Royal Cornwall Hospitals
NHS Trust

LocSSIP Guideline for: Bronchoscopy /Endobronchial Ultrasound-guided Transbronchial Needle Aspiration (EBUS-TBNA)

V1.0

April 2025

Summary

This guideline outlines the process to be followed for staff whilst undertaking the listed procedures.

It applies to all patients undergoing bronchoscopy / endobronchial ultrasound-guided transbronchial needle aspiration.

The guideline has been written as a result of the LocSIPPs Requirement (Local Safety Standards for Invasive Procedures)

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Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

The Royal Cornwall Hospital Trust is committed to providing high quality patient centered care and a safe environment for all patients undergoing bronchoscopy/ endobronchial ultrasound-guided transbronchial needle aspiration.

2. Background

2.1. This guideline is intended to build on the principles outlined in both national and international guidelines including British Thoracic Society guideline for flexible bronchoscopy in adults, British Thoracic Society guideline for advanced diagnostic and therapeutic flexible bronchoscopy in adults, NICE guidelines for endobronchial ultrasound-guided transbronchial needle aspiration for mediastinal masses and WHO surgical safety checklist.

2.2. This guideline is written for members of the RCHT Respiratory Medicine department who are responsible for managing patients undergoing bronchoscopy /endobronchial ultrasound-guided transbronchial needle aspiration procedure either as an outpatient or inpatient.

2.3. This guideline applies to the clinical areas where the specified invasive procedures are undertaken.

- Endoscopy Suite.
- Theatres.
- Emergency Department resuscitation area.

2.4. It will provide evidence of what additional requirements are needed i.e. training and education to fit with local working practices and staffing. This ultimately will enhance the National Safety Standards for Invasive Procedures (NatSIPPs), and mitigate the risk of never events, serious incidents or near misses. It will also provide a process for analysis or learning.

3. Definitions

3.1. Bronchoscopy is a test which allows the doctor to look directly down the trachea (windpipe) through the larynx (voice box) and into bronchial tubes of the lung using thin flexible tube called bronchoscope (telescope). Bronchoscopy is used to check for certain conditions including lung cancer and other unusual symptoms such as:

- Persistent cough.
- Coughing up blood.
- Recurrent / unusual chest infections.
- Breathlessness.
- Change in voice and hoarseness.

During the procedure, the doctor may need to take a biopsy of the lung and/ or sample of liquid from breathing tubes for analysis.

3.2. Endobronchial ultrasound -guided transbronchial needle aspiration (EBUS-TBNA) is a procedure which can be used for patients who are being tested for various diseases, including lung cancer. Under local or general anaesthesia, a thin flexible telescope (bronchoscope) is inserted via the patient's mouth into the lungs. Images of the region between the two lungs (the mediastinum) are obtained using an ultrasound probe attached to the bronchoscope. The operator uses these images as a guide when taking samples of cells from masses suspected of disease. The aim of the procedure is to help reach a diagnosis and establish whether the disease has spread.

4. Governance and Audit

4.1. The Respiratory Medicine governance group will monitor the implementation of this guideline and commission a bi-annual audit of adherence.

4.2. Significant morbidity events will be followed up via the Respiratory medicine departmental morbidity and mortality process.

4.3. This document incorporates the process undertaken as part of the WHO safety surgery checklist.

4.4. Patients must be assessed prior to the procedure and informed consent gained. If the patient lacks capacity, procedure should proceed in the best interests of the patient. Where patients have capacity, verbal consent should be sought. Consent 1 or Consent 4 form should be made if the procedure is felt to carry an unusually high risk for the patient.

4.5. The procedure will be recorded on HICCS/ “Scorpio” and report will be placed within the patient’s medical record.

5. Documentation of LocSSIP Guideline for: Bronchoscopy /Endobronchial Ultrasound-guided Transbronchial Needle Aspiration (EBUS-TBNA)

5.1. To ensure the patient (or in the case of paediatrics, the patient’s parent or legal guardian) has given their fully informed consent, and that the patient is aware of all risks and benefits of their procedure. The Consultant will gain appropriate consent and complete the relevant RCHT Consent Form, and discussion with the patient prior to the start of the procedure.

5.2. The invasive aspect – i.e. The WHO Checklist, Consent Form, and any other charts or documentation other and filed in the patient’s notes.

