Pleural Procedures (Chest drains)

Study protocol – June 2025

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Introduction

Diseases of the lining of the lung and the chest cavity, (the pleura) are common, and the demand for diagnosis and treatment is increasing. Removal of air or fluid from the pleural space can be done with a small needle (pleural tap), small tube (catheter) or a larger chest drain. More detailed exploration is possible with medical thoracoscopy or percutaneous pleural biopsy, which are specialist procedures.

Pleural interventions (especially chest drain insertion) have been associated with patient safety incidents frequently enough to have been the subject of a first patient safety alert in 2008 [1]
After identifying 12 deaths and 15 cases of severe harm in a three-year period, the 2008 alert set out best practice for chest drain insertion, in particular the need for consent, competent staff, supervision of the procedure and the importance of ultrasound in improving safety. It also highlighted the importance of learning from local incident reporting data. In 2020, another alert cited 16 further incidents of harm including two deaths and one cardiac arrest were identified following removal of fluid too rapidly via chest drains [2]. The British Thoracic Society (BTS) guidelines reinforce the recommendations in these alerts and recommend that pleural procedures for the removal of fluid should be done under ultrasound guidance [3].

There is however recent evidence that suggests very little has changed to reduce the number of patients harmed as a result of chest drain insertion. In 2022, an organisational audit by the BTS showed that 62% of hospitals (69/111 sites) reported a patient safety incident related to thoracic ultrasound and/or pleural procedures within the previous three years. A third of these incidents resulted in 'severe harm', and 20% resulted in 'catastrophic harm' or death. Out of hours, there were 63% of hospital sites without pleural disease management pathways and 53% without access to an emergency-level thoracic ultrasound operator. Concerns have also been raised regarding the training and experience of those tasked to deal with emergency out of hours pleural interventions. Urgent and emergency procedures performed out of hours are often done in the most complex and high-risk patients but are more likely to be done by less experienced staff [4].

A 2022 survey of members of the British Thoracic Society pleural specialist advisory group again revealed instances of harm from six trusts in England over the last two years[5]. There were 11 serious harm incidents described. These related to poor decision making, poor interpretation of chest imaging, inappropriate choice of pleural intervention, and similar patient harm to those described in the original safety alerts. Multiple examples of drains not properly secured and falling out and requiring further invasive procedures to re-site or replace are also reported and misplaced chest drains have been highlighted in a recent critical care safety bulletin [6]. If the survey results are extrapolated across the system, it would suggest that in just over 200 hospitals there would be as many as 370 incidences of serious harm over the same two-year period.

The NCEPOD Study will explore the patient pathway to include the indication for drainage, details of the operator and timing of the procedure (both appropriate and

inappropriate delays) as well as pre-procedure safety checks (including coagulation status), consent, use of ultrasound, correct use of equipment, and complications of the procedure. Organisational data will explore staff training, out of hours arrangements (which often vary depending on the size of hospital) and compliance with the recommendations of the two national patient safety alerts. Local incident reports and investigations will also be collected to ensure themes are identified and lessons are learned from local reporting systems.

1. NPSA Chest drains: risks associated with the insertion of chest drains. NPSA/2008/RRR003
2. Deterioration due to rapid offload of pleural effusion fluid from chest drains https://www.england.nhs.uk/2020/12/deterioration-due-to-rapid-offload-of-pleural-effusion-fluid-from-chest-drains/
3. Laws D, Neville E, Duffy J on behalf of the British Thoracic Society Pleural Disease Group, a subgroup of the British Thoracic Society Standards of Care Committee BTS guidelines for the insertion of a chest drainThorax 2003;58:ii53-ii59.
4. https://www.brit-thoracic.org.uk/media/455963/bts-pleural-service-organisational-audit-national-report-final-v2.pdf
5. Stanton AE, Juniper M, Bedawi E, McNaughton L, Clive AO, De Fonseka D, Aujayeb A, Evison M. Pleural procedural safety in the UK: is everyone's house in order? Reflections from the BTS National Pleural Service Organisational Audit and a national review of patient safety incidents. BMJ Open Respir Res. 2025 Mar 2;12(1):e002840. doi: 10.1136/bmjresp-2024-002840. PMID: 40024628; PMCID: PMC11877191.
6. FICM Safety Bulletin June 2025 https://www.ficm.ac.uk/sites/ficm/files/documents/2025-06/Safety%20Bulletin%20-%20JUNE%202025.pdf

