Acute Pancreatitis Study

Study protocol

Study Advisory Group

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Mr Murali Partha	Surgeon (joint proposer of study), Ipswich
Dr Stephen Pereira	Gastroenterologist, London
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Dr Pat Twomey	Chemical Pathologist, Bury St Edmunds
Ms Marion Thompson	Lay Rep

NCEPOD Clinical Coordinators

Mr Martin Sinclair	Consultant General Surgeon, Ipswich
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NCEPOD Non clinical staff

Dr Marisa Mason	Chief Executive
Dr Neil Smith	Deputy Chief Executive
Miss Kathryn Kelly	Researcher
Miss Donna Ellis	Administrative Officer

Introduction

The incidence of acute pancreatitis (AP) ranges from 150 to 420 cases per million populations in the UK. Gallstones and alcohol account for the majority (50% and 25 % respectively) and the rest are caused by a variety of other causes. A minority are being labelled as idiopathic, where no obvious cause is identified.

In order to determine the aetiology and severity, further investigations and imaging are necessary. Patients with severe pancreatitis are at significant risk of death, usually secondary to organ failure and should be managed in a HDU/ITU setting. However, the patient's condition, their co-morbidities and availability of resources such as HDU/ITU, radiology, endoscopy, operative skills, tertiary centre access etc may have a bearing on the patient's overall outcome.

Patients diagnosed with acute pancreatitis secondary to gallstones should have definitive surgical or endoscopic treatment of gallstones (cholecystectomy / ERCP) during the index admission or planned within two weeks of discharge. Delay in treatment carries the possibility of recurrent acute pancreatitis and complications and is associated with a higher mortality. Recurrence rate of biliary pancreatitis is 61% and the mortality for severe pancreatitis is 14%-25%. However definitive gallstone treatment may not be feasible within 2 weeks due to lack of resources and these patients may present with recurrent pancreatitis leading to higher morbidity and mortality as well as resource implications.

These patients are an extremely high risk group with significant morbidity and mortality. There are aspects of care that if not adhered to can result in death and suffering for patients.

Aims and Objectives

Aim

The aim of the study is to identify the remediable factors in the quality of care provided to patients treated for acute pancreatitis.

Objectives

Based on the issues raised by the expert group, the objectives of this study are to collect information on the following:

- Initial resuscitation and treatment
- Criteria to determine severity of acute pancreatitis

- The appropriateness of investigation request pattern and ITU support requests
- Timeliness of transfer to HDU/ITU
- Appropriateness of ERCP
- Timeliness of gallstone treatment (Laparoscopic cholecystectomy or ERCP)
- Timeliness of transfer to a tertiary centre
- Radiological imaging and intervention
- Use of step-up care / timing of interventions
- Inequalities in treatment
    - Secondary vs Tertiary
    - Geographical
- Appropriateness of antibiotic usage
- Networks, formal/informa
- Discussion at MDTs and presence of clinical leads

Methodology

Population / Inclusions

Patients aged 16 years or older that were coded for a primary diagnosis of Acute Pancreatitis and admitted to hospital between 1st January 2014 and 30th June 2014 inclusive. The included ICD10 codes are:

K85.0	Idiopathic acute pancreatitis
K85.1	Biliary acute pancreatitis
K85.2	Alcohol induced acute pancreatitis
K85.3	Drug induced acute pancreatitis
K85.8	Other acute pancreatitis
K85.9	Acute pancreatitis, unspecified

Exclusions

None

Case identification/patient

Local Reporters will be asked to complete a predefined spreadsheet listing all patients that meet the inclusion criteria. Details on any procedures performed (OPCS codes), admission to level 2 / 3 care, previous inpatient episodes for acute pancreatitis and details of the discharging clinician will also be collected. A group of patients admitted to level 2 / 3 care as well as a group who were not admitted will be included to allow assessment of different aspects of care.

Sample size

A sample size of approximately 500 patients will be selected from the identified patients for clinician questionnaire dissemination and case note review. The number of cases included will be limited to a maximum of five per hospital.

Method of data collection

Spreadsheet

As above, cases will be identified using a data collection spreadsheet. This will identify all patients meeting the study inclusion criteria, and include the patient's NHS number, date of birth, diagnosis codes (ICD10), procedure codes (OPCS), admission and discharge dates and the name of the discharging consultant.

Clinical questionnaire

A questionnaire will be sent to the consultant who was responsible for the patient's care at the time of discharge. This will collect data around the objectives listed above.

Casenotes

Photocopies of the case notes of each included patient will be requested at the time of questionnaire dissemination. A list detailing the required case note extracts will be included with each questionnaire.

Organisational questionnaire

An organisational questionnaire collecting information regarding facilities, equipment, policies and guidelines relevant to the management of patients with AP will be sent to the NCEPOD Local Reporter. We ask that the Local Reporter liaise with the relevant person(s) that can accurately complete the questionnaire.

Participating sites

Data will be collected from all hospitals in England, Wales, Northern Ireland, the Channel Islands and the Isle of Man. Scotland is not included but Scotland will be made aware of the work through links with the Scottish Audit of Surgical Mortality, with whom NCEPOD has excellent links. Data will be collected from NHS and large independent sector hospital groups, as well as many of the smaller private hospitals.

Pilot Study

A pilot study will be undertaken prior to ensure the data collection methods and questionnaires are robust.

Review of cases and analysis

Case reviewers

A multidisciplinary group of healthcare workers will be recruited to review the data and to provide expert opinion on the process of care and management of patients who have been diagnosed with acute pancreatitis.

Assessment form

For each case included in the peer review the case reviewers will be asked to complete a questionnaire outlining details of the case and giving their opinion on the quality of care provided to the patient.

Analysis

Questionnaire data will be electronically scanned into a preset database. Data will be analysed quantitatively and qualitatively

Confidentiality and data protection

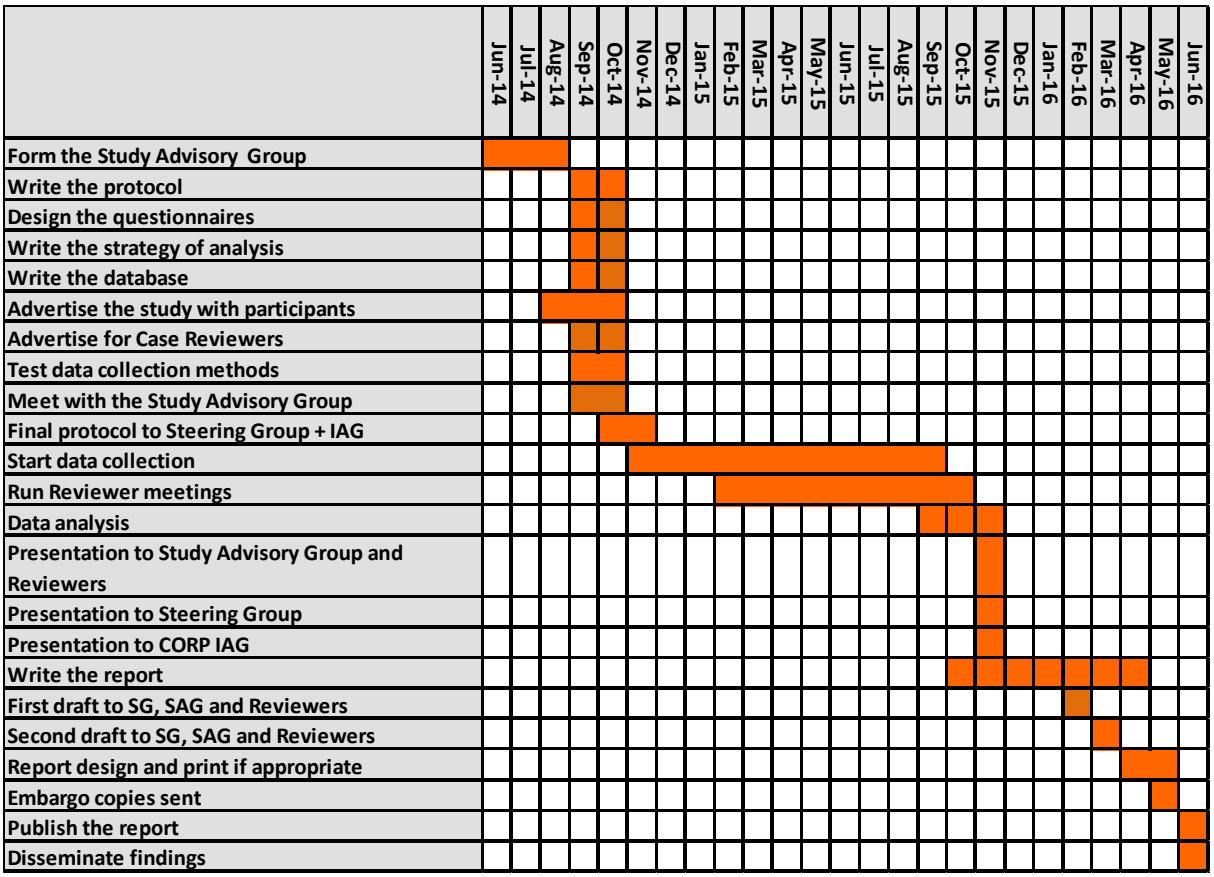
Once the data have been extracted by the NCEPOD researchers, the questionnaires and casenotes will be anonymised to remove patient identifiers prior to review by the Advisory Group.

All electronic data are held in password protected files and all paper documents in locked filing cabinets. As soon as possible after receipt of data NCEPOD will encrypt electronic identifiers and anonymise paper documents. Section 251 approval has been obtained to perform this study without the use of patient consent.

Dissemination

On completion of this study a report will be published and widely disseminated.

Timescale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Form the Study Advisory Group
Write the protocol
Design the questionnaires
Write the strategy of analysis
Write the database
Advertise the study with participants
Advertise for Case Reviewers
Test data collection methods
Meet with the Study Advisory Group
Final protocol to Steering Group + IAG
Start data collection
Run Reviewer meetings
Data analysis
Presentation to Study Advisory Group and Reviewers
Presentation to Steering Group
Presentation to CORP IAG
Write the report
First draft to SG, SAG and Reviewers
Second draft to SG, SAG and Reviewers
Report design and print if appropriate
Embargo copies sent
Publish the report
Disseminate findings