5.3. Checklist to attest that the appropriate safety checks and that all instructions and safety aspects of the Bronchoscopy /Endobronchial Ultrasound-guided Transbronchial Needle Aspiration have been met.

6. Workforce

6.1. The whole team is responsible for the safety of the patient the Procedure should proceed in a WHO safety checklist style as detailed on CHA4507: WHO Surgical Safety Checklist Endoscopic Ultrasound (cornwall.nhs.uk).

6.2. Minimum workforce requirements for these invasive procedures are as follows:

- Minimum of 1 bronchoscopist (Healthcare Professional, HCP) for EBUS-TBNA; ideally two bronchoscopists should be present (this may be an operating clinician and a trainee); but one bronchoscopist is acceptable if that operator has sufficient experience of solo procedures. Minimum 1 Operator should be signed off as "competent " for independent practice. Operator not recognised as competent should be supervised by a suitably trained HCP.
- One registered nurse.
- One biomedical scientist (for EBUS-TBNA only).
- One healthcare assistant.

6.3. Nurses/HCPs, and doctors who participate in procedures or provide post-procedural care should be competent. This includes recognizing problems, clinical worsening, and knowledge of the next step.

6.4. All staff without appropriate competency will be supervised and these arrangements will be made clear at briefing.

6.5. If these minimum levels of experience and staff numbers cannot be met for any reason, a procedure should not be performed.

6.6. It is the responsibility of each member of staff involved in the procedures outlined to: within their scope of competence under the terms of their professional body i.e. the General Medical Council (GMC) 'Good Medical Practice', the Nursing and Midwifery Council (NMC)'Code of Professional Standards for Conduct', or HCPC Standards Performance, Conduct and Ethics.

6.7. It is the responsibility of each member of staff to comply with these set of standards and escalate any concerns regarding competence. Incidents, near misses must be reported in the Datix system. All staff will communicate and work as a team and speak out if they have any concerns underpinned by undertaking annual training i.e., WHO, Patient Safety (human factors) available on ESR.

7. Scheduling and List Management

7.1. These procedures will be performed as necessary when safe to do so in an appropriate environment. This should take into account the clinical necessity (e.g., symptomatic or cancer pathway related) and the available procedure capacity.

7.2. Non-urgent procedures are best done between 8am-5pm when staffing is higher and resources to mitigate complications are in place.

8. Handovers and Information Transfer

8.1. The whole team is responsible for the safety of the patient. A good briefing before the list or a particular patient promotes good handover of information between colleagues and teams. Any concerns related to safety, including correct information must be escalated as soon as the team members becomes aware of it. If the critical information shared as part of the WHO checklist is missing/ unavailable, the procedure cannot continue until this is resolved.

8.2. Pre-Procedure checks by Nursing staff:

8.2.1. Access to the cardiac arrest/crash trolley should be easily accessed.

8.2.2. The cardiac arrest/crash trolley must be checked daily and ensured all items are stocked and within the expiry date.

8.2.3. The controlled drugs locked within the controlled drugs cupboard must be checked daily to ensure the correct amount of stock are supplied and that they are within the expiry date.

8.2.4. The relevant cupboards / trolleys containing equipment within the procedure rooms should be checked and restocked at the start of each clinical session.

8.2.5. Prepare procedure notes; including specific bronchoscopy/ EBUS consent form Fiberoptic Bronchoscopy and Endobronchial Ultrasound (EBUS) CHA3234and EUS safety checklist CHA4507: WHO Surgical Safety Checklist Endoscopic Ultrasound (cornwall.nhs.uk).

8.2.6. Confirm patient details.

8.2.7. Check and document vital signs/ observations, allergy/medications/coagulation status, fasting status, capillary glucose where applicable (diabetic patients), Infection risk, e.g. MRSA status.

8.2.8. Obtain IV access and any pre-procedure blood tests (FBC and coagulation screen if no result on maxims within last 3 months, or previous result abnormal).

