



British Thoracic Society
National Safety Standards for Invasive
Procedures (NatSSIPs)
Bronchoscopy and Pleural Procedures

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Appendices

Appendix 1 – Flexible Bronchoscopy Checklist

Appendix 2 – Pleural Procedures Checklist

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1. Background

In 2015 the National Safety Standards for Invasive Procedures (NatSSIPs) were published with the aim to standardise, harmonise and educate¹. The document was written with input from a number of relevant healthcare bodies including the Care Quality Commission, General Medical Council, Association for Perioperative Practice and Royal Colleges. The NatSSIPs build on the national learning from near misses, harm and never events² to provide a universal tool in the prevention of harm from invasive procedures conducted in hospitals.

2. Purpose of this document

This document has been written to address the need for NatSSIPs guidance on respiratory procedures and should be used to inform and harmonise the Local Safety Standards for Invasive Procedures (or LocSSIPs) which are required for every hospital which practices these interventions. The aim of this document is to summarise a series of organisational standards and sequential steps as applied to common Respiratory Invasive Procedures, and thereby provide a structure and guidance on the important principles of LocSSIPs.

This document is focussed on the following procedure areas:

- **Pleural interventions** – pleural aspiration, chest drains, pleural biopsy, local anaesthetic (or “medical”) thoracoscopy and indwelling pleural catheters.
- **Diagnostic bronchoscopy** – including flexible bronchoscopy and endobronchial ultrasound bronchoscopy or EBUS.

The guidance in this document is generic – each individual hospital will need to carefully assess its own staffing, procedure capability and resources to create a suitable and applicable LocSSIPs document.

This document will detail some of the generic principles from the NatSSIPs document and then indicate specific guidance for Pleural and Bronchoscopic procedures.

3. Definitions and Responsibilities

An invasive procedure is defined as:

- Any procedure where a hole is made in the patient’s body or a body cavity is accessed and
- Where consent is required

The definition excludes peripheral venous cannulation, urinary catheter insertion and blood tests.

It is made clear in the NatSSIPs document that it is everyone’s responsibility to meet the standards laid out. Never events, near misses and preventable harm need to cease, and the overriding aim of the NatSSIPs / LocSSIPs process is to re-shape the way interventional procedures are done to minimise harm.

¹ NHS England Patient Safety Domain. National Safety Standards for Invasive Procedures. 2015. <https://improvement.nhs.uk/resources/national-safety-standards-invasive-procedures/> (accessed 26.11.18)

² NHS England Patient Safety Domain. Report of the NHS England Never Events Taskforce. 2014. <http://www.england.nhs.uk/wp-content/uploads/2014/02/sur-nev-ev-tf-rep.pdf> (accessed 26.11.18)

4. Areas of application

As the purpose of the NatSSIPs / LocSSIPs process is to ensure safe and effective delivery of invasive procedures to ALL patients undergoing the specified procedures, it is important to appreciate that the guidance should apply in all clinical areas in which such procedures might occur.

For pleural procedures this might include (varying according to local hospital arrangements):

- Emergency Departments
- Medical wards
- Surgical wards
- The Intensive Care Unit*
- Radiology departments
- Outpatient departments
- Surgical theatres*
- Endoscopy theatres*
- Respiratory Intervention suites / rooms*

*For bronchoscopy and EBUS, this is likely to include only the starred areas above.

5. Indications for use of LocSSIPs

The standards set out in LocSSIPs documents should apply to all patients undergoing bronchoscopy and pleural procedures. The exception to this is in emergency procedures in a life threatening situation, where immediate intervention is required, and any delay would result in harm to the patient. This applies to pleural procedures in particular and for a rare number of cases of bronchoscopy; for example, acute tension pneumothorax which requires immediate intervention. In such cases of life-threatening emergency requiring urgent intervention, it is likely that much of the LocSSIPs guidance may not apply. A LocSSIPs document should reflect the importance of conducting urgent procedures in the best interests of the patient in particular (and thankfully rare) situations.

6. Governance

Good governance results in the delivery of safer care and this can be summarised by the following principles:

- Accountability
- Responsibility
- Organisational culture
- Good record keeping
- Team education / training
- Audit of practice

To apply these principles to the NatSSIPs / LocSSIPs process directly:

- Each team member is responsible for delivery of safe care.
- Team members should be given the opportunity to make suggestions / improvements to LocSSIPs documents.
- Effective teamwork in a supportive environment makes patient care safer – thus any member of the procedural team should feel confident to express concerns about patient safety at any time during the procedural pathway.

