44. Other abdominal surgery?</td>
</tr>
<tr>
<td>45. Did the patient proceed to ERCP?</td>
</tr>
<tr>
<td>Indication:</td>
</tr>
<tr>
<td>Findings:</td>
</tr>
<tr>
<td>Prophylactic sphincterotomy:</td>
</tr>
<tr>
<td>46. Cholecystectomy? (NA=not gallstone aetiology or done previously)</td>
</tr>
<tr>
<td>Not considered yet ☐ Done during admission ☐ Done or date within 2 weeks of discharge ☐ On waiting list: date &gt;2 weeks from discharge</td>
</tr>
<tr>
<td>47. If had chole, intraoperative imaging?</td>
</tr>
<tr>
<td>Were CBD stones found?</td>
</tr>
</tbody>
</table>

PANC Study - Pancreatitis: A National Cohort Study v.5 14 Dec 2020
<table>
<thead>
<tr>
<th>REDCap ID:</th>
</tr>
</thead>
</table>

### OUTCOMES at 30 days

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>Yes within 48h</th>
<th>Yes after 48h</th>
<th>No</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>48. Were they admitted to HDU/ITU?</td>
<td></td>
<td>Length of stay: ....days</td>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>49. Were they readmitted to HDU/ITU?</td>
<td></td>
<td>Length of stay: ....days</td>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>50. What was the highest level of clinical expertise provided?</td>
<td></td>
<td>Tock one only</td>
<td>Generalist care only</td>
<td>Admitted under specialist care</td>
<td>Tertiary unit advice</td>
</tr>
<tr>
<td></td>
<td>Did not have respiratory failure</td>
<td></td>
<td>Local specialist advice</td>
<td>Local specialist care</td>
<td>Tertiary unit care</td>
</tr>
<tr>
<td>51. Did respiratory failure occur?</td>
<td>No</td>
<td>Transient &lt;48h</td>
<td>Persistent &gt;48h</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>52. State severity of respiratory failure (NA=did not have respiratory failure)</td>
<td>Yes</td>
<td>O2 only</td>
<td>NIV required</td>
<td>Intubated</td>
<td>No</td>
</tr>
<tr>
<td>53. Did cardiovascular failure occur?</td>
<td>No</td>
<td>Transient &lt;48h</td>
<td>Persistent &gt;48h</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>54. State severity of cardiovascular failure (NA=did not have CV failure)</td>
<td>Fluids only</td>
<td>Inotropes required</td>
<td>NA</td>
<td>Fluids only</td>
<td>Renal replacement</td>
</tr>
<tr>
<td>55. Did acute renal failure occur?</td>
<td>No</td>
<td>Transient &lt;48h</td>
<td>Persistent &gt;48h</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>56. State severity of renal failure (NA=did not have renal failure)</td>
<td>Fluids only</td>
<td>NG feed</td>
<td>NJ feed</td>
<td>Supplement</td>
<td>day started</td>
</tr>
<tr>
<td>57. Was additional enteral nutrition required?</td>
<td>No</td>
<td>Yes</td>
<td>mg/d</td>
<td>days from presentation</td>
<td></td>
</tr>
<tr>
<td>58. Was parenteral nutrition required?</td>
<td>Gallstones</td>
<td>Alcohol</td>
<td>Trauma</td>
<td>Medication</td>
<td>Other</td>
</tr>
<tr>
<td>59. The highest CRP in the first 30 days</td>
<td>No</td>
<td>Yes</td>
<td>Rebook US</td>
<td>IgG4</td>
<td>Triglycerides</td>
</tr>
<tr>
<td>60. What was the cause of pancreatitis?</td>
<td>No</td>
<td>Yes</td>
<td>Booked (not yet performed)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>61. If gallstones were not found on admission which of the following tests were carried out?</td>
<td>No</td>
<td>Yes</td>
<td>NA</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>62. Was an MRCP performed?</td>
<td>Gallbladder stones found?</td>
<td>CBD stones found?</td>
<td>No</td>
<td>Yes</td>
<td>Equivocal</td>
</tr>
<tr>
<td>Recruit to Sunflower study:</td>
<td>Indication:</td>
<td>To diagnosis gallstones</td>
<td>To exclude CBD stones</td>
<td>Other</td>
<td>To diagnosis gallstones</td>
</tr>
<tr>
<td>63. Was a diagnostic EUS performed?</td>
<td>Gallbladder stones found?</td>
<td>CBD stones found?</td>
<td>No</td>
<td>Yes</td>
<td>Equivocal</td>
</tr>
<tr>
<td>Indication:</td>
<td>No</td>
<td>Yes</td>
<td>Booked (not yet performed)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>64. Are they still an inpatient at 30 days?</td>
<td>Discharged</td>
<td>Still inpatient at 30 days</td>
<td>Transferred out</td>
<td>Died within 30 days</td>
<td>Cause of death:</td>
</tr>
<tr>
<td>65. What was the length of stay?</td>
<td>No</td>
<td>Yes</td>
<td>Already on Creon</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>66. Was Creon required by 30 days?</td>
<td>No</td>
<td>Yes</td>
<td>Required oral</td>
<td>Yes, required insulin</td>
<td>No</td>
</tr>
<tr>
<td>67. Did their diabetic requirements change?</td>
<td>No</td>
<td>Yes</td>
<td>Referred</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>68. Was follow up arranged?</td>
<td>No</td>
<td>Yes</td>
<td>Referred</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>69. Unplanned reattendence within 30days?</td>
<td>No</td>
<td>ED</td>
<td>Ward review</td>
<td>Admitted</td>
<td>......day</td>
</tr>
<tr>
<td>70. Reason for unplanned reattendance (tick all that apply)</td>
<td>Unrelated</td>
<td>Recurrent pancreatitis</td>
<td>Complications of pancreatitis</td>
<td>Complications of ERCP</td>
<td>Complications of cholecystectomy</td>
</tr>
</tbody>
</table>
Appendix 4.