8.3. **Team Pre-Brief**

This should take place at the start of the clinical session, before calling the first patient into the procedure room. It is a verbal discussion, led by a designated member of the team and recorded on the ‘Team Brief Form’. All team members should be present at the time of pre-brief. Silent cockpit principles should be adopted during all steps, all team members must show respect for the process, be present and fully participate in all steps of the team brief. Team brief elements include:

- Team introductions.
- Any staffing issues/ (Bucket filling).
- Any additional / special equipment required?
- List order and timings.
- A brief discussion of each case and the planned procedures reviewed (diagnostic / staging, number of stations to be sampled).
- Expected procedure duration/concern?
- Available equipment.
- Required medication and preferred sedative agents and anticipated total lignocaine doses.
- Imaging available on PACS.
- Any specific equipment or patient-related requirements should be discussed.
- Any recovery /bed issues -post procedure destination.
- All staff given the opportunity to raise any concerns of any nature.
- Any changes or alterations to the list order should be agreed and a new list printed once these have been confirmed by the team.
- The list should not proceed until any concerns have been addressed to the satisfaction of the whole team.

9. Procedural Verification and Site Marking

9.1. The team involved in the procedure will participate in the combined safety check as per the relevant checklist in the appendices, including confirming the procedure to be undertaken. The following information should be confirmed and agreed by the team with the involvement of the patient where possible:

9.1.1. Intended procedure (bronchoscopy / EBUS).

9.1.2. Likely sampling required (biopsy/ brush/ wash/ lavage / diagnostic vs. staging EBUS) and location of main diagnostic target(s).

10. Safety Briefing

If any issues have arisen or problems such as equipment difficulties, a debriefing is to be undertaken and recorded by the responsible practitioner in the patient note, and a Datix completed if appropriate.

11. Sign In

11.1. All patients undergoing these procedures must undergo safety checks on arrival at the procedure area: the sign in, before commencing these procedures.

11.2. At least 2 people should complete the sign in process, alongside the patient. All members of the team must introduce themselves and observe “silent cockpit,” whilst a designated member of the team performs the WHO “sign in.” out loud and records on the WHO safety checklist. This includes:

- All team members should be present to introduce themselves by name and role.
- Patient to confirm his/her identity and procedure, using name, date of birth and the staff should check the hospital number/ CRN is correct.
- Written Consent form checked.
- Oxygen supply and suction checked.
- Medication drawn up and labelled and monitoring equipment checked. This includes cold/iced saline.
- Adrenaline is drawn up (if operator has requested) sedation is checked, labelled and in date (usually midazolam and fentanyl or alfentanil).
- 1% lignocaine is drawn up, labelled and sufficient for anticipated length of procedure – and not in excess of safe dose, including expected number of xylocaine sprays (10mg/ spray): 8mg/kg ideal body weight (for obese patients where body weight is >30% in excess of ideal body weight, use adjusted body weight).
- All patients should have cardiac monitoring, oxygen saturations and blood pressure monitoring in place and working correctly.
- Patient allergies confirmed.
- Antiplatelet and anticoagulation status.
- Imaging reviewed and displayed.
- Equipment (bronchoscope, forceps, brush, transbronchial needles, Ultrasound machine) checked.
- Blood results including INR reviewed.
- Any additional risk factors for the procedure identified.
- Loose teeth/ dentures.
- The sign in section of the procedural checklist must be signed and dated.

12. Prevention of Retained Foreign Objects

12.1. Any sharps used during the procedure need to be safely accounted for and/or disposed of in accordance with the Trust Sharps Policy.

12.2. Balloons (if applied) should be removed from the EBUS scope and verbally confirmed with the team.

13. Sign Out

13.1. This final part of the WHO checklist should be performed by a designated member of the team at the end of the procedure out loud before the patient and involved staff leave the procedure room. “Silent cockpit” must be observed.

13.2. Sign out includes:

- Confirm details of the procedures have been recorded.
- Confirm all controlled drugs have been accounted for
- Specimens have been labelled /checked.
- Confirm the key concerns for recovery and management of the patient recorded and communicated to the appropriate staff. This should include as a minimum:
    - target saturations in recovery and to be achieved before discharge.
    - Nil by mouth period (2 hours from last local anaesthetic application/end of procedure).
    - Plan for restarting antiplatelet /anticoagulation therapy.
    - Management of any complication encountered during procedure. Any additional tests or treatment required, e.g. chest x-ray, ECG or prescription for antibiotics or painkillers to go to pharmacy.
    - Person to contact in case of deterioration.
- Follow-up arrangements are clear.