- Continuous safety improvements depend on continuous audit of outcome and compliance with safety standards.
- Adverse patient events and near misses should be reported through the suitable local incident reporting system.
- There should be a “no blame” culture of transparency, and all such incidents should be discussed at Audit / Clinical Governance meetings as locally appropriate.
- Learning points of incidents if applicable should be disseminated within the Trust.

7. Documentation

Good documentation is key to effective implementation of standards. This includes the use of “checklists” to ensure safety (please see later) and an accurate procedure record, all of which promote important steps in the pre-procedural, procedural and post procedural pathway. In order to accurately record and audit adverse incidents and near misses good documentation is essential.

The procedure record should include details of (at least):

- The intervention conducted
- Use of local anaesthesia, sedation and other medication (which may require prescription)
- The recovery plan and observations required post procedure
- Any immediate complications

8. Scheduling

A procedure should be in place to appropriately schedule patients for procedures. This process should take account of the clinical need (e.g. symptomatic, cancer pathway related) and the available procedure capacity.

In general, for all invasive procedures elective scheduling is preferable (rather than out of hours procedures) where this is clinically appropriate. For pleural procedures specifically, a local protocol should be in place to triage patients to the most appropriate intervention and timing (for example, elective aspiration for symptomatic pleural effusion, rather than emergency drain insertion). Out of hours pathways with a clear escalation policy to appropriately trained operators and clinicians with the appropriate knowledge base to guide whether a procedure is appropriate in the out of hours setting is recommended. These will vary depending on local resources and infrastructure but there should be a hospital policy, easily accessible with those named with specific roles within such a pathway aware of their duties.

9. Workforce

It is essential for safe patient care that all members of the team performing an invasive procedure have appropriate skills and experience. This was highlighted in the National Patient Safety Agency recommendation after evidence of serious harm from pleural procedures, which encouraged practitioners to consider the following issues (applicable to both bronchoscopy and pleural procedures):

- Does this need to be done as an emergency – can it wait?
- Do I need to do this?
- Have I enough training to feel confident to do this?
- Are senior staff to hand?
- Am I familiar with the equipment?

- (For pleural procedures) Is ultrasound available, with trained* staff?

*Competence and training in thoracic ultrasound will not be specified in detail here, but this training should at minimum require an individual to have a national recognised qualification for independent practice in thoracic ultrasound. For example, the current Royal College of Radiology Competence Level I training, or Focussed Ultrasound Training. Training guidance is available at:

- https://www.rcr.ac.uk/system/files/publication/field_publication_files/bfcr173_ultrasound_training_med_surg.pdf
- https://www.rcr.ac.uk/system/files/publication/field_publication_files/BFCR%2812%2918_focused_training.pdf

The British Thoracic Society is currently developing a thoracic ultrasound training document for respiratory physicians in the UK, and once this work is completed, it will be referenced here.

There are well established training guidelines in pleural and bronchoscopic procedures, which are in general competency (rather than numbers based) and will not be repeated here. However, the main principles for staffing and skills are:

Pleural Procedures:

- A trust induction programme should be provided to all new operators in pleural procedures which covers the out of hours pathways and escalation policies, other relevant hospital policies (e.g. checklist documentation, sedation policy) and trust-specific kit. This also provides an opportunity for review of competency in a clinical skills type environment and a local accreditation process.
- Trusts require reliable and timely access to appropriate training programmes for any clinicians identified as requiring more training to complete the criteria for local accreditation. This may be informal on-site training, dedicated local training courses or linked to an external training course.
- The use of thoracic ultrasound is mandatory in all cases where fluid is being drained / accessed. An ultrasound competent practitioner must be involved in the procedure (although does not necessarily have to conduct the procedure).
- Healthcare professionals (HCPs) conducting pleural procedures should be appropriately trained and these training standards defined locally.
- Only operators who have been “signed off” as competent for independent practice should be recognised as “trained” (according to local standards, whether applied locally or regionally).
- Pleural procedures undertaken by HCPs who are not recognised as competent should be supervised by an HCP who is appropriately trained.

Bronchoscopy:

- A trust induction programme should be provided to all new operators in bronchoscopic procedures which covers the department, local consent process and relevant hospital policies particularly focusing on the local sedation policy.
- Healthcare personnel expected to conduct bronchoscopy should be suitably trained until considered competent.
- Only operators who have been locally “signed off” as competent for independent practice should be recognised as “trained” (according to local standards).
- Bronchoscopy undertaken by HCPs who are not recognised as competent should be supervised by an HCP who is appropriately trained.

General

- A procedure can only start when the minimum number of staff with the correct skill mix to maintain patient safety are present. This should be defined in the LocSSIPs document according to local standards, and include (as required) consideration of staff in the procedure room and recovery.
- Suggested staffing levels are included in the specific guidance on pleural procedures and bronchoscopy at the end of this document.
- Nurses / HCPs / doctors assisting in an invasive respiratory procedure or providing care for patients post procedure should be suitably competent. This includes recognition of complications, clinical deterioration and knowledge of next steps (even if this is only to contact a team member).
- Emergency protocols and members' roles within an emergency situation should be clearly defined and agreed, the latter at the beginning of every procedure.
- Staff should practise within their limits and competencies or, if training, under the supervision of their mentor or senior.
- Local standards should specify the minimum number of staff (including practitioner, support staff and recovery staff) required for a procedure to be conducted.

Staff present pre-operatively, during the procedure and post-operatively should be recorded for audit and traceability. If this changes during the procedure, this should be documented with the time of the change. Trainees and students should be clearly identified and supervised with a designated mentor for the shift.

10. Pre-procedure

Consideration should be given as to the correct environment in which to conduct a procedure.

Suggested Procedure room requirements

Pleural Procedures

Suggested requirements include the following and consideration of sufficient floor space:

- Scrubbing facilities / sink which should be in the room
- Sufficient space and presence of an ultrasound machine
- Sterile trollies (number dependant on procedure to be conducted) and space for sample initial processing
- Oxygen supply and suction
- Sufficient space for monitoring equipment
- Access to the crash trolley with availability of an advanced life support (ALS) trained individual
- Consideration of safe equipment storage both during and after procedures.

Bronchoscopy

Suggested requirements include the following and consideration of sufficient floor space:

- Sufficient space and presence of the bronchoscopy stack and all associated equipment
- Sterile trollies (number dependant on procedure to be conducted) and space for sample initial processing
- Oxygen supply and suction
- Access to the crash trolley with availability of an ALS trained individual
- Consideration of safe equipment storage both during and after procedures.

Pre-procedure patient checks

On the day of the procedure, a number of checks may be required, for example:

- Anti-coagulations / anti-platelet therapy
- Presence of diabetes / use of diabetic medication
- Other medication
- Fasting status of the patient
- Home situation (who will stay with the patient overnight and availability of a suitable escort or appropriate travel arrangements if sedation used)
- Blood tests: coagulation, platelets
- Imaging
- Allergy status
- Full set of observations

Consent:

Where possible (i.e. for elective work especially), information on the procedure suitable to patients should be sent to patients to read in their own time, which aids the consent process. The consent procedure should be standardised and following GMC guidance on consent (<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/consent>), with those taking consent either specifically trained in this area, or able to perform the procedure. A locally agreed and standard set of expected complications and frequencies should be used where possible for the consent process. Procedures for suitable consent in those lacking capacity should be present.

11. Procedural Checklists

The use of checklists prior to procedures has been shown to reduce harm and complications. The use of a safety checklist (such as the WHO checklist) should be undertaken prior to the start of any procedure and should include “sign in” “time out” and “sign out” steps (the first two steps are often combined for non-general anaesthetic procedures).

Individual hospitals will need to create suitable local checklists. Example checklists are included as appendices to this document:

Appendix 1 – Flexible Bronchoscopy Checklist

Appendix 2 – Pleural Procedures Checklist

Trusts are welcome to adapt the appendices to local requirements. Each document contains details of the authors and/or source organisation – please acknowledge the authors/source in any materials produced using these appendices.

The main principles for procedural checklists are as follows.

Sign In

- **The process should read out loud.**
- **Key important patient factors to document include:**
 - Side / site of intended procedure
 - Verification of patient name and checked against identity band
 - Review of the consent form
 - Review all applicable radiology

- Allergy review
- Review of the risk of bleeding / other risks (such as sedation)
- Marking the site for the procedure if appropriate
- Key observations / function of monitoring equipment
- **Key important procedure factors to document include:**
 - Checks of monitoring equipment / ultrasound equipment
 - Other safety considerations (patient position / pre-medication given)
- **Patient involvement should be encouraged** where possible.
- **All members of the interventional team must be present in the room for the checklist.** These staff members must not leave the room until sign out at the end of the procedure and no other staff members can enter unless under special circumstances, for example staff change overs.
- **Sign in must occur before any procedure starts.** All patients having an invasive procedure must undergo the sign in.
- **Key parts of the procedure should be dependent on the checklist** – e.g. Controlled medications must not be given in the procedure room if the checklist has not been completed.
- **The interventional practitioner and the designated nurse must check the medications before use.**
- **Provisions should be made for those patients who cannot speak English or have special requirements,** for example the help of an interpreter or someone trained in sign language.
- **Any issues should be raised and addressed before the procedure starts,** and should be documented both in the patient notes and on the checklist.

Sign Out

- **Must be completed at the end of a procedure.**
- **Must be announced out loud before the interventional practitioner leaves the room.**
- **All team members must be present.**
- **The interventional practitioner must verbally confirm the name of the procedure and the site and side** as the procedure may have been altered or expanded. This must be recorded on the checklist, patient notes / electronic report and on the report.
- **The count and correct label of specimens must be confirmed.**
- **Recovery management** should be discussed, including aftercare, x-rays and oxygen use.
- **Equipment issues should be communicated and documented.**
- **The procedural report must be completed by the interventional practitioner** as soon as feasible. This and the patient's medical notes must be removed from the procedural room before the next patient enters.
- **Medications used must be accurately signed for and checked** by both the intervention practitioner and the designated staff nurse.
- **Disposal of equipment** must be confirmed – especially guidewires and sharps.

12. Retained Foreign Objects

Accurate counting and reconciliation must be completed for all items during a procedure, as specifically detailed in NatSSIPs guidance. Items must be counted as used and **clearly displayed** and **clearly documented** in the procedure record.

Items to be counted and reconciled include all needles, guidewires, scalpels, sutures (and swabs in some cases).

13. Handover

Post respiratory procedures, there should be a formal handover from the procedure team to the post procedure team caring for the patient. This should include:

- Suitable patient identification
- Actual procedure undertaken
- Post-operative management plan including:
 - Frequency of observations
 - Rate of drainage of fluid (for pleural procedures)
 - Use and definition of suction (for pleural procedures)
 - Actions required for any specimens taken during the procedure
 - Analgesia regimen
 - Additional medications including antibiotics
 - Complications encountered during procedure and interventions to correct them
 - Further investigations required (such as chest x-ray)
 - Person to contact in case of deterioration

14. Debrief

Debriefing is essential for continued improvement within procedure units and improves team communication. This process should involve the whole team who took part in the procedure and can be conducted at the end of a list or case-by-case.

Key elements of the debrief include:

- Things that went well
- Things that went poorly
- Areas for improvement
- How the team can change / adapt processes if required.

It is encouraged to keep a debrief action log which should include problems or issues that have been identified, actions that have been put in place to resolve issues and the timeframe for the action. The themes from the debrief should be openly available and shared with the whole team.

15. Procedure Specific Guidance

15.1 Pleural Procedures

Skill mix / workforce:

The suggested minimum requirement for pleural procedures is as follows:

- Pre-assessment and recovery
 - At least one healthcare practitioner competent at patient recovery including conduct of observations, recognition of a sick patient (for example, recovery nurse, healthcare assistant etc.).
 - The number of staff members will depend on the number of planned procedures and the number of patients requiring regular observation / recovery support at any one time.

- Procedure room (pleural)
 - **Thoracoscopy (involving sedation):** 1 interventionist (usually consultant if lone operator), and 1-2 other staff members to provide assistance to the procedure (for example providing sterile equipment), sedation and patient observations.
 - **Pleural biopsy and indwelling pleural catheters:** 1 interventionist, 1 other staff member to provide assistance to the procedure and patient observations. If sedation is used, a second member of other staff is recommended.
 - **Drain insertion / Aspiration:** 1 interventionist, 1 other staff member to provide assistance to the procedure and patient observations.

15.2 Diagnostic Bronchoscopy Procedures

Skill mix / workforce:

The suggested minimum requirement for diagnostic bronchoscopy is as follows:

- Pre-assessment and recovery
 - At least one healthcare practitioner competent at patient recovery including conduct of observations, recognition of a sick patient (for example, recovery nurse, healthcare assistant etc.).
 - The number of staff members will depend on the number of planned procedures and the number of patients requiring regular observation / recovery support at any one time.
- Procedure room (diagnostic bronchoscopy)
 - **Diagnostic bronchoscopy (involving sedation):** 1 interventionist (usually consultant if lone operator), and 1-2 other staff members to provide assistance to the procedure (for example providing sterile equipment), sedation and patient observations.
 - **EBUS:** 1 interventionist (it is recognised that some services require a second operator for the needling component), 1-2 other staff members to provide assistance to the procedure (for example providing sterile equipment), sedation and patient observations.