Protocol for Wessex Surgical Trainee research collaborative multicentre audit on the management of acute pancreatitis (PanWessex)
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1. **Protocol management group**

Wessex Surgical Trainee Research Collaborative:

Trainees: Fergus Noble, Ioanna Panagiotopoulou and Jack Broadhurst.

Consultants:  
Mr Colin D. Johnson  
University Hospital Southampton NHS Foundation Trust  
Mr Benjamin Knight  
Portsmouth NHS Trust  
Mr Simon Toh  
Portsmouth NHS Trust  
Mr Christian Wakefield  
Royal Hampshire County Hospital

2. **Data Management team**

Fergus Noble and Jack Broadhurst.
3. Summary

This is a trainee-led multicentre audit on the management of acute pancreatitis that aims to identify variations of practice against the national standards recommended by the UK Working Party on Acute Pancreatitis [1]. It was duely adopted by the Wessex Surgical Trainee Research Collaborative on 14th March 2014 to be run as a regional audit.
4. Introduction

Acute pancreatitis is common in surgical practice and its incidence appears to be rising with currently 150 to 420 cases per million [2-5]. The spectrum of the disease varies from a mild self-limiting attack to severe illness resulting in significant local and systemic complications and even death [5-7]. The management of acute pancreatitis is multidisciplinary with surgeons working with radiologists, intensivists, gastroenterologists and dietitians in order to provide optimum care.

The British Society of Gastroenterology (BSG) issued evidence-based guidelines for the management of acute pancreatitis in 1998 with a revision of these recommendations by the UK working party on acute pancreatitis in 2005 [1,8]. Since the generation of these guidelines several audits have been performed against the set standards [9-12] but no multicentre audit has been conducted. Despite the presence of the guidelines for over 14 years wide variations in practice exist across the UK [9,11,13]. As accurate audit data against nationally set standards are important in evaluating the increasingly costly management of patients with acute pancreatitis [9,14] we identify the usefulness for a multicentre audit of the management of acute pancreatitis.
5. Aim

5.1. Primary aim

The primary aim of this multicentre audit is to examine whether the management and outcome of patients with acute pancreatitis across Wessex is compliant with nationally agreed standards, and to identify variations in practice. Patient outcome will be measured in terms of hospital stay, treatment of gallstones and management of complications.

5.2. Secondary outcomes

The secondary outcomes for this multicentre audit are:

A) To report the rate of antibiotic use in acute pancreatitis in the absence of infection and its effect on patient morbidity, mortality and hospital stay
B) To map the referral process to tertiary referral centres for severe pancreatitis both in terms of specialist opinion and the need for intervention
C) To report the rate of idiopathic pancreatitis
D) To provide a database that will inform of the sample size calculation required for future studies in acute pancreatitis. This database will also serve as a resource for observational and hypothesis generating studies.
6. Methods

6.1. Audit Standards

This multicentre audit will be conducted against the audit standards defined by the 2005 UK guidelines on the management of acute pancreatitis [1]. The data collected will also allow audit against the new standards proposed in the current revision by the UK Pancreatic Guideline Development Group (in progress). These standards span across the following areas of patient management.

6.1.1. Diagnosis

A) The correct diagnosis of acute pancreatitis should be made within 48 hours of admission.
B) The aetiology of acute pancreatitis should be determined in 80% of cases.
C) Ultrasound scan should be obtained within 24 hours of diagnosis of acute pancreatitis to check for gallstones.
D) The diagnosis of acute pancreatitis can be based on elevated enzymes (amylase or lipase) together with clinical symptoms or on radiological evidence.

6.1.2. Assessment of severity

A) Prognostic features of severity: clinical impression of severity, obesity, APACHE II>8 in the first 24 hours and CRP>150 mg/L, Glasgow score 3 or more, persisting organ failure after 48 hours in hospital.
B) CT recommended if patient deteriorates 6-10 days after admission.

6.1.3. Prevention of complications

A) Antibiotic prophylaxis should not exceed a maximum of 14 days in the absence of positive cultures.
B) Nasogastric route/enteral route for feeding is preferred.