Definitions and clarifications for Data collection sheet

The question numbers here correspond to the questions on the protocol.

Acute pancreatitis
The revised Atlanta classification requires that two or more of the following criteria be met for the diagnosis of acute pancreatitis:
(a) abdominal pain suggestive of pancreatitis,
(b) serum amylase or lipase level greater than three times the upper normal value, or
(c) characteristic imaging findings

Duration / Length of stay
Day of admission = Day 0

1. Sex: Male or female, as defined by sex at birth

2. Age: Age in years on the day of presentation

3. Length of symptoms: Day 0 = The day symptoms began

4. Method of referral:
   GP: Referral made directly from GP to emergency admission team
   ED: Admission via referral from the Emergency department
   Other hospital specialty: patient under the care of another team, when pancreatitis develops or when the diagnosis is made

5. Previous pancreatitis
   Yes, acute: The patient has been previously admitted to hospital with a confirmed case of acute pancreatitis
   Yes, known chronic: Patient is known to have a diagnosis of chronic pancreatitis (supported by previous history/imaging) Admission for chronic pain on the background of chronic pancreatitis in the absence of radiological/biochemical features of acute inflammation is not an indication for inclusion in the study.

6. BMI: Body mass index = kg/m²

7. Smoking status: To be classified as an ex-smoker the patient must have stopped smoking at least 28 days prior to the admission.

8. Alcohol consumption: Estimate given by the patient in units (u) per week
9. **None or diet controlled**: Any patient not on diabetic medication
   **Uncomplicated**: On oral medication or insulin, but without evidence of end organ damage
   **End organ damage**: Evidence of retinopathy, nephropathy, or neuropathy due to diabetes

10. **MI (Myocardial infarction)**: History of definite or probable MI (ECG changes and/or enzyme changes)
    **CCF (Congestive cardiac failure)**: Exertional or paroxysmal nocturnal dyspnoea and has responded to digoxin, diuretics, or afterload reducing agents
    **PVD (Peripheral vascular disease)**: Intermittent claudication or previous bypass for chronic arterial insufficiency, history of gangrene or acute arterial insufficiency, or untreated thoracic or abdominal aneurysm (≥6 cm)
    **CVA (Cerebrovascular Accident) or TIA (Transient Ischaemic Attack)**: History of a cerebrovascular accident with minor or no residua or transient ischemic attacks
    **Dementia**: Chronic cognitive deficit
    **Liver disease**: Severe/moderate = cirrhosis and portal hypertension, mild = chronic hepatitis (or cirrhosis without portal hypertension)
    **COPD (Chronic obstructive pulmonary disease)**: Spirometry is required to make this diagnosis. Traditionally, an FV1/FVC of <0.7 is defined as COPD. For this study, we accept the diagnosis of COPD if it is in the patient's clinical or GP record.
    **Connective Tissue disease**: includes rheumatoid arthritis, scleroderma and lupus.
    **Hemiplegia**: sustained disability follow CVA
    **CKD (Chronic Kidney Disease)**: Needs to be chronic (> 3 months) and moderate to severe CKD or worse. Using the KDIGO guidelines, this states an eGFR of <4412.
    **AIDS (Acquired Immune Deficiency Syndrome)**: Stage 3 HIV infection (CD4+ T-cell counts under 200/µL)
    **Peptic ulcer disease**: Any history of treatment for ulcer disease or history of ulcer bleeding
    **Leukemia**: Any variant of this disease
    **Lymphoma**: Any variant of this disease
    **Solid tumour**: None / Localised / Metastatic