Guidelines and standards

The updated British Thoracic Society (BTS) Pleural Disease guidance and the Clinical Statement on pleural procedures are the 2 standards to be covered in this study:

1. https://thorax.bmj.com/content/78/Suppl_3/s1
2. https://thorax.bmj.com/content/78/Suppl_3/s43.abstract

Aim and objectives

Aim

To identify areas for improvement in the quality of care for patients undergoing pleural procedures.
To review the incident investigations relating to 'pleural procedures (chest drains)' and associated lessons learned.
To identify patient safety incidents that have not been reported.

Objectives

Organisational issues

- Protocols, standards, safety procedures and the use of guidelines for chest drain insertion in the emergency department, acute medicine and critical care
- Training in chest drain insertion and the retention of skills, including the record/ monitoring of staff competency
- Record of staff competency re: chest drains insertion
- Access to ultrasound, recording/ preservation/sharing of images
- Audit of standards/guidelines
- Presence of a dedicated pleural service and access (hours/areas of the hospital)
- Mechanism for incident reporting and sharing of learning

Clinical issues

Data can be collected from the clinical questionnaire, the reviewer assessment form and clinician survey.

To explore and investigate areas for improvement in the following areas:

- The initial recognition of the need for a pleural procedure
- The decision-making process for chest drain insertion – experience/ specialty/ training of decision maker
- Consent for chest drain insertion
- Department / location of chest drain insertion
- Timing of procedure / Out-of-hours procedures/ delays
- Peri-procedure investigations (use of ultrasound), processes and care provided
- Procedure complications
- Post-procedural care (days following chest drain insertion)
- Documentation of the procedure

Methods

Inclusion criteria

Patients aged 18 and older who were admitted to hospital between 01/01/2024 and 31/12/2024 and had a chest drain inserted (OPCS code T12.0-T12.9) during their hospital stay will be included in the initial patient identification. Retrospective OPCS coding and/or ICD10 coding will be used to identify patients.

Exclusions

Trauma patients will be excluded as there is a different pathway and covered by the upcoming NCEPOD study on Rib fractures

Data sampling

Up to 8 patients per hospital will be selected for inclusion in the study.

Primary selection criteria: Patients admitted out of hours, including weekends; Patients admitted as an emergency will be selected as a priority (NB for hospitals with low numbers of patients identified, we will also include elective admissions). Where a clinical incident has been reported, these patients will be selected in up to 50% of cases from each hospital's selection.

Participating providers of healthcare

Data will be collected from all hospitals in England, Wales, Northern Ireland and Jersey, which admit and treat patients who require insertion of chest drains (including independent hospitals where applicable).

Incidence and prevalence

Table 1: HES data: Number of admissions for relevant ICD10 codes related to pleural procedures

ICD10	Description	Number of admissions 22/23	Median LOS	Emergency admissions
J86	Empyema	486	7.5	394
J930	Spontaneous tension pneumothorax	433	6	375
J931	Other spontaneous pneumothorax	3,660	4	2,975
J938	Other pneumothorax	675	4	442
J939	Pneumothorax, unspecified	3,573	3	2,473
J90	Pleural effusion	24,387	3	13,728

Scoping exercise

Early scoping work has identified 3569 patients from 9 Trusts/Health Boards over a 12 month period. This is an average of 394 per Trust/Health Board per week (range, 151-827). 320 /3569 were identified as having an incident reported. Based on data returns from 125 Trusts/Health Boards, this would identify approximately 49250 patients in 12 months for inclusion in the study.