6.1.4. Treatment of gallstones

A) Indications for urgent Endoscopic Retrograde Cholangiopancreatography (ERCP) include actual or predicted severe gallstone pancreatitis, cholangitis, dilated CBD and jaundice. Emergency ERCP should be carried out within 72 hours from the onset of pain.
B) If ERCP is done, sphincterotomy should be performed whether or not stones are found in the bile duct.
C) Definitive management of gallstones is recommended during the index admission or within two weeks of discharge.
D) In severe acute pancreatitis, cholecystectomy should be delayed until signs of lung injury and systemic disturbance have resolved.

6.1.5. Management of necrosis

A) All patients with severe acute pancreatitis should be managed in HDU/ITU.
B) All patients with persistent symptoms or >30% pancreatic necrosis or smaller areas of necrosis but suspicion of sepsis should have image-guided fine needle aspiration (FNA) to obtain material for culture 7-14 days following the onset of pancreatitis. Patients with infected necrosis require radiological or surgical drainage. In practice, radiological drainage may be performed at the time of FNA prior to obtaining culture results. Hence, we will also be auditing the culture and sensitivity results with respect to the timing of radiological drainage and patient outcome.
C) The choice of surgical technique for necrosectomy depends on individual features and locally available expertise. Auditing this will enable us to identify current practice as no current standard exists.

6.1.6. Provision of services

A) A single nominated clinical team in each hospital should manage all patients with acute pancreatitis.
B) Referral or discussion with a specialist HPB unit is necessary for patients with extensive necrotising pancreatitis (>30% necrosis) or with other complications that may require ITU care or interventional radiological, endoscopic or surgical procedures.

6.1.7. Follow-up

A) A follow-up CT is recommended if the patient fails to show clinical improvement or some would advise a follow-up CT in patients making an uncomplicated recovery to check for asymptomatic complications such as pseudocyst or arterial pseudoaneurysm.
B) The diagnosis of idiopathic pancreatitis should not be accepted until:
   - Two good quality ultrasound scans are obtained
   - Magnetic Resonance Cholangiopancreatography (MRCP)
Endoscopic Ultrasound (EUS) to detect microlithiasis
Fasting blood lipids
Serum calcium concentration
Viral antibody titres (Coxsackie B4, mumps)
Underlying neoplasm or chronic pancreatitis is excluded
7. Eligible Centres

All units in Wessex that care for patients with acute pancreatitis may participate in this prospective audit. We anticipate district hospitals and tertiary referral centres participating in this multicentre audit. This will allow the collection of high quality data within a referral population and allow the tracking of the patients' journey between district hospitals and specialist hub units.
8. Patient Eligibility

All adults aged 18 years and above who are admitted with acute pancreatitis between the 1\textsuperscript{st} of November 2014 and the 28\textsuperscript{th} of February 2015 in the participating centres will be prospectively included in the audit (Appendix 1). Patients who had an index admission with gallstone pancreatitis prior to the start of the audit and are admitted with a further attack of pancreatitis during the audit period whilst awaiting laparoscopic cholecystectomy will also be included. The patient cases that will be excluded from the audit are those with:

- Chronic pancreatitis
- Acute exacerbation of existing pancreatitis
- More than one attack of alcohol-related pancreatitis in the past


9. Audit Phases

9.1. Collaboration call

A collaboration call will be sent out in August 2014 via the Wessex trainee research collaborative to all surgical trainees, Upper Gastrointestinal consultants in Wessex and the University of Southampton Surgical Society. We will be looking for a lead registrar and his/her lead consultant from each hospital to collaborate in the recruitment of their centre and a team of auditors (Appendix 1).

9.2. Recruitment of centres

Recruitment of a centre will involve identifying a responsible consultant and a lead auditor registrar (appendix 2). The lead trainee auditor will identify a team of auditors, register the audit with the hospital’s audit department by using the audit protocol and data collection tool (see attached Excel spreadsheet) and complete the site specific questionnaire (Appendix 3). The lead auditor registrar will complete the site specific questionnaire, hospital registration form and return this together with the hospital’s audit approval letter to the audit data management team during October 2014 (Appendix 3 + 6).

The lead auditor for each participating centre will also ensure an agreement is reached with the Radiology and Biochemistry departments prior to the start of the audit so that all cases of pancreatitis with radiological or biochemical evidence are communicated to the lead auditor and no cases are missed from the initial surgical admission lists. After the audit period the clinical coding department will be contacted to identify all cases coded with acute pancreatitis to assess completeness of data capture of cases with acute pancreatitis.

9.3. Multicentre audit phase

The main audit will be performed across eligible centres between the 1st of November 2014 and 30th of February 2015. All patients with the inclusion criteria outlined in section 7 that present in the participating centres within these dates will be included. The data collection tool will be used for the prospective collection of data and this process is outlined in Section 5 of the protocol. The follow-up period for each patient included in this prospective audit will end upon treatment of gallstones or a maximum of 2 months from the day of discharge, whichever is sooner. In cases
of severe pancreatitis that require prolonged ITU stay, the follow-up period will end at 2 months from the date of admission.

9.3.1. Audit pick-up rate

After all eligible cases are entered prospectively in the audit database, the lead auditor will check for any cases missed from the audit process. This will be done by running a request of all acute pancreatitis cases with the hospital’s coding department for the period of interest (1st November 2014 to the 30th February 2015). The audit pick-up rate will be recorded and sent to the data management team together with the submission of the audit data.

9.3.2. Database Locking

The patient database will lock once the final patient from each participating centre has reached follow-up as defined above. The complete database of all participating centres will lock once data are received from all participating centres or by the 30th of April 2015.

A flow chart of the audit phases is shown in Appendix 4.

9.3.3. Projected Numbers

Based on specific hospital episode statistics data, pilot data from a pilot study, data from a previous audit on acute pancreatitis within Wessex, approximate accrual rates were estimated. Recruitment from 8 centres over 4 months with an average of 2 patients per week will return 245 patients or if 10% of patients are not recruited or lost to follow-up.

9.4. Data Collection

9.4.1. Site Specific Questionnaire

Hospital related variables will be collected at the start of the audit with a site specific questionnaire (Appendix 3) that will be filled in by the lead auditor from each participating centre. These variables will concentrate on i) identifying the centre as district hospital or tertiary referral centre ii) determining the availability of ERCP, interventional radiology and emergency laparoscopic cholecystectomy iii) identifying the hospital’s nominated team caring for patients with pancreatitis and iv) identifying referral units if a district hospital entered and the distance from this hub unit. The site specific questionnaire will be returned to the data management team prior to the start of the audit.
9.4.2. Data Collection Tool

The data collection tool spans across the areas of patient management included in Section 5 and it is included in the attached Excel spreadsheet. The data collection tool will be available as an Excel file to all centres. The lead auditor in each participating centre will ensure that all eligible cases of acute pancreatitis are prospectively entered in the Excel dataset. The data collection file will be kept on an NHS secure computer of the participating centre and this will be the responsibility of the lead auditor of each participating centre. The patients’ journey from district general hospitals to tertiary referral centres and back will be mapped using centre and date identifiers in the data collection tool and the patients’ NHS number.

9.4.3. Data Handling

The complete dataset from each participating centre will be transferred electronically from the nhs account of the lead auditor to the nhs account of the Data Management Lead. The patients’ NHS numbers will be required so that the patients’ journey between district hospitals and specialists units is mapped. This mapping will be performed by the Data Management Lead. Once this mapping process is complete then NHS numbers will no longer be required. Anonymised patient data will be collated centrally on a database held on a secure NHS computer within University Southamp ton Hospital NHS Foundation Trust. The Data Management Team will be responsible for the “cleaning” of the database, i.e. the Data Management Team will contact auditors for any missing data or when inaccurate data are entered in the dataset, so that good quality data are obtained overall. The statisticians from University of Southampton will assist with the statistical analysis of the data as and when required.

9.4.4. Statistical Analysis

Data collected with this audit will provide information on the management of acute pancreatitis and the delivery of care will be assessed against national standards. Data analysis will be performed using parametric or non-parametric tests as appropriate. Each test variable may be represented with an overall pooled rate and ranges for each participating centre. Each variable will then be compared against the audit standard baseline. Multivariable regression models may be built in order to test for significance of the test variables against outcomes of interest. Variation in outcomes between participating centres will be shown with funnel plots. Since this is a multicentre audit, multi-level modelling may also be considered to
analyse the data in order to obtain valid individual-level effects that will appropriately account for the data structure including subgroup analysis by anonymised centre. The results of this multicentre audit will be reported in accordance with STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) [15].

9.4.5. Database

The anonymised database obtained from this multicentre audit will be retained on an NHS secure computer within University Southampton Hospital NHS Foundation Trust and may be used for future research purposes, including sample size calculations, hypothesis generation and exploratory data analyses.
10. Authorship

The names of all auditors participating in this multicentre audit will be PubMed citable to the final manuscript via “Wessex Trainee Research Collaborative”. The role of all authors in this audit will be clearly stated. Five names from each participating centre will be accepted as citable authors. More names may be included in the acknowledgements section but these will not be citable.
11. Definitions

11.1. Definitions of severity of acute pancreatitis

*Mild acute pancreatitis:* transient or no organ dysfunction (<48hrs) and absence of symptomatic local or systemic complications

*Moderate acute pancreatitis:* presence of symptomatic local or systemic complications in the absence of persistent organ failure and/or organ failure that resolves within 48 hours

*Severe acute pancreatitis:* persisting organ dysfunction of one or more organ systems on more than two consecutive days or significant pancreatitis associated complications [5, 16]

11.2. Systemic Inflammatory Response Syndrome (SIRS)

≥2 of the following parameters meets SIRS criteria [5, 16]:

A) Temperature >38°C or <36°C
B) Heart rate >90beats/min
C) Respiratory rate >20/min or PaCO2 <32mmHg
D) WBC >12000 cells/mm3 or <4000 cells/mm3

11.3. Definition of organ failure

Organ failure is defined as a score of 2 or more for one of three organ systems (respiratory, cardiovascular, renal) using the modified Marshall scoring system (Appendix 5) [16, 17].

Definitions of local complications

11.3.1. Acute peripancreatic fluid collection

Peripancreatic fluid associated with interstitial oedematous pancreatitis with no associated peripancreatic necrosis. This term applies only to areas of peripancreatic fluid seen within the first 4 weeks after onset of interstitial oedematous pancreatitis and without the features of a pseudocyst [16].
11.3.2. **Pancreatic pseudocyst**

Defined as an encapsulated collection of fluid with a well defined inflammatory wall usually outside the pancreas with minimal or no necrosis. This occurs after more than 4 weeks from the onset of acute interstitial oedematous pancreatitis [16].

11.3.3. **Acute necrotic collection (ANC)**

A collection containing variable amounts of both fluid and necrosis associated with necrotising pancreatitis [16].

11.3.4. **Walled-off necrosis (WON)**

Defined as a mature, encapsulated collection of pancreatic and/or peripancreatic necrosis that has developed a well defined inflammatory wall [16].

11.3.5. **Infected necrosis**

This is infection of an ANC or a WON that can be suspected by the patient’s clinical course or by the presence of gas seen within the collection on CT [16].

11.3.6. **Hepatic portal/ splenic vein thrombosis**

This is a complication following extensive pancreatic necrosis diagnosed on CT.

11.3.7. **Haemorrhage**

This complication may occur with erosion of vessels within or close to the pancreas.

11.3.8. **Colonic necrosis**

This may occur because of involvement of colonic vessels.

11.4. **Definition of systemic complications**

In the 2012 revision of the Atlanta classification, systemic complication is defined as the exacerbation of previous co-morbidity, such as coronary artery disease or chronic lung disease, precipitated by the acute pancreatitis [16].
12. **Funding**

No sources of funding exist for this audit.
Fergus Noble is supported by a CRUK funded Clinical Lectureship in Surgery.

13. **Conflicts of interest**

None to declare
14. References

15. **Appendices**
15.1. **Appendix 1 Timeline**

**Collaboration Call**
1st August 2014 – 31st October 2014
- Centre recruitment and define team of auditors
- Registration of audit with participating centre’s audit department
- Return of site specific questionnaire and audit registration letter to data management team

**Main Audit Phase**
1st November 2014 – 28th February 2015

**Follow up**
1st March 2015 – 31st April 2015
- Follow-up defined as:
  - treatment of gallstones or 2 months following date of discharge, whichever sooner
  - 2 months from day of admission for severe cases of pancreatitis

**End of Audit**
30th April 2015

**Analysis**
May 2015
15.2. Appendix 2 How to register the audit

The audit department of your hospital should advise on the local paperwork required to register the project. Please contact them as soon as you register the audit.