11. **Other factors**: please tick all that apply

12. **Frailty score**: Please use the Rockwood score, from the British geriatric society (Appendix 5):
    https://www.bgs.org.uk/sites/default/files/content/attachment/2018-07-05/rockwood_cfs.pdf

13. **COVID status**
    **Not tested**: no PCR swab test around the time of presentation
    **Negative**: Negative test around the time of presentation
    **Positive on presentation**: Patient had a positive test PCR (swab) during that admission or within the last 10 days preceding the presentation
Previously positive: Know to have had COVID previously, either by positive PCR swab or antibody test

Months: number of months prior to this presentation the result was positive (either PCR swab or antibody). 0 months is within the last 28 days.

14-29. Initial assessment: First blood tests available within the first 24 hours of presentation. If no bloods were taken on presentation to hospital but bloods were taken before referral please use these.

14. NEWS2: National Early Warning Score 2 - use the pre calculated value, or if not measured at your trust calculate here

15. pH: As venous and arterial samples’ pH is highly correlated, either value can be given

16. Lactate: As venous and arterial samples’ lactate is highly correlated, either value can be given, although venous samples are shown to give a consistently higher reading

17. Arterial PaO2: Only provide if patient has undergone an arterial blood gas as part of routine care

18. WCC: White cell count

19. LDH: Lactate dehydrogenase - only provide if taken as part of routine care

20. ALT: Alanine Aminotransferase

21. Bilirubin: Units can vary between trusts - if using mg/dL please convert to umol/L

22. Amylase/Lipase: Please select whichever you use for routine diagnosis at your hospital

25. Glucose: Can be provided from either finger prick or serum sample

26. CRP: C Reactive Protein

27. Corr Ca\(^{2+}\): Provide corrected calcium level, not total calcium level

30. Fluids in first 24 hours: Total number of litres or units where appropriate

31. Was pancreatitis diagnosed within the first 48 hours of admission?
   Diagnosis based upon 2 or more of the following:
   (a) Classical history
   (b) Amylase/ Lipase > 3 times the upper limit of normal
   (c) Features on imaging in keeping with acute pancreatitis
34. **Antibiotics within the first 48 hours:** Proven infection must be based upon positive microbiology cultures (e.g. blood, sputum, urine, fluid)

35. **Urine output:** Please indicate the worst record in the first 48 hours from presentation

36. **Able to tolerate oral intake on admission?**
   - **Not known as put NBM:** NBM for more than the first 24 hours of admission

37. **Type of analgesia used**
   - Additional analgesia prescribed to patients normal medication
   - Please tick all that apply
   - **PCA:** Patient controlled analgesia

39. **Abdominal USS**
   - Time from presentation to scan being performed; not the time from request.
   - **NA:** Gallstones previously confirmed on another scan
   - **Equivocal:** Uncertainty in the report, possibly suggesting further imaging for clarification.
   - This includes sludge without the presence of stones.

40 - 41. **CT**
   - **Confirm the diagnosis:** if diagnosis is unclear at presentation, or if there is concern there may be additional problems such as perforation
   - **Assessment of severity:** Assessment of pancreatic damage
   - **Look for aetiology:** performed in a clinically well patient to search for a cause (i.e. malignancy) as part of the work up of idiopathic pancreatitis

   **Interstitial pancreatitis**: Acute inflammation of the pancreatic parenchyma and peripancreatic tissues, but without recognisable tissue necrosis

   **Necrosis**: Lack of pancreatic parenchymal enhancement by IV contrast agent

   **Peripancreatic fluid collections**: Occurs in the setting of interstitial oedematous pancreatitis
   - Homogeneous collection with fluid density
   - Confined by normal peripancreatic fascial planes
   - No definable wall encapsulating the collection
   - Adjacent to pancreas (no intrapancreatic extension)

   **Did CT affect management?** Did performing the CT affect any aspect of the patient's care including starting antibiotics, need for intervention (radiology/endoscopy), surgery, transfer to tertiary centre, discharge.
42. **Interventional radiological procedure - options available on REDCap**
   - FNA: Fine needle aspiration to assess for infection
   - Vascular: for bleeding
   - Vascular: for pseudoaneurysm
   - Vascular: other
   - Drain: for peripancreatic fluid collections
   - Drain: for necrosis
   - Wire: for necrosectomy access
   - EUS: for pigtail drain placement
   - EUS: for hot axios stent
   - Other

43. **Necrosectomy performed**: any action of removing dead pancreatic tissue. Not passive removal with purely a drain. Please give the date of the first procedure if multiple performed.

44. **Other abdominal surgery**: Please specify any other surgical procedures other than cholecystectomy and necrosectomy.

45. **Did the patient proceed to ERCP?**
   - **Indication**: please tick all that apply
   - **Findings**: Duct clear - no stones found at rime of procedure.
   - **Prophylactic sphincterotomy**: Was a sphincterotomy performed to prevent further episode of pancreatitis.

46. **Cholecystectomy**?
   - **NA**: gallstones not the cause of pancreatitis or cholecystectomy previously performed
   - **Not fit for operation**: decision made not suitable for an cholecystectomy at anytime
   - **Not considered yet**: no decision has been made
   - **Done during admission**: performed on index admission
   - **On waiting list**: date within 2 weeks of discharge
   - **On waiting list**: date >2 weeks from discharge

47. **If they underwent cholecystectomy, was any intraoperative imaging performed?**
   - **OTC**: On Table Cholangiogram
   - **Lap USS**: Laparoscopic ultrasound scan of the bile ducts.
   - **Were CBD stones found?**: This refers to intraoperative findings of CBD stones only.

48. **Were they admitted to HDU/ITU?** Please indicate the number of complete days spent on HDU/ITU. Less than one day will be 0 days.

49. **Were they readmitted to HDU/ITU?** Less than one day will be 0 days. NA for those who were never admitted to HDU/ITU.
50. **Highest level of expertise offered**: Consider this specific to your trust. E.g. If you are in a tertiary unit and you have completed the site survey stating this, you can select ‘Local specialist’ advice or care, rather than ‘Tertiary specialist’ advice or care.

51. **Respiratory failure**: For the purposes of data collection, we are assessing if acute respiratory failure occurred (i.e. not if the patient is known to be in type 2 failure). Respiratory failure is classified according to blood gases:
   - Arterial oxygen tension (PaO2) of <8.0 kPa (60 mmHg)
   - Arterial carbon dioxide tension (Pa,CO2) of >6.0 kPa (45 mmHg) or both

52. See Q51

53. **Cardiovascular failure**: defined as a reduced state of cardiac output where the heart cannot effectively pump blood around the body. For the purposes of data collection, we are assessing if decompensated heart failure has occurred. This is largely a clinical diagnosis and symptoms may include:
   - Peripheral oedema
   - Pulmonary oedema
   - Renal dysfunction
   - Decreased peripheral perfusion
   - Changes in BP, heart rate and ECG

54. See Q53

55. **Acute renal failure**: For the purposes of this study, the KDIGO criteria have been used:
   - Stage 1:
     - Increase in serum creatinine to 1.5 - 1.9 times baseline or
     - Increase in serum creatinine by more than 0.3mg/dL or
     - Reduction in urine output to less than 0.5ml/kg/hour for 6 to 12 hours
   - Stage 2:
     - Increase in serum creatinine to 2 - 2.9 times baseline or
     - Reduction in urine output to less than 0.5ml/kg/hour for more than 12 hours.
   - Stage 3:
     - Increase in serum creatinine to 3 times baseline or
     - Increase in serum creatinine to more than 4 mg/dl or
     - Reduction in urine output to less than 0.3ml/kg/hour for more than or equal to 24 hours or
     - The initiation of renal replacement therapy or
     - (in under 18 year olds), a decrease in eGFR to <35.

   **If any stages have occurred, select yes.**

56. See Q55
57. **Was additional enteral nutrition required?** Please tick all that apply. On REDCap you will have space to add the day started for each type of additional nutrition. Day of presentation is day 0.

58. **Was parenteral nutrition required?** If yes, please state the day started. Day of presentation is day 0.

59. **What was the highest CRP in the first 30 days:** Please state the peak CRP and the day this was recorded (day of presentation is day 0.)

60. **What was the cause of pancreatitis?** Please choose the best answer. If the cause is unclear, please tick all that apply (i.e. if known alcohol excess, and has gallstones please choose both.)

61. **If gallstones were not found or if classed as idiopathic/unknown, which of the following tests were carried out?** Please tick all that apply. Only include tests that have been done within the 30 days from presentation.

62. **Was an MRCP performed?**
   - **Equivocal:** when the report is unclear (e.g. Sees sludge, but not sure there are definitely stones present)

63. **Was a diagnostic EUS performed?**
   - **Equivocal:** when the report is unclear (e.g. Sees sludge, but not sure there are definitely stones present)

64. **Are they still and inpatient at 30 days?** For patients who died, or were transferred to another hospital, please indicate the number of days they were in the trust.

65. **What was the length of stay?:** Day 0 is the day of admission. Please choose NA if the patient is still an inpatient.

66. **Was Creon required by 30 days?** Did the patient require treatment for new signs of pancreatic enzyme insufficiency with Creon or other replacement therapy.

67. **Did their diabetic requirements change?** (tick all that apply)
   - **No:** Indicates the patient was discharged on the same medication (none, oral or insulin) as admission
   - **Yes, required oral:** Newly prescribed oral medication, when previously not taken
   - **Yes, required insulin:** Newly prescribed oral medication, when previously not taken

68. **Was follow up arranged?** This includes planned return to the ward for repeat blood test or wound reviews.
69. **Unplanned reattendance within 30 days**: please check the best answer only. Please give the number of days between initial presentation and reattendance. There will be space for multiple reattendance to be recorded on REDCap if needed.

70. **Reason for unplanned reattendance**: please choose the best answer, but multiple can be chosen if appropriate.
Appendix 5.

Acronyms and their definitions

AIDS: Acquired immunodeficiency syndrome
ALT: Alanine aminotransferase
APA: American Pancreatic Association
ASGBI: Association of Surgeons of Great Britain and Ireland
AUGIS: Association of Upper GI Surgeons
BP: Bloods pressure
CBD: Common bile duct
CCD: Congestive cardiac failure
CKD: Chronic kidney disease
COPD: Chronic obstructive pulmonary disease
CRP: C-Reactive protein
CT: Computed tomography
CVA: Cerebrovascular accident
BMI: Body mass index
ECG: Electrocardiogram
ED: Emergency department
ERCP: Endoscopic retrograde cholangiopancreatography
EUS: Endoscopic ultrasound
FNA: Fine Needle Aspiration
GP: General practitioner
HPB: Hepatopancreatobiliary
IAP: International Association of Pancreatology
IgG4: Immunoglobulin G4
IV: Intravenous
LDH : Lactate dehydrogenase
MI: Myocardial infarction
MRCP: Magnetic resonance cholangiopancreatography
NBM: Nil by mouth
NEWS2: National early warning score 2
NG: Nasogastric
NJ: Nasojejunal
NSAIDs: Non steroidal antiinflammatories
OTC: On Table Cholangiogram
PANC Study: Pancreatitis: A National Cohort Study
PaO2: Partial pressure of oxygen
PCA: Patient controlled analgesia
PI: Principle Investigator
PSGBI: Pancreas Society of Great Britain and Ireland
PVD: Peripheral vascular disease
REDCap: Research Electronic Data Capture. Secure web platform for online databases
SpO2: Oxygen saturation
TIA: Transient ischaemic attack
UGI: Upper Gastrointestinal
USS: Ultrasound
UK: The United Kingdom of Great Britain and Northern Ireland
WCC: White cell count
### Rockwood Clinical Frailty Score

<table>
<thead>
<tr>
<th>Clinical Frailty Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 Very Fit</strong> – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.</td>
</tr>
<tr>
<td><strong>2 Well</strong> – People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.</td>
</tr>
<tr>
<td><strong>3 Managing Well</strong> – People whose medical problems are well controlled, but are not regularly active beyond routine walking.</td>
</tr>
<tr>
<td><strong>4 Vulnerable</strong> – While not dependent on others for daily help, often symptoms limit activities. A common complaint is being &quot;slowly up&quot;, and/or being tired during the day.</td>
</tr>
<tr>
<td><strong>5 Mildly Frail</strong> – These people often have more evident slowing, and need help in higher order IADLS (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.</td>
</tr>
<tr>
<td><strong>6 Moderately Frail</strong> – People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.</td>
</tr>
<tr>
<td><strong>7 Severely Frail</strong> – Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).</td>
</tr>
<tr>
<td><strong>8 Very Severely Frail</strong> – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.</td>
</tr>
<tr>
<td><strong>9 Terminally Ill</strong> – Approaching the end of life. This category applies to people with a life expectancy &lt;6 months, who are not otherwise evidently frail.</td>
</tr>
</tbody>
</table>

#### Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common symptoms in mild dementia include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In moderate dementia, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In severe dementia, they cannot do personal care without help.
References

7. National Confidential Enquiry into Patient Outcome and Death. Treat the Cause—a Review of the Quality of Care Provided to Patients Treated for Acute Pancreatitis.