Study promotion

Prior to data collection, NCEPOD will contact all hospitals providing care to this group of patients. The study will also be promoted via NCEPOD Local Reporters (sending the study

poster on to the relevant departments), the relevant Colleges and Associations, and any relevant patient groups and third sector organisations.

Study method test
The data collection methods and data collection tools will be tested to ensure they are robust before the full study is run.

Methods of data collection

There will be five main methods of collecting data for the study:

1. Patient and carer views will be collected through an online anonymous survey. We will work with Local Reporters, study contacts and relevant charities to encourage involvement.

2. Clinician views will be collected through a collaboration with the pleural team at Guys and St Thomas's NHS Foundation Trust, who are running a nationwide survey of confidence and competence in chest drain insertion (very similar to the planned clinician survey by NCEPOD). There is agreement to share the data from this survey and we will work with the NCEPOD Local Reporters and study contacts to encourage maximum involvement of clinicians in this.

3. An organisational questionnaire will be sent to all hospitals where patients requiring chest drain insertion might present (including independent hospitals).

4. Clinical data collection – retrospective data collection: For a sample of patients, a questionnaire will be sent to the clinician responsible for the patient at the time of discharge (clinician questionnaire).

5. Case note review: Copies of selected extracts of case notes will be collected for peer review. For patients who have clinical incidents reported, the report and investigating manager's response will also be collected.

Further details on the methods of each method of data collection are given below.

1. Anonymous online patient survey
The survey will gather data on the patient/ carer views of the services available to them and their experience of chest drain insertion. It will also collect information about support services and information they were provided. The data will not be linked to any other aspects of data collection. We plan to ask respiratory teams to pass the survey link on to patients who are attending for recurrent drainage so they can answer questions on prior acute care received.

2.Anonymous online clinician survey
The survey will gather data on clinician views of the services available for them to provide care to patients who require chest drain insertion. It will also collect information around confidence, competency, training and support available when providing care to this group of patients. As mentioned above, for this part of the study we will collaborate with the Pleural team at Guys & St. Thomas's NHS Foundation Trust who are currently running a survey nationwide that will look at this. The data will not be linked to any other aspects of data collection.

3. Organisational questionnaire

Data will be collected at a hospital level and will collect information around decision making tools, the organisation of services, protocols and pathways of care, networks of care, transfer arrangements, staffing arrangements, the appropriateness of care settings, the availability of equipment, diagnostics and radiology, the availability of information, training, and audit and data collection. An organisational questionnaire will be sent to all participating hospitals (NHS and independent) via the online questionnaire system.

4. Clinical data collection – retrospective data collection

Patient identification

The Local Reporter will be asked to complete the patient identification spreadsheet with the details of all patients who were admitted/ attended ED during the study timeframe and had a pleural procedure (from listed OPCS codes, table 2).

Table 2: Included OPCS codes

Procedure	OPCS CODE
Puncture of pleura	T12.0
Drainage of lesion of pleura NEC	T12.1
Drainage of pleural cavity NEC	T12.2
Aspiration of pleural cavity	T12.3
Insertion of tube drain into pleural cavity	T12.4
Attention to tube drain into pleural cavity	T12.5
Insertion of tunnelled catheter into pleural cavity	T12.6
Attention to tunnelled catheter in pleural cavity	T12.7
Other specified	T12.8
Unspecified	T12.9

The data fields requested will include NHS number, hospital number, date of birth, sex, ethnicity, date and time of admission, source of admission, ICD10 codes, OPCS codes, time of procedure, discharge destination, date of discharge, clinician code and specialty for the consultant responsible at the time of discharge, whether there was an incident reported for that admission and the level of harm reported.

Clinician questionnaires

A clinician questionnaire will be used to collect clinical data that may not be found in the case notes for this study. It will have key questions about the care this patient received before, during and after the insertion of their chest drain. Clinician questionnaires are to be completed by the consultant responsible for the patient at time of discharge via the NCEPOD online questionnaire portal.

Questionnaires will be sent to the NCEPOD Local Reporter for dissemination via the online questionnaire system. A reminder will be sent at six weeks and ten weeks where the data is outstanding. Up to 8 patients per hospital will be sampled for inclusion in the study.

5. Case note review

Photocopied/ scanned case note extracts will be requested for each patient included in the study sample.

Notes requested will include:

- Ambulance patient report form
- Emergency department clerking
- Medical from /admission to admission to discharge
- Nursing notes from /admission to admission to discharge
- Imaging reports
- Observation charts (including fluid balance charts re: offloading pleural fluid (and note where absent)
- Consent forms (should be in medical notes but would state specifically)
- Investigation results
- Drug charts
- Discharge summary
- Incident report
- Investigating manager's response

Upon receipt at NCEPOD the case notes will be redacted if not already done so prior to sending.

Reviewer assessment form

A multidisciplinary group of reviewers (detailed below) will be recruited to assess the case notes and questionnaires and provide their opinion on what went well and what did not go well during the process of care via the reviewer assessment form.

Table 2 summarises the data sources for significant points along the pathway.

Area of enquiry	**Method of data collection**	**Confidentiality**
Acute care	Case notes, clinician questionnaire, organisational questionnaire	Identifiable
	Online clinician survey	Anonymous

Sample Size

Data source	**Target number**
Organisational questionnaire	~250
Clinician questionnaires	Up to a maximum of 8 per hospital
Case note review	Up to a maximum of 8 per hospital
Clinician online survey (non-identifiable)	300
Patient survey	Up to 100

Analysis and Review of Data

Reviewers

A multidisciplinary group of reviewers will be recruited to assess the case notes and questionnaires and provide their opinion on what went well and what did not go well during the admission.

- Acute physicians
- Advanced nurse practitioner/ advanced clinical practitioners
- Anaesthetists
- Cardiothoracic surgeons
- Critical care physicians
- Emergency medicine clinicians

- General nurses
- General physicians
- Radiologists
- Respiratory physicians
- Resident doctors

An advertisement will be sent to Local Reporters to disseminate throughout the relevant departments. It will also be placed on the NCEPOD website and social media channels. Successful applicants will be asked to attend a training day where they will each assess the same two cases to ensure consistent assessment. A number of meeting dates will be arranged, and each reviewer will then be asked to attend a minimum of a further 4 meetings. NCEPOD staff will ensure there is a mix of specialties at each meeting from across the UK. Each meeting will be chaired by an NCEPOD clinical coordinator who will lead discussion around the cases under review. The meetings will either be held in person in the NCEPOD office, or over Microsoft Teams with secure and temporary access to the case notes for review (not downloadable or printable by the case reviewer). Towards the end of the study the reviewers will be invited to attend a meeting where the data will be presented to and discussed with them. The reviewers will also be sent two copies of the draft report for their comment as this is developed.

Confidentiality and data protection

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 in England and Wales.

Ethical approval will not be required to undertake this study. Duty of candour is covered by the NCEPOD Cause for Concern policy, which ensure that any cases reviewed as less that satisfactory and as a cause for concern are discussed and action taken where required.

Study outputs

On completion of the study a report will be published and widely disseminated to all stakeholders to encourage local quality improvement (QI) (further details available in the communication plan). In addition to the report, supporting tools will be made available including:

- A summary report and summary sheet
- A patient information leaflet
- Infographics
- The recommendation checklist
- An audit tool
- A slide set
- A guide for commissioners
- Quality improvement tools
- Useful links

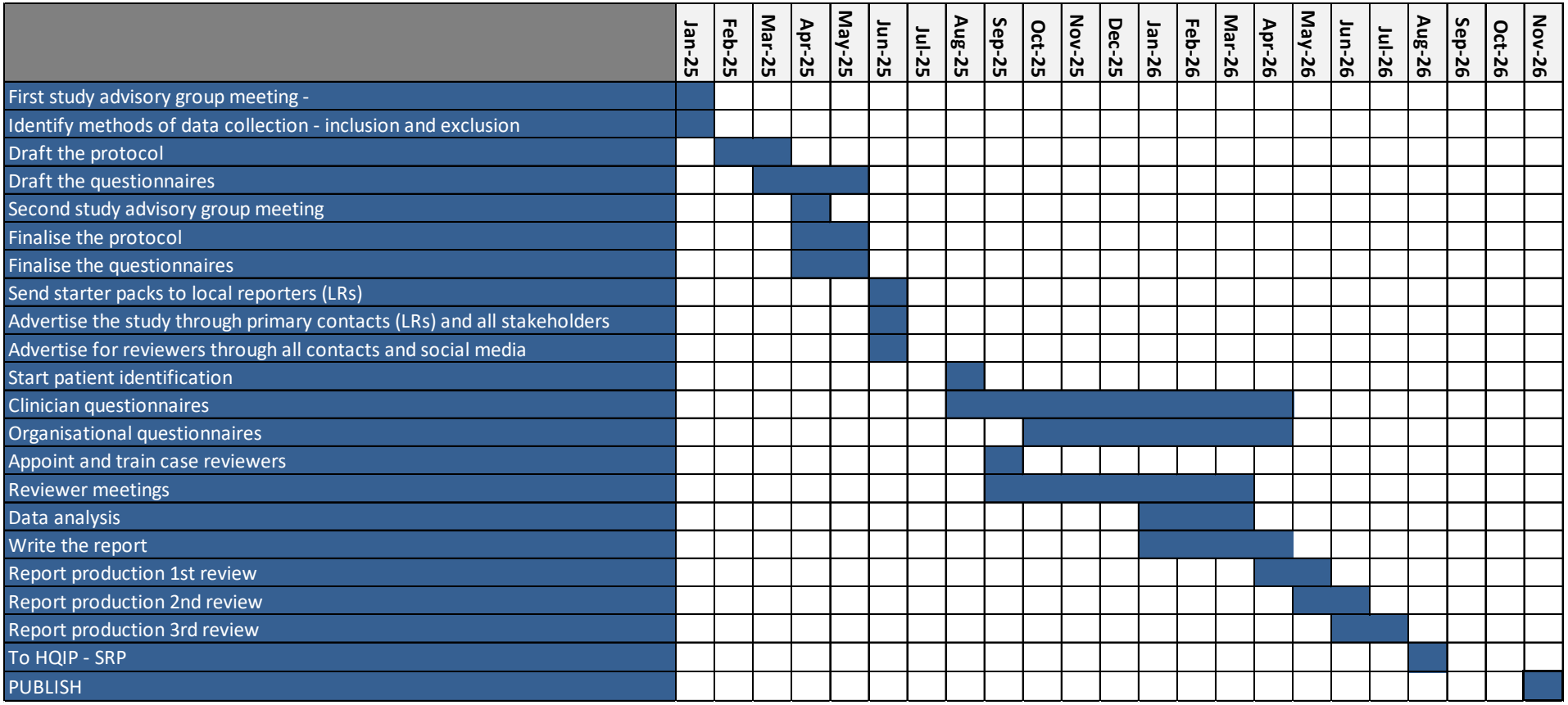
Examples of good practice will be shared, and additional QI tools will be developed where appropriate. Key messages from the report will be shared via social media.

Following publication, the report findings will be shared at national and local conferences, study days and other events; and papers submitted to journal for consideration for publication.

Data sharing

Post publication of the study there is the potential to share anonymised data sets with interested parties working in the same field. This will be undertaken following a strict process and will ensure the data does not become identifiable in their nature due to small numbers.

Timescale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First study advisory group meeting -
Identify methods of data collection - inclusion and exclusion
Draft the protocol
Draft the questionnaires
Second study advisory group meeting
Finalise the protocol
Finalise the questionnaires
Send starter packs to local reporters (LRs)
Advertise the study through primary contacts (LRs) and all stakeholders
Advertise for reviewers through all contacts and social media
Start patient identification
Clinician questionnaires
Organisational questionnaires
Appoint and train case reviewers
Reviewer meetings
Data analysis
Write the report
Report production 1st review
Report production 2nd review
Report production 3rd review
To HQIP - SRP
PUBLISH