At hospital level:
1) Identify a Clinical lead (Consultant level) at your hospital to support the study.
2) Create a team to collect the data (Medical Students, FY1-2, CTs and Specialty registrars.
3) Contact the audit department.
   a. Complete hospital audit proforma
   b. Include in the proforma that this will part of a multicenter audit and anonymized data will be sent for central collation via secure nhs.net email addresses.
4) Forward approval to ….
## 15.3. Appendix 3 Site Specific Questionnaire

### SITE SPECIFIC QUESTIONNAIRE (SSQ)

<table>
<thead>
<tr>
<th>HOSPITAL NAME</th>
<th>CONSULTANT LEAD</th>
<th>TRAINEES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Is there a single nominated team that looks after patients with acute pancreatitis in your hospital?**

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**What is the name of the team?**

…………………………………………

**What biochemical test do you use for the diagnosis and what is the upper limit of normal (IU/ml)?**

<table>
<thead>
<tr>
<th>Amylase</th>
<th>Lipase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Which investigations/treatment options are available in your hospital?**

<table>
<thead>
<tr>
<th>CT</th>
<th>MRCP</th>
<th>ERCP</th>
<th>Interventional radiology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Available 24 hours</td>
<td>Monday-Friday daytime</td>
<td>7 days/week with on call rota</td>
<td>No list on site</td>
</tr>
<tr>
<td>Daytime only</td>
<td>Specific days</td>
<td>7 days/week daytime</td>
<td>7 days/week with on call rota</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Monday-Friday daytime</td>
<td>7 days/week daytime</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Specific days</td>
<td>Monday-Friday daytime</td>
</tr>
</tbody>
</table>

**Do you perform emergency laparoscopic cholecystectomies as 1st line treatment?**

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Which subspecialties perform “hot gallbladders”?**

…………………………………………

**What are your tertiary referral centres?**

How far away are they from your centre?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
15.4. Appendix 4 Audit Consort diagram

**Study Period**
Acute pancreatitis 1st November to 30th April 2015

**Excluded**
- Chronic Pancreatitis
- <18 years old
- Acute exacerbation of existing pancreatitis
- More than 1 case of previous alcohol related pancreatitis

**Data Collection**
Index Admission
1st November 2014 to 28th February 2015

**Follow-Up**
Follow Up
1st March 2015 to 30th April 2015

**Analysis**
Central Analysis
May 2015
### Appendix 5 Modified Marshall Scoring System for Organ Dysfunction

Adapted from Banks et al [16].

<table>
<thead>
<tr>
<th>Organ system</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory (Pao2/Fio2)</td>
<td>0</td>
</tr>
<tr>
<td>Respiratory (Pao2/Fio2)</td>
<td>&gt;400</td>
</tr>
<tr>
<td>Renal*</td>
<td>≤134</td>
</tr>
<tr>
<td>(serum creatinine, μmol/l)</td>
<td>&lt;1.4</td>
</tr>
<tr>
<td>Cardiovascular (systolic blood pressure, mm Hg)*</td>
<td>&gt;90</td>
</tr>
</tbody>
</table>

For non-ventilated patients, the Fio2 can be estimated from below:

<table>
<thead>
<tr>
<th>Supplemental oxygen (l/min)</th>
<th>Fio2 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room air</td>
<td>21</td>
</tr>
<tr>
<td>2</td>
<td>25</td>
</tr>
<tr>
<td>4</td>
<td>30</td>
</tr>
<tr>
<td>6–8</td>
<td>40</td>
</tr>
<tr>
<td>9–10</td>
<td>50</td>
</tr>
</tbody>
</table>

* A score for patients with pre-existing chronic renal failure depends on the extent of further deterioration of baseline renal function. No formal correction exists for a baseline serum creatinine ≥134 μmol/l or ≥1.4 mg/dl.

10 All inotropic support.

A score of 2 or more in any system defines the presence of organ failure.
15.6. **Appendix 6 Hospital registration form**

Please return to …… by 10\textsuperscript{th} October 2014

PanWessex – Registration Form

<table>
<thead>
<tr>
<th>Name of Hospital</th>
<th>YES / NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant Supervisor</td>
<td></td>
</tr>
<tr>
<td>Trainee</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Confirmation of audit approval attached</th>
<th>YES / NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completion of baseline site specific questionnaire</td>
<td>YES / NO</td>
</tr>
</tbody>
</table>