14. Debriefing

14.1. All members of the team must feel comfortable to contribute to the discussion and raise any queries or concerns. This can be carried out at the end of a list or case -by-case and should involve the entire team who participated in the procedure.

14.2. Key points of the debrief include:

- Things that went well

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

15. Dissemination and Implementation

15.1. The document is available on the document library. Significant updates will be communicated via Trust wide email.

15.2. Implementation of the policy will be via Trust wide communication and supported by appropriate training for the relevant members of staff.

16. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Quantitative and qualitative compliance with WHO checklists and documentation requirements.
Lead	Mathew Berry, Respiratory Consultant.
Tool	WHO auditing feeds into the safer surgery committee.
Frequency	WHO checklist to be used for procedures and monitored for each patient.
Reporting arrangements	Any compliance issues alongside areas of failure within this procedure to be escalated to Safer Surgery Committee and shared within Respiratory Governance Meetings.
Acting on recommendations and Lead(s)	Any compliance issues will be highlighted at respiratory governance and acted upon by the respiratory clinical team.
Change in practice and lessons to be shared	Changes in practice or changes in practice will initiate review of standards and review of this LocSSIP.

17. Updating and Review

17.1. The document review process is managed via the document library. Document review will be every three years unless best practice dictates otherwise. The author remains responsible for the policy document review. Should they no longer work in the organisation or in the relevant practice area then an appropriate practitioner will be nominated to undertake the document review by the designed director.

17.2. Revision activity will be recorded in the versions control table to ensure robust document control measures are maintained.

18. Equality and Diversity

18.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion and Human Rights Policy' or the Equality and Diversity website.

18.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	LocSSIP Guideline for: Bronchoscopy / Endobronchial Ultrasound-guided Transbronchial Needle Aspiration (EBUS-TBNA) V1.0
This document replaces (exact title of previous version):	New Document
Date Issued/Approved:	December 2024
Date Valid From:	April 2025
Date Valid To:	April 2028
Directorate / Department responsible (author/owner):	Dr P Arooj and Dr M. Berry, Respiratory Medicine
Contact details:	07776559286
Brief summary of contents:	Local safety standards in invasive procedures in relation to endobronchial ultrasound guided bronchoscopy including sampling by transbronchial needle aspiration.
Suggested Keywords:	Endobronchial, ultrasound, guided, bronchoscopy, transbronchial, needle, aspiration.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Respiratory Medicine Speciality Governance. Specialist Medicine Care Group Governance. Safer Surgery and Invasive Procedures Group.
General Manager confirming approval processes:	Racheal Pearce
Name of Governance Lead confirming approval by specialty and care group management meetings:	Siobhan Hunter/Paul Evangelista

Information Category	Detailed Information
Links to key external standards:	National Safety Standards in Invasive Procedures Version 2, 2023)
Related Documents:	Safety Standards in Surgery and Invasive Procedures Policy
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Respiratory

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
April 2024	V1.0	Initial issue	Dr Arooj and Dr Berry, Respiratory Medicine

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	LocSSIP Guideline for: Bronchoscopy /Endobronchial Ultrasound-guided Transbronchial Needle Aspiration (EBUS-TBNA) V1.0
Directorate and service area:	Acute and Emergency Medicine
Is this a new or existing Policy?	New
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Dr Mathew Berry, Respiratory Consultant
Contact details:	07776559286

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Staff performing bronchoscopy and EBUS
2. Policy Objectives	To meet LocSIPPs Requirement (Local Safety Standards for Invasive Procedures)
3. Policy Intended Outcomes	To ensure all staff are following an accepted safe method of Bronchoscopy /Endobronchial Ultrasound-guided Transbronchial Needle Aspiration (EBUS-TBNA).
4. How will you measure each outcome?	Audit and debrief following each patient.
5. Who is intended to benefit from the policy?	Staff, patients and RCHT.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: Yes
6b. Please list the individuals/groups who have been consulted about this policy.	Respiratory and Endoscopy departments Also checked against published British thoracic society guidance
6c. What was the outcome of the consultation?	Opinions and suggestions incorporated into document
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	

Protected Characteristic	(Yes or No)	Rationale
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Matthew Berry Respiratory Consultant.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis