8-1-2023

Proposed quality indicators and recommended standard reporting items in performance of EBUS bronchoscopy: An official world association for bronchology and interventional pulmonology expert panel consensus statement

Daniel P. Steinfort

Matthew Evison

Ashleigh Witt

Georgios Tsaknis

Fayez Kheir

See next page for additional authors

10.1111/resp.14549

Steinfort, D. P., Evison, M., Witt, A., Tsaknis, G., Kheir, F., Manners, D., . . . Van Der Heijden, E. H. F. M. (2023). Proposed quality indicators and recommended standard reporting items in performance of EBUS bronchoscopy: An official world association for bronchology and interventional pulmonology expert panel consensus statement. Respirology, 28(8), 722-743. https://doi.org/10.1111/resp.14549

Received: 3 April 2023 | Accepted: 28 June 2023

DOI: 10.1111/resp.14549

POSITION PAPER

Official Journal of the Asian Pacific Society of Respirology
Respirology
APSR
WILEY

Proposed quality indicators and recommended standard reporting items in performance of EBUS bronchoscopy: An official World Association for Bronchology and Interventional Pulmonology Expert Panel consensus statement

Daniel P. Steinfort[1,2] | **Matthew Evison**[3] | **Ashleigh Witt**[1,2] | **Georgios Tsaknis**[4,5] | **Fayez Kheir**[6] | **David Manners**[7,8] | **Karan Madan**[9] | **Calvin Sidhu**[10] | **Alberto Fantin**[11] | **Daniel A. Korevaar**[12,13] | **Erik H. F. M. Van Der Heijden**[14] | **on behalf of the WABIP Taskforce on Quality Indicators in EBUS Bronchoscopy**

[1]Department of Medicine, Faculty of Medicine, Dentistry & Health Sciences, University of Melbourne, Parkville, Victoria, Australia

[2]Department of Respiratory Medicine, Royal Melbourne Hospital, Melbourne, Victoria, Australia

[3]Lung Cancer & Thoracic Surgery Directorate, Wythenshawe Hospital, Manchester University NHS Foundation Trust, Manchester, UK

[4]Department of Respiratory Sciences, College of Life Sciences, University of Leicester, Leicester, UK

[5]Department of Respiratory Medicine, Kettering General Hospital, UK

[6]Division of Pulmonary and Critical Care Medicine, Department of Medicine, Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts, USA

[7]St John of God Midland Public and Private Hospitals, Midland, Western Australia, Australia

[8]Curtin Medical School, Curtin University, Perth, Western Australia, Australia

[9]Department of Pulmonary, Critical Care and Sleep Medicine, All India Institute of Medical Sciences (AIIMS), New Delhi, India

[10]School of Health Sciences, Edith Cowan University, Perth, Western Australia, Australia

[11]Department of Pulmonology, University Hospital of Udine (ASUFC), Udine, Italy

[12]Department of Respiratory Medicine, Amsterdam University Medical Centers, Amsterdam, The Netherlands

[13]University of Amsterdam, Amsterdam, The Netherlands

[14]Department of Pulmonary Diseases, Radboud University Medical Center, Nijmegen, The Netherlands

Correspondence
Daniel P. Steinfort
Email: daniel.steinfort@mh.org.au

Associate Editor: Ioannis Kalomenidis; **Senior Editor:** Phan Nguyen

Abstract

Background: Since their introduction, both linear and radial endobronchial ultrasound (EBUS) have become an integral component of the practice of Pulmonology and Thoracic Oncology. The quality of health care can be measured by comparing the performance of an individual or a health service with an ideal threshold or benchmark.

The taskforce sought to evaluate quality indicators in EBUS bronchoscopy based on clinical relevance/importance and on the basis that observed significant variation in outcomes indicates potential for improvement in health care outcomes.

Methods: A comprehensive literature review informed the composition of a comprehensive list of candidate quality indicators in EBUS. A multiple-round modified Delphi consensus process was subsequently performed with the aim of reaching consensus over a final list of quality indicators and performance targets for these indicators. Standard reporting items were developed, with a strong preference for items where evidence demonstrates a relationship with quality indicator outcomes.

Results: Twelve quality Indicators are proposed, with performance targets supported by evidence from the literature. Standardized reporting items for both radial and linear EBUS are recommended, with evidence supporting their utility in assessing procedural outcomes presented.
Conclusion: This statement is intended to provide a framework for individual proceduralists to assess the quality of EBUS they provide their patients through the identification of clinically relevant, feasible quality measures. Emphasis is placed on outcome measures, with a preference for consistent terminology to allow communication and benchmarking between centres.

KEYWORDS
bronchoscopy, interventional techniques, lung cancer

BACKGROUND

Since the publication of landmark papers in 2004,[1,2] both linear and radial endobronchial ultrasound (EBUS) have become an integral component of the practice of Pulmonology and Thoracic Oncology, and have driven the rapid expansion of the field of Interventional Pulmonology. Despite many subsequent technologic advances, linear EBUS remains the recommended technique for mediastinal lymph node sampling/staging, and the diagnostic performance of radial EBUS for peripheral lesions remains consistent with that reported for more advanced (and expensive) bronchoscopic navigation techniques.

Evidence regarding optimal use and performance of EBUS is well established, and described in clinical guidelines and statements.[3–5] However, the presence of significant variance in outcomes such as diagnostic accuracy and complications across centres and operators suggests that the availability of such documents does not immediately guarantee uniformly high performance. Some degree of variance is expected depending on patient selection, with certain clinical and radiologic factors known to influence diagnostic performance and complication rates. However, variance may also be explained by differences in quality of care. Assessment of quality of care is invaluable in identifying opportunities to improve care and patient outcomes. Valid, reliable and useful indicators of the quality of care can assist in measuring the state of care and variations in practice, and in tracking the impact of quality improvement activities. However, quality assessment is frequently not integrated into clinical practice guidelines.[6]

The quality of health care can be measured by comparing the performance of an individual or a health service with an ideal threshold or benchmark.[7] The particular parameter used for comparison is termed a quality indicator. Defining a quality indicator does not result in improved health outcomes *per se*: services and individuals are unlikely to improve unless they are aware of their performance and how it compares with benchmark performance targets. Therefore, it is essential that local performance is regularly measured against established benchmarks. This allows the identification of potential underperformance, which provides an opportunity for targeted interventions to improve this situation and reduce variance in care. In addition, the simple act of monitoring a service has often been shown to improve performance[8] (the 'Hawthorne effect'). For these reasons, monitoring is crucial, as it is a powerful, low-cost service, that results in improved quality of patient care.[9]

Quality indicators have been developed for numerous other interventional specialities, including endoscopy, thoracic surgery, interventional cardiology, interventional radiology and radiation oncology.[10–13] However, very few studies have addressed quality in EBUS/bronchoscopy. The few publications to date encouragingly suggest that consistent performance measurement may improve procedural and patient outcomes. For example, the institution of quality measures in bronchoscopy resulted in improved rates of diagnosis of malignancy,[14] regular use of EBUS is known to improve the proportion of patients receiving guideline-consistent lung cancer care,[15] and monitoring of quality standards in EBUS reduces variance in care between centres.[16]

This taskforce had three aims:

1. To establish a set of quality indicators for EBUS bronchoscopy,
2. to establish performance targets for each of these quality indicators, and
3. to develop a list of standard reporting items for inclusion in EBUS bronchoscopy reports.

Recommended standard reporting items have been established to aid collection of data for reporting of quality indicators, and to provide more detailed data to allow interpretation of quality indicators, where relevant.

METHODOLOGY

Taskforce and scope

A taskforce was composed, consisting of 12 members with experience in EBUS bronchoscopy as well as methodologic expertise. The taskforce sought to evaluate quality

indicators in EBUS bronchoscopy based on clinical relevance/importance and on the basis that observed significant variation in outcomes indicates potential for improvement in health care outcomes. Feasibility of measurement of proposed indicators was prioritized, however, evaluation in discussion was based on the ISFU (Importance, Scientific acceptability, Feasibility, and Usability) framework described by the National Quality Measures Clearinghouse.[17]

As previously noted,[11] quality indicators can be divided into three categories:

1. Structural measures—these assess characteristics of the entire health care environment (e.g., availability and maintenance of endoscopy equipment at a hospital),
2. Process measures—these assess performance during delivery of care (e.g., rate of localization of target lesion by radial EBUS, or use of rapid on-site evaluation). These are likely to represent surrogate measures of high-quality care or are known to influence the likelihood of optimal diagnostic and/or safety outcomes, and
3. Outcome measures—these assess the results of the care provided (e.g., diagnostic sensitivity of radial EBUS, or frequency of pneumothorax following transbronchial lung biopsy).

This statement is intended to address process and outcome measures in the performance of EBUS bronchoscopy. Structural measures have been described previously in the British Thoracic Society (BTS) on quality standards for flexible bronchoscopy,[18] and are assumed to apply to EBUS bronchoscopy also. Furthermore, structural measures related to resourcing and the organizational structure of health systems are commonly not actionable by clinicians.

Equally, the American Society for Gastrointestinal Endoscopy (ASGE) has published quality indicators common to all bronchoscopic/endoscopic procedures,[19] including indicators relevant to post-procedural instructions, follow-up, and patient satisfaction which have not been examined as part of this EBUS-specific taskforce.

Literature searches and selection

A comprehensive literature review was completed with the assistance of a medical librarian with the intent of identifying evidence that might suggest contributors to variance in care, or that are likely to be integral components of high-quality care in the performance of EBUS. Search strategies were intended to identify a broad scope of evidence on markers of high-quality care in EBUS. These included previously reported or expected performance targets, clinical and radiologic factors expected to influence the likelihood of clinically important outcome measures, and specific studies examining performance monitoring and quality improvement in EBUS bronchoscopy. Specifically, two separate literature searches were performed in Medline from inception to 01 August 2022. The first search included terms specifically related to 'quality' or 'performance' in EBUS, while the second focussed on identifying published systematic reviews and meta-analyses in EBUS. The complete search strategies are detailed in Table 1. These searches were supplemented by studies volunteered by taskforce members, which could also include literature on quality indicators in other clinical fields than EBUS.

Identification of candidate quality indicators

Following review of identified studies, a comprehensive list of candidate quality indicators was composed and circulated for review prior to detailed discussion at a virtual meeting by all taskforce members. Further items were proposed by individual taskforce members for consideration.

TABLE 1 Search strategies used.

Database: Ovid MEDLINE(R) ALL <1946 to 01 August 2022> search strategy:	Database: Ovid MEDLINE(R) ALL <1946 to 01 August 2022> search strategy:
1 ((endobronchial adj3 (ultrason* or ultrasound* or sonograph* or scan*)) or ebus*).tw,kf. (3336)	1 ((endobronchial adj3 (ultrason* or ultrasound* or sonograph* or scan*)) or ebus*).tw,kf. (3336)
2 *quality assurance, health care/ or *quality indicators, health care/ or *"outcome and process assessment, health care"/ or *quality of health care/ or *guideline adherence/ or *clinical competence/ or *standard of care/ (153979)	2 (systematic review or meta-analysis).pt. or (systematic review or meta-analysis).ti. (340325)
3 ((quality or performance) adj3 (indicator* or assurance or assessment* or measure* or improve* or standard* or evaluat* or monitor* or effective* or metrics or methods or adherence or competenc*)).tw,kf. (554636)	3 1 and 2 (87)
4 2 or 3 (670546)	4 limit 3 to english language (87)
5 exp lung neoplasms/ (263329)	
6 (((lung or thoracic or pulmonary or intrapulmonary or bronchial or bronchogenic or endobronchial or mediastin*) adj3 (cancer* or tumo?r* or malignan* or carcinoma* or neoplasm* or adenocarcinoma* or lesion* or mass* or nodule* or nodal staging or node staging)) or nsclc or ppl*).tw,kf. (327984)	
7 5 or 6 (400755)	
8 1 and 4 and 7 (104)	

Components of EBUS were separated into pre-procedure, intra-procedure and post-procedure indicators, and quality indicators were subdivided across these domains.

Twenty candidate quality indicators were identified based on clinical relevance/importance and on the basis that observed significant variation in outcomes indicates potential for improvement in clinical performance. In discussion, each proposed quality indicator was reviewed according to the potential validity, feasibility, and relevance of the indicator through evaluation, as per Mazzone et al.,[20] within the following domains:

- *Evidence or consensus of a link to outcome*: The evidence base supporting a link between this indicator and patient outcome is robust, or a consensus of experts is likely to feel that a link is present.
- *Practical*: This indicator is capable of being translated into practice.
- *Measurable*: This indicator can be measured from the documentation that would reasonably be expected to be available within the medical record.
- *Potential for improvement*: There is room to improve the performance of this indicator in current clinical practice across the spectrum of current practice settings.
- *Variability among practices*: The performance of this indicator is likely to vary across the spectrum of current practice settings.
- *Important to a large portion of patients of interest*: This indicator is likely to be relevant to a large portion of patients to whom it applies.

Selection of quality indicators through Delphi consensus

A multiple-round modified Delphi consensus process was subsequently performed with the aim of reaching consensus over a final list of quality indicators. Each Delphi round was preceded by a virtual consensus meeting, in which proposed items and/or wording thereof were discussed in detail. Subsequently, anonymous electronic voting was performed, and all task force members were invited to participate. Voting for each proposed item was undertaken using a modified Delphi consensus process on a 5-point Likert scale (with a score of 1 corresponding to 'strongly disagree', and a score of 5 to 'strongly agree').[21] If ≥90% agreement ('agree' or 'strongly agree') was achieved, the quality indicator was accepted for inclusion on the final list. If agreement was 50%–90%, the item was discussed at the subsequent virtual consensus meeting and potentially re-worded prior to repeat anonymous electronic voting. If agreement was <50% the proposed item was rejected.

Detailed results of the modified Delphi consensus process are provided in Appendix Tables A1 and A2. Following the first round of voting, seven indicators scoring ≥90% agreement were accepted, while three items scoring <50% were rejected. The remaining 10 items were discussed in the second virtual consensus meeting, which resulted in acceptance of three additional quality indicators (each initially receiving 80% agreement in the first round), and in re-wording for voting on six items (with two items merged). At the second round of voting, three of these scoring ≥90% were accepted, while two items accepted in the first round were merged, resulting in a total of 12 quality indicators. The remaining four items were prioritized for consideration as standard reporting items.

Establishing performance targets

After finalizing the list of quality indicators, we aimed to establish performance targets for each quality indicator. Such performance target refers to the minimum proportion of reports or procedures that should fulfil this quality indicator to be considered as 'sufficient' (i.e., to have reached the benchmark). This was done in three sub-groups, each covering a domain of the EBUS procedure (i.e., pre-procedure, intra-procedure and post-procedure). The three sub-groups informally screened studies identified through the literature searches (Table 1) as well as other evidence sources proposed by task force members, and subsequently proposed performance targets (if possible informed by published literature) for each of the selected quality indicators in their domain.

These performance targets were then proposed to the task force and discussed during a virtual consensus meeting. When expert consensus considered performance of a given quality indicator to be preferred in all cases, such as monitoring vital signs during sedation, then the performance target was listed as >98%. Consensus over a performance target was considered reached if no concerns were raised during an online meeting dedicated to identification of performance targets; otherwise, the point was discussed until consensus regarding in- or exclusion was reached.

Establishing standard reporting items

Finally, standard reporting items were developed by the three sub-groups, with emphasis again placed on the characteristics described by Mazzone et al.,[20] with a strong preference for items where evidence demonstrates a relationship with quality indicator outcomes. Proposed performance targets (Table 2) and candidate standard reporting items were reviewed prior to another virtual consensus meeting where items were discussed to achieve consensus with the option provided for anonymous dissenting views. Final standard reporting items were confirmed, with evidence supporting their utility in assessing procedural outcomes presented in Table 3. It is not suggested that all standard reporting items be recorded in all cases. Individuals and institutions should consider which items are most likely to inform understanding of procedural outcomes, and select items felt to be most relevant to their practice.

TABLE 2 Summary of proposed quality indicators for EBUS bronchoscopy.

Quality indicator Domain: PRE-PROCEDURE INDICATORS	Type of measure	Outcome—performance target
1. Frequency with which indication for EBUS is documented	Process	>98%[a]
2. Frequency with which consent is obtained, and fully documented, including specific discussions of risks associated with EBUS and sedation.	Process	>98%
3. Frequency with which EBUS examinations are performed/supervised by trained EBUS operators	Process	>98%
4. Frequency with which a sedation plan is developed and documented based on clinical co-morbidities and anaesthetic/sedation risks	Process	>98%
Domain: INTRA-PROCEDURE INDICATORS		
5. Frequency with which anaesthetic/sedation management is recorded	Process	>98%
6. Frequency with which the appearance of relevant structures, specific to the indication for the EBUS, is recorded.	Process	>98%
7. Frequency with which patients with ACCP radiographic group B and C (cN1/2/3) undergo systematic mediastinal LN staging.	Process	>95%
Domain: POST-PROCEDURAL INDICATORS		
8. Frequency with which immediate adverse events are observed.	Outcome	<2%
9. Incidence of complications following EBUS (including individual complications)	Outcome	Varies according to indication—See Table 5
10. Frequency with which inadequate specimens are reported from an individual LN station	Outcome	<10%
11. (a) Diagnostic performance of EBUS-TBNA according to indication/ACCP radiographic group. (b) Diagnostic performance of radial EBUS for diagnosis of peripheral pulmonary lesions	Outcome	Varies according to diagnosis—See Table 6
12. Frequency with which tissue/specimens are inadequate for required molecular testing	Outcome	<10%

Abbreviation: ACCP, American College of Chest Physicians.
[a]Preference to be recorded in procedure report, though documentation in medical notes may suffice in some cases.

RESULTS

PRE-PROCEDURE QUALITY INDICATORS

1. ***Frequency with which indication for EBUS is documented***

* if performed for suspected/known NSCLC, the procedure should be documented as 'staging' or 'diagnostic' EBUS.

***Type of measure*:** process
***Performance target*:** >98%
***Data source*:** procedure report, medical notes

DISCUSSION: The indication for a procedure is likely to be apparent in medical notes, however subsequent interpretation of the report may be influenced by the stated indication. Additionally, audit of outcomes would be greatly aided if all information is recorded together. It is therefore preferred by the Taskforce that indication be specified in procedure reports.

Linear EBUS

Initially developed for lymph node staging in NSCLC, the use of linear EBUS in adults has expanded significantly to include numerous indications where the diagnostic utility has been confirmed (Table 4). The indication for linear EBUS has evolved from diagnostic confirmation of mediastinal metastatic disease to potentially entail a full staging procedure with the intent to exclude malignant disease by using a highly standardized and systematic approach.

A linear EBUS procedure should be recorded as a 'Diagnostic EBUS' when the focus of the procedure is to obtain adequate tissue from a suspected pathological lymph node, or centrally positioned parenchymal lesion, to make a confirmatory diagnosis. For patients with advanced-stage lung cancer, a diagnostic EBUS includes obtaining adequate tumour samples to perform molecular and genomic profiling to guide the choice of systemic therapy.

Linear EBUS procedures should be recorded as a 'Staging EBUS' in patients with lung cancer that may be suitable for curative-intent treatment and nodal staging is required to define the optimal treatment. A staging EBUS

TABLE 3 Recommended Standard reporting items for EBUS bronchoscopy.

Pre-procedure	Relevant quality indicator(s)		References
Indication	1		(29–31)
Name of proceduralist (and assistant/trainee)	3		
(*for **Linear EBUS** in suspected lung cancer*) • clinical stage (TNM) (or ACCP radiographic group)	7, 11	Clinical stage may influence intra-procedural approach to sampling (e.g., targeted vs. systematic staging)	(4, 101, 102)
(*for **radial EBUS***) • target lesion size (diameter in mm) • location (upper, lower, right or left) Consider: position central/middle/outer 1/3 of lung; bronchus sign (Y/N); nodule description: solid, subsolid and ground glass	6, 11	Radiologic features known to influence diagnostic performance	(42, 72, 114, 115)
Intra-procedure			
(linear EBUS)			
• characteristics (size, shape, margin, echogenicity, hilar structures) as per Fujiwara	6, 7, 11	*Photo-documentation should ideally be performed to aid review of results by colleagues/MDT* EBUS imaging characteristics may help determine NPV of EBUS-TBNA in the event of a benign/inadequate pathologic finding	(47, 122–124)
• Use of ROSE			(68, 101)
• TBNA needle gauge			(61, 66)
Number LN sampled per procedure		Useful metric for aggregate analysis but not a component of individual procedure reporting	(60)
(radial EBUS)			
• Probe position within/adjacent • Sampling instrument(s) used • Use ROSE (document Y/N)	6, 11		(51) (69, 84)
Post-procedure			
Immediate adverse events (& management)	-	-	-

Abbreviations: ACCP, American College of Chest Physicians; MDT, multidisciplinary team; NPV, negative predictive value; ROSE, rapid on-site cytologic evaluation; TNM, tumour, node, metastasis.

TABLE 4 Indications for linear EBUS.

Indications for linear EBUS
Diagnosis, staging/restaging of lung cancer (including molecular diagnosis) • targeted sampling of pathologic mediastinal/(hilar) lymphadenopathy • systematic staging of patients with NSCLC ACCP radiographic group B and C • diagnostic assessment of centrally positioned parenchymal lung lesion
Suspected granulomatous disease • Sarcoidosis • Mycobacterial infection (including tuberculosis)
Suspected extra-pulmonary malignancy • Intra-thoracic lymphoma • Suspected nodal or pulmonary parenchymal metastases

Abbreviations: ACCP, American College of Chest Physicians; NSCLC, non-small cell lung cancer.

requires a systematic examination of all accessible mediastinal and hilar lymph nodes with sampling of any lymph node station that meets pre-defined criteria in order to accurately map the extent or prove the absence of nodal metastases. Staging EBUS generally requires a higher degree of skill because a greater number of sites are often sampled and the nodes can be small.

Use of the EBUS bronchoscope to perform Endoscopic ultrasound (EUS-B) allows more complete examination of the mediastinum and may be safely be performed by interventional pulmonologists,[64] frequently combined with EBUS within the one procedure,[4] to achieve increased diagnostic accuracy in mediastinal LN staging of NSCLC.[65]

Radial EBUS

Radial EBUS remains most commonly used for confirmation of localization of peripheral lesions to direct bronchoscopic sampling. The technique most commonly uses a guide sheath and fluoroscopic imaging to assist the accurate deployment of sampling instruments to the site of the target parenchymal lesion. Recent preliminary studies have also

described the use of radial EBUS for assessment of suspected benign pulmonary disease, including the targeting of cryobiopsy in diffuse parenchymal lung disease,[66,67] however diagnostic utility/sensitivity for assessment of DPLD remains unknown and investigation of suspected lung cancer or lung metastases is the predominant indication for radial EBUS.

2. ***Frequency with which consent is obtained, and fully documented, including specific discussions of risks associated with EBUS and sedation***

Type of measure: process
Performance target: >98%
Data source: medical notes

The consent should address the relevant and substantial adverse events pertaining to each specific EBUS procedure, in addition to the risks associated with all bronchoscopic procedures.

DISCUSSION: EBUS-TBNA is generally safe procedure but might present risks beyond those associated with standard bronchoscopy. A comprehensive review of the adverse events specific to EBUS-TBNA had been published previously.[68] The highest complication rate of 1.44% was reported in the prospective AQuIRE registry.[22] The most reported complications in the literature are bleeding, infection, and pneumothorax. However, such complications did not seem to be related to lymph node size, number of passes, lymph node station and needle gauge.[22,23] More detailed discussion is presented below (quality indicator #8).

3. ***Frequency with which EBUS examinations are performed/supervised by trained EBUS operators***

Type of measure: process
Performance target: >98%
Data source: procedure report

The diagnostic yield of EBUS-TBNA has been associated with operator experience, procedural training, and performance in high-volume centres.[40–42] It is beyond the scope of this document to discuss the attainment of and credentialing requirements for mastery of EBUS bronchoscopy. Furthermore, such requirements will be jurisdiction-specific, and will depend on the nature of clinical practice for individuals. What constitutes 'trained EBUS operators' should be agreed upon internally at each institution where the procedure is performed.

DISCUSSION: Procedural training in EBUS-TBNA requires longitudinal assessments over time to develop technical and cognitive skills needed to achieve competency which is not automatically reflected by the number of procedures performed.[69,70] The European Respiratory Society (ERS) and American Thoracic Society (ATS) published volume-based guidelines for establishing competence in EBUS over 20 years ago,[71] however, more recent evidence demonstrates that learning curves vary widely among practitioners suggesting that a threshold of cases completed may not be sufficient to establish competency.[70] Use of simulation in training may allow trainees to achieve competence with fewer clinical cases completed.[72,73]

4. ***Frequency with which a sedation plan is developed and documented based on clinical co-morbidities and anaesthetic/sedation risks***

Type of measure: process
Performance target: >98%
Data source: medical notes

Information is not required to comprise part of the procedure report, but should be readily available, and should include type of anaesthetic (sedation vs. general anaesthetic), clinician administering anaesthetic, and type and dose(s) of sedation/anaeshetic agents.

DISCUSSION: Numerous approaches to anaesthesia are reported in published literature, both regarding mode (GA with LMA vs. sedation), sedative agents, use of neuromuscular blockade, and specialty of clinician administering anaesthetic agents (Anaesthetist-,[74,75] Pulmonologist-,[76,77] and nurse-led[78] are all described).

Pre-procedure recommended standard reporting items

All procedures

- Indication for procedure
- Name of proceduralist (and assistant/trainee, anaesthetist where relevant).

For linear EBUS

- Clinical stage (TNM)
- (in patients with suspected/known NSCLC)—'Diagnostic' versus 'Staging' EBUS.
- American College of Chest Physicians (ACCP) radiographic group (see Indicators 7 and 11)

These features will both influence the extent of mediastinal sampling performed and are also known to impact the diagnostic sensitivity of EBUS-TBNA.

For radial EBUS

- Target lesion size (maximal diameter, mm)
- lobar location of target lesion/sampling.
- Position of target lesion (central/middle/outer third of lung)
- Lesion description: solid, sub-solid, pure ground glass
- presence of CT bronchus sign[38,39,45,79]

These items have all been identified as important factors when evaluating quality indicators and outcomes. They also

are useful to interrogate if under-performance is identified during the quality assurance review. For example, if the sensitivity for malignancy for a radial EBUS service is below that of the recommended quality indicator, it is important to evaluate how many procedures are in bronchus sign positive cases as this will impact on diagnostic outcomes and may point to areas for improvement within the patient selection.

INTRA-PROCEDURE QUALITY INDICATORS

5. ***Frequency with which anaesthetic/sedation management is recorded***

Type of measure: process
Performance target: >98%
Data source: medical notes

DISCUSSION: The level of sedation is a continuum ranging from minimal sedation (anxiolysis), moderate sedation, deep sedation to general anaesthesia. Optimal sedation for bronchoscopy procedures is that which allows the proceduralist to perform the procedure efficiently whilst maintaining patient comfort and minimizing risk. Moderate sedation, where a patient has depressed consciousness but is able to respond to verbal commands, is commonly used in bronchoscopic procedures, and appears safe and well tolerated.[74,80] General anaesthesia is also widely used for EBUS-TBNA, and there appears to be no significant difference between the two approaches on procedural outcomes.[75]

6. ***Frequency with which the appearance of relevant structures, specific to the indication for the EBUS, is recorded***

Type of measure: process
Performance target: >98%
Data source: procedure report

For linear EBUS, lymph node features should be described, using previously noted imaging characteristics known to be predictive for distinguishing between benign and malignant nature of lymph nodes.[49] While not mandated, photo-documentation within procedure reports is considered best practice for a number of reasons. Photo-documentation may support clinical decision-making (in the exact same way radiology imaging tests are always uploaded for review), such as in tumour board meetings which may not have the benefit of the EBUS operator present to contribute to the discussion to support clinical decision-making. This may be particularly relevant for cases of negative staging EBUS suggesting no evidence of mediastinal nodal metastases. Numerous international guidelines recommend mediastinoscopy in cases where the suspicion of nodal metastases remains high despite the negative staging EBUS. No definition of 'high suspicion' has been provided and sonographic[49,81,82] or elastographic[83] features can play an important part of assessing this risk. It also provides appropriate governance and documentation in the event of adverse events.

For radial EBUS, whether or not the target lesion(s) could be visualized should be recorded, including whether the probe could be positioned within, or adjacent to the lesion.[24]

DISCUSSION: Endoscopic evaluation of the mediastinal and hilar lymph nodes, or central mass lesion occurs prior to transbronchial needle aspiration. Sonographic features of the lymph node which may be examined include size (generally recorded as a short axis measurement), shape (rounded or oval), margin (regular or irregular), echogenicity (homogenous or heterogenous), presence or absence of a central hilar structure (CHS), and presence or absence of coagulation necrosis sign (CNS). Features suggestive of metastatic lymph nodes are: short axis diameter >10 mm, round shape, distinct margin, heterogeneous echogenicity, absence of CHS, or presence of CNS. A retrospective study of 487 patients to determine sensitivity and specificity of malignant lymph node involvement for each of these elements to be; size >10 mm had a sensitivity of 78% and specificity of 76%, round shape had a sensitivity of 88% and specificity of 76%, distinct margin had a sensitivity of 94% and specificity of 54%, absence of CHS had a sensitivity of 90% and specificity of 54%, and presence of coagulation necrosis sign had a sensitivity of 69% and specificity of 93%.[49]

7. ***Frequency with which patients with ACCP radiographic group B and C (cN1/2/3) undergo systematic mediastinal lymph node staging***

Type of measure: process
Performance target: >95%.
Data source: procedure report, medical notes (including imaging studies).

Systematic staging allows the most accurate establishment and quantification of lymph node involvement in NSCLC. A *systematic* staging EBUS is when all accessible lymph node stations are examined sequentially beginning with N3 nodal stations followed by N2 and then N1 stations. Any lymph node meeting pre-defined criteria is sampled with EBUS-TBNA. Importantly, these pre-defined criteria vary across international guidance. The National Institute for Health and Clinical Excellence (NICE, UK) recommends any lymph node that is abnormal on CT, PET or during sonographic evaluation should be sampled during systematic staging EBUS.[84] The European Society of Thoracic Surgeons (ESTS) guidelines for pre-operative mediastinal lymph node staging recommends any lymph node >5 mm in short axis is sampled during systematic staging EBUS.[85] A differing strategy is a '*targeted* staging EBUS' when only abnormal lymph nodes identified on pre-procedure imaging (CT/PET) are imaged and sampled during a staging EBUS procedure. When a staging EBUS is performed, this consensus statement recommends a 'systematic' approach is optimal as it allows the most accurate establishment and quantification of lymph node involvement in patients with

lung cancer including CT- and PET-occult lymph node metastases.

The American College of Chest Physicians 2013 guidelines on the diagnosis and staging of lung cancer suggested four clinical groups in patients with clinical stage I–III based on CT imaging alone which defines the optimal staging pathway. Group A is conglomerate, bulky and invasive mediastinal lymph node involvement, group B is discrete mediastinal lymph node enlargement, group C is a central tumour or N1 lymph node enlargement with a normal mediastinum, and group D is a peripheral tumour with normal hilar and mediastinal anatomy. Multiple studies demonstrate the ability of systematic staging with EBUS to identify radiologically and PET-occult lymph node metastases in patients with Group B and C findings on CT chest, with potential for significant impact on treatment decision-making in terms of suitability for resection,[44] and radiation field planning.[86,87]

The detection of nodal metastases during pre-operative work-up and staging has now gained even more important with the publication of the Checkmate 816 trial demonstrating the significant improvements in outcomes from neoadjuvant chemotherapy and immunotherapy prior to surgical resection of NSCLC with a 40% reduction in disease recurrence or death and an 14 times higher complete pathological response rate compared to neoadjuvant chemotherapy and surgery alone.[88] In the United Kingdom, NICE has recommended treatment with neoadjuvant chemotherapy-immunotherapy and surgery for patients with NSCLC greater than 4 cm or with lymph node metastases. The detection of lymph node metastases during staging EBUS is therefore critical to identify patients eligible for this treatment and provides further support to the recommendations made in this consensus statement.

This taskforce recommends the minimum criteria for a systematic staging EBUS is:

- Any patient with an abnormal intra-thoracic lymph node based on size (short axis on CT) or FDG avidity (on PET)

OR

- Any patient with a central tumour as defined in the ACCP 2013 guidelines

WHERE

- The detection of occult nodal metastases will influence management

This expert group agreed that virtually all patients within ACCP group B and C would be eligible for systematic staging EBUS within these criteria and therefore chose to base the quality standard for systematic staging EBUS on this cohort as a measure of high-quality patient care, whilst leaving flexibility for other scenarios.

DISCUSSION: Consensus exists within international guidelines that a systematic staging EBUS is indicated in any patient with clinical stage II and III lung cancer based on any enlarged intra-thoracic lymph node >10 mm in short axis on CT or any intra-thoracic lymph node with increased FDG avidity on PET-CT, and the appropriate physiological capacity for curative-intent treatment. Systematic staging EBUS has generally been recommended in patients with discrete lymph node enlargement rather than bulky, invasive and clearly malignant lymph nodes where the diagnosis and nodal stage is not in doubt.

In the United Kingdom, NICE recommends a staging EBUS is performed in any patients with suspected lung cancer (and deemed suitable for curative intent treatment) and any intra-thoracic lymph node measuring >1 cm in short axis or FDG avidity above the mediastinal blood pool. ESTS guidelines suggest further indications for staging EBUS in clinical stage I lung cancer (adenocarcinoma subtype, primary tumour >3 cm) even with radiologically normal hilar and mediastinal lymph nodes.[85] ACCP guidelines recommended staging EBUS is performed for all patients in group B and C given a high false positive and false negative rate of CT and PET imaging for detecting nodal metastases in these groups. This consensus statement recognizes that may also be scenarios in which patients in group D (e.g., peripheral tumour with normal mediastinum on CT but the FDG avid lymph nodes on PET) and group A (e.g., to accurately map nodal metastases[86] to aid radiation treatment planning[87]) require a staging EBUS as well.

In a prospective, multi-centre trial of systematic versus targeted endoscopic nodal staging 229 patients were evaluated to generate the sensitivity of systematic nodal endoscopic staging versus the hypothetical sensitivity had a targeted endoscopic staging procedure been performed that targeted FDG avid lymph nodes only. The systematic staging protocol included sampling any abnormal lymph node based on CT, PET and sonographic assessment plus any lymph node measuring >8 mm at stations 4R, 7 and 4L. Systematic staging EBUS improved the sensitivity for N2/3 metastases to 82% from 73% for targeted staging EBUS.[89] In a retrospective study with a similar design but involving 107 patients all of which had PET positive N2 nodes, where the systematic staging EBUS protocol was to sample any lymph node measuring >5 mm, systematic staging EBUS did not increase the overall sensitivity for the detection of N2/3 nodal metastases over targeted staging EBUS, both at 94%.[90] However, systematic staging EBUS provided greater granularity of nodal staging within the cN2/3 group in 13% of patients, including the detection of occult N3 nodal metastases that would preclude surgical resection in 3% and the detection of additional unsuspected N2 disease (increasing from single station to multi-station N2). This additional granularity may influence treatment decisions and treatment planning such as radiotherapy. This specific benefit on radiotherapy delivery has been studied in a prospective pilot study of 30 patients with locally advanced NSCLC where systematic staging EBUS identified radiologically occult lymph node metastases in 13% of patients[86] which substantially altered radiotherapy field planning.[87]

Evidence regarding the impact on diagnostic sensitivity of the number of lymph node stations sampled per procedure in EBUS is variable, but favours sampling of a higher

number of lymph nodes. In a regional study of 642 staging EBUS procedures across three different centres in the United Kingdom, the average lymph node stations sampled ranged from 1.3 to 1.9. The service with the lowest average of lymph node stations sampled reported the lowest sensitivity and the highest average was associated with the highest sensitivity.[16] A study of 1304 EBUS procedures, performed by 10 proceduralists, evaluated the determinants of sampling adequacy. Proceduralists with a higher average number of lymph node stations sampled per procedure had improved sampling adequacy.[91] This result was mirrored in a US-based procedural registry of 891 patients at six hospitals where diagnostic yield was associated with biopsy of more than two sites.[15] In contrast, in a meta-analysis of EBUS and mediastinoscopy (999 participants undergoing EBUS-TBNA, 915 participants undergoing mediastinoscopy) where pooled sensitivities were 84% and 86% respectively, subgroup analyses demonstrated no impact on sensitivity according to the number of lymph node stations sampled.[40] The taskforce notes that multiple international thoracic society guidelines recommend a minimum of three lymph node sites be sampled during intra-operative staging of the mediastinum in order to maximize diagnostic accuracy.[3,85]

Intra-procedure recommended standard reporting items

For linear EBUS

- Sonographic appearances of all lymph node stations examined including size, shape, margin, echogenicity, central hilar structure and coagulation necrosis sign.[49,82]
- Number and location of lymph node station sampled.
- Number of punctures per lymph node station.
- TBNA needle gauge used.
- Use of ROSE.

For radial EBUS

- Type of bronchoscope used (e.g., ultrathin, standard).
- Adjuncts used: guide sheath, double-hinged curette, fluoroscopy and navigational aids.
- Localization of lesion: Yes/No.
- If localized, probe position: within the target lesion versus adjacent to the target lesion.
- Sampling type completed: lavage, brush, biopsy and TBNA.
- Number of biopsies taken.
- Use of ROSE.

Linear EBUS

The number of lymph nodes sampled per procedure is considered an important metric. If the EBUS service does not meet the recommended performance outcomes, then review of the number of lymph node stations sampled per procedure could form part of the action plan to improve performance. Rate of FN EBUS findings are significantly reduced when satisfactory samples are obtained from a minimum of three LN stations.[59] Therefore, whilst no specific recommendation is possible on an absolute number of lymph node stations to be sampled per procedure, it is important this information is recorded for each EBUS procedure and used to evaluate service performance and forms part of any action plan to improve performance.

EBUS-TBNA is most commonly performed with gauge 22 needles, however, both 21- and 19-gauge needles are available. Studies examining the effect of needle gauge have not shown any difference in diagnostic yield when a 22 gauge needle is compared to the larger gauge[54] and 19 gauge,[55,56] including for lymphoma.[31,57,58] Therefore, no specific recommendation for needle gauge can be made, but increasing the size of needle used might be considered as part of an action plan if key performance indicators have not been met during the quality assurance review. Newer endoscopic needle types are being developed, including those designed to replicate histological biopsy rather than traditional FNA.[92] The role of these newer technologies in EBUS and consideration to their inclusion in the standards will need to be evaluated.

The utility of Rapid On-Site Cytologic Evaluation (ROSE) in EBUS-TBNA is uncertain. A recent systematic review of three randomized controlled trials totalling 342 participants identified a reduced number of needle passes when ROSE was used, but no significant improvement in diagnostic yield, nor decrease in overall procedure time or complication rate.[53] Notably, the Chest Technical Guideline for EBUS-TBNA recommends that in the absence of ROSE, a minimum of three separate needle passes be performed per site to optimize diagnostic performance.[60] Despite conflicting evidence, the use of ROSE remains a feasible quality indicator. Whilst ROSE is not considered to be a mandatory component of an EBUS service, its implementation might be considered as part of an action plan if key performance indicators have not been met during the quality assurance review.

Radial EBUS

Quality indicators recommended included those previously described to be associated with increased diagnostic yield and test sensitivity for the diagnosis of peripheral pulmonary lesions. Overall, the pooled sensitivity for radial EBUS in the detection of lung cancer has been reported to range from 0.70 (95% CI 0.68–0.73) to 0.72 (95% CI 0.70–0.75),[24,61] with significant study heterogeneity noted. Factors associated with the improved diagnostic yield that could be incorporated as intra-procedural quality measures include the size of peripheral lesion on axial CT, the presence of air-filled bronchus in close proximity (Bronchogram sign) and position of the R-EBUS probe within the target lesion.[24,93] Location of the target lesion within the lung (e.g., inner or outer lung) was considered, but thought not to be feasible to consistently document without clear definitions. Similarly, literature on impact

of lesion-to-pleura distance on diagnostic performance is conflicting.[45,46,94] Consequently, the taskforce suggests consideration of recording the distance from the lesion to the pleura on axial CT image as this should be able to be recorded in a standardized way.

Navigational aids including electromagnetic navigation (EMN) bronchoscopy or CT-derived virtual bronchoscopic navigation are associated with diagnostic yields similar to that reported for radial EBUS.[95,96] Randomized data on virtual bronchoscopic navigation improving yields is conflicting.[97,98] Only randomized two studies have addressed EMN in combination with radial EBUS, both suggesting modest increases in diagnostic yield.[99,100] The use of EBUS and EMN in sequence has also been described, achieving a very modest increase in diagnostic yield, with reduced consumables cost, compared to routine use of EMN.[101]

More recently, novel navigational aids, including cone beam CT[102] or robotic bronchoscopy[103] have been described, including in combination.[104] Early studies of both techniques suggest diagnostic accuracy may approach 90%.[103–105] These techniques should could be considered for inclusion as an intra-procedural reporting item where used.

In a systematic review on sensitivity of radial EBUS, ROSE was associated with increased sensitivity in lung cancer patients.[61] One single-centre study described a high positive predictive value for NSCLC with use of ROSE examination of radial EBUS-directed bronchial brushings, with bronchoscopic diagnosis of 4 of 76 patients with a final diagnosis of NSCLC the result of redirection of sampling following initial ROSE-negative results. Procedure times were also significantly shorter, predominantly due to obviating need for transbronchial biopsy.[62]

POST-PROCEDURE QUALITY INDICATORS

8. ***Frequency with which immediate adverse events are observed***

Type of measure: outcome
Performance target: <2%
Data source: procedure report, medical notes (including radiology reports)

TABLE 5 Complication rates following EBUS bronchoscopy.

Complication	Performance target: Rate of complication	References
Hospitalization	<1%	22,23
Bleeding		
Grade 1–2	<2%	24
Grade 3–4	<1%	
Pneumothorax		
Linear EBUS	<1%	22,23
Radial EBUS	<3%	24,25
Pneumomediastinum	<1%	22,23
Respiratory failure	<1%	22,23,25

EBUS-TBNA is recognized to be a very safe procedure with a low overall adverse event rate (Table 5). Radial EBUS is also well tolerated (Table 5), and is recognized to have a superior safety profile to percutaneous biopsy of peripheral pulmonary lesions, with excellent outcomes described even in patients with significant background lung disease.[25,38]

DISCUSSION: Both techniques are now widely established as a cornerstone of diagnosis (linear and radial EBUS) and staging (linear EBUS) of lung cancer, as well as a useful tool when investigating other cancers or benign diseases that affect both the lung parenchyma and the mediastinal/hilar lymph nodes. The reported overall complication rates have been low. Data used herein to reach the current recommendations come from national registries (e.g., AQuIRE), large prospective series and systematic reviews. However, any effort to summarize complication rates in widely used advanced invasive diagnostic techniques carries inherent biases and confounders (operator skill and experience variability, practice patterns, equipment used, case selection, nature of studies concentrating on technique efficacy instead). For example, in early work by Casal et al., immediate sedation-related complications were reported to be as high as 17%, but in the AQuIRE registry and the Japanese registry, the reported rate was much lower (<1%).[22,23,75] Therefore, we believe that by having a consensus between the expert task force members after independently reviewing the available literature comprising of thousands of patients, we were able to provide a comprehensive recommendation of performance indicators for both linear and radial probe EBUS.

8.1 Serious adverse events

In one of the most extensive systematic reviews analysing 16,181 patients of which 9119 underwent linear EBUS, the overall rate of serious adverse events (SAE) was 0.05%.[106] In the AQuIRE registry which prospectively included 1317 patients, the overall complication rate leading to further intervention or hospitalization was 1.44%.[22] For radial EBUS, the most recent meta-analysis by Ali et al., which included 57 studies (7872 lesions), reported an overall SAE rate of 2.8%, with pneumothorax unexpectedly being the most common (chest drain insertion was required in only 0.2%).[24]

We recommend a target of <2% for immediate SAEs for both linear and radial probe EBUS.

9. ***Incidence of complications following EBUS (including individual complications)***

Type of measure: outcome
Performance target: variable—see Table 5
Data source: medical notes (including radiology reports)

DISCUSSION:

a. *Linear EBUS*

Unplanned hospitalization

The incidence of immediate SAE leading to hospitalization or intervention appears to be low in all the large prospective studies and registries. In the AQuIRE registry, 6 individual centres reported an incidence of hospitalization following EBUS varying from 0.5% to 3.26%.[22] Age >70 years, and performance of transbronchial biopsy were associated with unplanned admission. Consistent with this report, a Japanese registry reported the incidence of hospitalization following EBUS-TBNA to be 1.4%.[23]

We recommend a target of <1% for immediate complications requiring hospitalization.

Bleeding

The definitions of bleeding used in many registries vary, creating some challenges in establishing overall incidence. We recommend the use of the Nashville Bleeding Scale to aid uniformity of reporting and data collection, and a target of <2% for Grade 1–2, and <1% for Grade 3–4 bleeding.[107]

Incidence of major bleeding requiring either intervention, intubation or hospitalization (Grade 3–4, Nashville Bleeding Scale) in patients who had linear EBUS in the Japanese registry study was <1%.[23] For events similar to Grade 1–2 Nashville Bleeding Scale, the incidence was <2%. In our literature search, we did not identify any strong signal to suggest an increased incidence of significant bleeding when larger gauge needles were used.

Pneumothorax/pneumomediastinum

Pneumothorax incidence is very low for linear EBUS, and varies between 0.03% and 0.5% in the existing large registries, with only a handful of cases requiring chest drain insertion or hospitalization. Pneumomediastinum *per se* is an extremely rare complication of linear EBUS, with <20 reported cases in the literature. The common theme in all cases appears to be a pre-existing advanced interstitial or parenchymal lung disease (fibrosis or emphysema). Consequently, routine chest imaging following EBUS-TBNA is not recommended.

We recommend a target of <1% for both pneumothorax and pneumomediastinum.

Infection

The overall incidence of infection for both linear and radial EBUS is very low, with mediastinitis ranging from 0.1% to 0.3%, and other infections (pneumonia, pericarditis, and 'sepsis') appear to have similar incidence.[22] The caveat is that many registries only documented complications occurring within the first 24–48 h, potentially missing few later events. Prospective studies with longer follow-up have suggested rates of acute infective complications may be as high as 4% in high-risk groups, with sampling of necrotic lesions associated with highest risk.[108]

We recommend a target of <1%.

Respiratory failure

Mild and transient elevation of arterial CO_2 following conscious sedation bronchoscopy may be frequently observed,[109] though significant respiratory failure requiring ventilatory support is rare. The reported incidence does not exceed 0.3%,[22] and appears to be associated more with pre-existing patient factors than procedural or anaesthetic practice.[110]

We recommend a target of <1%.

Cardiac event/death

The incidence of significant arrythmias or death during or immediately after linear and radial EBUS is very low. In the AQuIRE registry, there were none reported, whereas in the Japanese registry, three arrhythmic events occurred (0.04%), with an overall incidence of death as low as 0.01%.[23,25]

b. *Radial EBUS*

Hospitalization

Similar to existing literature for linear EBUS, there is significant variability in technique, skillset, patient selection and data collection for radial EBUS. The incidence of SAE leading to hospitalization is not specifically reported, however, the overall incidence of serious complications has been very low. Based on the calculated assumption that only a small proportion of SAE would require immediate hospitalization, we recommend a target of <1%.

Bleeding

Minor and self-limiting bleeding appears to be the most common complication in the published studies. The pooled overall bleeding incidence in the meta-analysis by Ali et al., was 0.74% (59 bleeds in 7872 lesions sampled),[24] unchanged from initial meta-analysis published in 2011.[38] As observed in literature for linear EBUS, reporting of bleeding is not consistent, with a handful of studies not reporting it at all, and the vast majority of those who do report it, do not provide a consistent grading to allow a concrete target recommendation.

We recommend the use of the Nashville Bleeding Scale to aid uniformity of reporting and data collection, and a target of <2% for Grade 1–2, and <1% for Grade 3–4 bleeding.[107]

Pneumothorax/pneumomediastinum

Pneumothorax appears to be the most common complication in radial EBUS sampling of peripheral pulmonary lesions, with incidence of 1.7% in the AQuIRE registry, and

2.8% in the meta-analysis by Ali et al.[24,25] However, chest drain insertion is not frequently required, with overall rates of <0.5%. Of note, none of the variables evaluated in the existing radial EBUS registries showed any significant association with the development of pneumothorax. We could not find any specific reports for the incidence of pneumomediastinum in radial EBUS.

We recommend a target of <3% for pneumothorax.

Respiratory failure

Respiratory failure is uncommon, with an incidence as low as 0.34% ($n = 2$) in the AQuIRE registry of 581 patients,[25] though may be higher in patients with advanced COPD.[111]

We recommend a target of <1% for significant hypoxia/respiratory failure.

Cardiac event/death

In the existing literature, there is no reported significant arrhythmia or death related to sampling alone when radial EBUS was used, though arrhythmia related to use of endobronchial adrenaline has been reported.[112]

TABLE 6 Diagnostic performance targets according to indication.

Final diagnosis	Performance target: Diagnostic sensitivity	References
Linear EBUS		
Lung cancer	>90%	26,27
Parenchymal lung mass	>90%	28
Sarcoidosis	>80%	29,30
Lymphoma	>65%	31–33
Tuberculosis	>60%–80%	34–36
Extra-thoracic lymph node metastases	>85%	37
Radial EBUS		
NSCLC	>70%	24,38,39
Lesion <2 cm	>60%	

10. ***Frequency with which inadequate specimens are reported from an individual lymph node station***

Type of measure: outcome
Performance target: <10%
Data source: pathology reports

DISCUSSION: Adequacy of EBUS-TBNA specimens is dependent on the target area that is being sampled, for example, lymph nodes or lung tissue. When TBNA is performed from lymph nodes, cytopathologists can categorize the quality of the specimen depending on the numbers of observed atypical or malignant cells, or otherwise lymphocytes/anthracotic material to declare benignity. Criteria have been developed by certain groups to assist with classifying the quality of EBUS-TBNA specimens.[113] Analysing specimens from lung tissue or other structures accessible via EBUS requires appropriate cytological considerations of when determining adequacy. In their prospective multicentre review of the AQuIRE registry, Ost et al. reported sample adequacy (per node) of 90.7%, with adequacy rates significantly associated with lymph node size.[40] A meta-analysis comparing needle sizes (21 vs. 22 gauge) reported sample adequacy of 89.1% with 21-gauge needles and 90% with 22-gauge needles from three studies involving 1345 patients.[114]

11. ***Diagnostic performance of EBUS***

Performance targets according to indication for EBUS are summarized in Table 6.

11.1 ***Diagnostic performance of EBUS-TBNA according to indication/ACCP radiographic group***

Type of measure: outcome
Performance target: variable—see Tables 6 and 7
Data source: pathology reports, (subsequent medical notes/radiology reports where follow-up required to confirm benign/non-diagnostic findings)

Although linear EBUS has become a validated technique in delineating thoracic radiological abnormalities, its performance is dependent on multiple factors. EBUS diagnostic

TABLE 7 Recommended minimum standards for *staging EBUS* according to the prevalence of N2/3 nodal metastases in the population undergoing EBUS (from ACCP evidence-based clinical practice guidelines[3,115]).

	Sensitivity		Negative predictive value	
N2/3 prevalence	ACCP meta-analysis	Minimum standard	ACCP meta-analysis	Minimum standard
>80%	96%	**>90%**	83%	**>80%**
60%–80%	91%	**>88%**	83%	**>80%**
40%–60%	87%	**>85%**	89%	**>85%**
20%–40%	87%	**>80%**	95%	**>90%**
<20%	78%	**>75%**	96%	**>92%**

accuracy and sensitivity can be affected by pre-test diagnosis probability, disease prevalence, location of area/node sampled and size of area/node sampled, technical factors such as transbronchial needle size, use of rapid on-site examination (ROSE) and operator factors such as experience, to name a few.

a. Non-small cell lung cancer diagnosis and staging

Performance Target: see Table 6 (diagnostic EBUS) and Table 7 (staging EBUS).

Numerous systematic reviews evaluating the diagnostic performance of EBUS-TBNA in the diagnosis and staging of NSCLC have been published. Pooled sensitivity after meta-analysis range from 79% to 93%,[43,116–120] with higher sensitivities reported if EBUS is combined with EUS/EUS-B.[65] Importantly, as noted by the ACCP,[3] sensitivity in systematic staging EBUS for detection of lymph node metastases will differ according to the underlying prevalence of cN2/3 disease in the cohort examined (Table 7).

As an illustration of this, a meta-analysis of 13 studies with 1441 patients with a radiological normal mediastinum (cN0/cN1), and low mean prevalence of pN2/3 disease of 15%, reported a low pooled sensitivity of EBUS-TBNA for mediastinal staging of 55% (95% CI 46%–63%).[44] Prospective studies of centres performing EBUS for a mix of diagnostic/staging indications (i.e., patients with cN1-3, M0/1) suggest prevalence of pN2/3 disease may range from 29% to 61%.[121] As noted in this study, reduced diagnostic accuracy may in fact reflect patient selection, emphasizing the importance of reporting diagnostic sensitivity of EBUS-TBNA in NSCLC according to prevalence of pN2/3 disease in the cohort examined, particularly if concerns regarding performance exist.

The ACCP have also described radiographic groups for lung cancer patients based on index CT of the thorax (without evidence of stage 4 metastatic disease).[3] Reporting of diagnostic sensitivity according to ACCP radiographic group (A–D) may be less resource-intensive as this feature is identifiable at the time of EBUS, and therefore can be recorded in the procedure report. Approximate prevalence of disease is described according to radiographic group, and may aid reporting of diagnostic performance of EBUS-TBNA.[122]

b. Non-small cell lung cancer central parenchymal lesions

Performance Target: Sensitivity ≥90%.

Kuijvenhoven et al. performed a systemic review of EBUS-TBNA diagnosis of central lung tumours and found a pooled sensitivity of 91% (95% CI 88–94%) from 14 studies.[28]

c. Lymphoma diagnosis

Performance Target: Sensitivity ≥65%.

DISCUSSION: The use of EBUS-TBNA in mediastinal lymphoproliferative disease from a diagnostic perspective has always been questioned, but offers the benefits of being less invasive than surgery. One systematic review has been performed by Labarca et al. From their meta-analysis of 14 studies (425 patients), they found a pooled sensitivity of 66.2% (95% CI 55%–75.8%) with use of either 21 or 22-gauge TBNA needles.[32] New diagnosis of lymphoma had a pooled sensitivity of 67.1% (95% CI 54.2%–77.9%), while recurrence was higher at 77.8% (95% CI 68.1%–85.2%).[32] Crucial also is the ability to subtype the lymphoma, with pooled results of 63.9% (95% CI 49.9%–78%) further supporting its role as a first-line investigation.[105] Use of 22-gauge needles had a sensitivity of 82.3% (95% CI 73.6%–88.6%) compared to 63.8% (95% CI 49.6%–75.9%) with the 21-gauge, but 10/14 studies used the smaller needle size.[105] Limited evidence suggests the use of larger 19 gauge needles does not appear to further improve diagnostic performance in lymphoma.[31] The CHEST guideline for EBUS-TBNA found a pooled diagnostic accuracy of at least 68.7% (95% CI 61.9%–75.5%) in lymphoma for EBUS-TBNA.[60]

d. Sarcoidosis diagnosis

Performance Target: Sensitivity ≥80%.

DISCUSSION: Sarcoidosis is a differential for mediastinal lymphadenopathy, either detected incidentally or from the investigation of sarcoidosis-associated systemic symptoms. Trisolini et al. performed a meta-analysis of EBUS-TBNA in sarcoidosis and found a pooled sensitivity of 84% (95% CI 79%–88%) and diagnostic yield of 79% from the 14 selected studies (2097 patients).[123] A meta-analysis by Hu et al. of 14 studies (1823 patients) about the different bronchoscopic modalities used in sarcoidosis found EBUS-TBNA had a diagnostic yield of 83.1%, which further increased to ∼90% when combined with endobronchial and transbronchial biopsies.[124]

e. Tuberculosis diagnosis

Performance Target: Sensitivity ≥80%, Diagnostic Yield ≥80%.

DISCUSSION: Tuberculosis can present with a spectrum of thoracic abnormalities including parenchymal changes and mediastinal lymphadenopathy (tuberculous lymphadenitis). Tuberculous lymphadenitis is present in ∼35% of patients with tuberculosis.[125] Yield from EBUS-TBNA is linked to local prevalence of the infection. Two systematic reviews have been performed in this area, both identifying pooled sensitivity of 80%–85%.[126,127] Use of a composite clinicopathologic diagnostic approach may improve yield.[34]

11.2 *Diagnostic performance of radial EBUS for diagnosis of peripheral pulmonary lesions*

***Type of measure*:** outcome
***Performance target*:** variable—see Table 6

***Data source*:** pathology reports, (subsequent medical notes/radiology reports where follow-up required to confirm benign/non-diagnostic findings)

Different measures may be used to report diagnostic outcomes.

DISCUSSION: Single-centre institutions propose sensitivity results above 60% for all peripheral pulmonary lesions, with considerable variability in diagnostic yields.[45,47] Diagnostic sensitivity and accuracy are increased when sampling lesions with a bronchus sign and a solid radiological pattern.[46] Rapid on-site cytologic evaluation may improve diagnostic performance.[48,62]

Systematic reviews suggest a sensitivity above 70% for radial EBUS for the diagnosis of malignant peripheral pulmonary lesions; a meta-analysis including 1420 patients identified a specificity of 1.00 and point sensitivity of 0.73 for the detection of lung cancer.[38] Malignant diagnosis is a predictor for a higher diagnostic yield.[79] Lower diagnostic sensitivity is reported for lesions smaller than 20 mm,[38,39] A minimum size suitable for EBUS is not described, though studies very rarely include patients with lesions <10 mm and it is suggested diagnostic sensitivity for lesions below this size is likely to be poor.

We recommend a target sensitivity of ≥70% for diagnostic performance for malignancy for radial EBUS for the diagnosis of peripheral pulmonary lesions.

12. ***Frequency with which tissue/specimens are inadequate for required molecular/ancillary testing***

***Type of measure*:** outcome
***Performance target*:** < 10%
***Data source*:** pathology reports

Accurate subtyping and genotyping of NSCLC remains a critical aspect of the diagnostic assessment of patients with Stage IV NSCLC, where due to safety and ease of procedure, EBUS-TBNA may be the sole diagnostic sampling performed. The results of these tests may be pivotal to define optimal treatment in lung cancer and are an important performance indicator.

Expert guidelines in lung cancer recommend testing for EGFR, ALK, ROS1, BRAF mutations and performance of PD-L1 immunohistochemistry in all cases of adenocarcinoma. RET, MET exon 14 skipping and NTRK1/2/3 may also be considered, although each of these mutations accounts for approximately 1% of all adenocarcinoma cases.[128]

Not all patients in whom EBUS is performed will require molecular subtyping (e.g., TBNA of central mass), hence the performance target is chosen to describe the rate of inadequate cases (rather than the rate for which patients have molecular testing successfully performed).

DISCUSSION: Although there is considerable variability between different studies, the available evidence

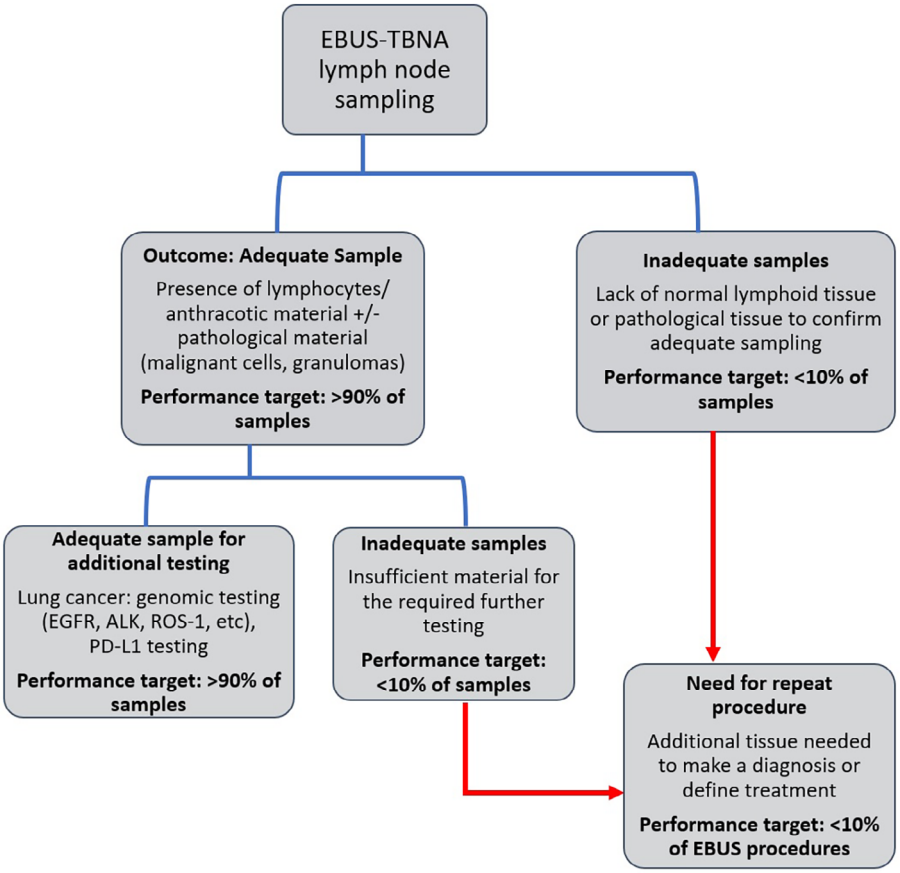

FIGURE 1 Quality standards (performance targets) for adequacy of pathological specimens obtained during EBUS-TBNA, and need for repeat biopsy procedure. Need for repeat biopsy may arise due to either lack of diagnostic tissue OR due to insufficient tissue to complete all required further sub-typing and genotyping testing (Quality Indicator #12).

suggests that molecular analysis is feasible in 90% to over 95% of successfully sampled malignant lesions.[121,129] In a systematic review and meta-analysis examining 2698 patients, the pooled probability of obtaining a sufficient sample for molecular testing by EBUS-TBNA was 94.5%.[130]

Equally, multi-centre studies confirm that over 94% of EBUS-TBNA specimens are suitable for PD-L1 testing,[131] and that testing on EBUS-TBNA cell block specimens with adequate cellularity demonstrates high agreement with paired histology specimens in NSCLC.[132] Limited evidence to date suggests that a 19G TBNA needle may provide more adequate material for molecular analysis.[58,133]

It is also important to record the number of repeat procedures required to provide additional tissue which is a marker of quality, as well as of poor patient experience (quality indicator also <10%). The need for a repeat procedure (including mediastinoscopy) may arise due to either inadequate specimen or inadequate tissue to complete required molecular testing (Figure 1).

We recommend a target of <10% for tissue specimen inadequacy, and <10% need for repeat biopsy for linear probe EBUS.

DISCUSSION AND CONCLUSION

The development and widespread uptake of EBUS has revolutionized patient care. The excellent safety profile of EBUS and overall high diagnostic performance of EBUS have supported the successful introduction of the techniques into institutions worldwide. Techniques differ between centres, and significant variance in clinical outcomes suggests that some patients may not be receiving the highest quality care. Although the impact of a sub-optimal EBUS may not be catastrophic (e.g., non-diagnostic procedure, minor pneumothorax), the collective outcome in delayed diagnoses, increased number of procedures, increased healthcare resource utilization cannot be discounted.

This expert panel statement is intended to provide a quality improvement framework to Interventional Pulmonologists internationally, regardless of the setting of their practice. We have identified 12 quality Indicators in the performance of EBUS bronchoscopy, and identified minimum performance standards, based on published literature. It is not intended that every measure be used in every setting for every procedure. Where resource constraints limit the ability of centres to address every proposed quality indicator, emphasis should be placed on outcome measures, which have the clearest relationship with important clinical outcomes.

Standardized reporting of procedures is central to efforts in quality improvement. Inconsistent procedural reporting results in significant challenges to internal audit and external benchmarking, thus limiting opportunities for quality improvement. In contrast, consistent procedural reporting in performance of endoscopic ultrasound has demonstrated in quality indicator adherence by ensuring comprehensive documentation while limiting error.[122] Significant variation in reporting of EUS is well recognized,[28] though no such evidence exists for EBUS bronchoscopy.

The taskforce aimed to provide recommended standard reporting items to improve ease of audit, and to provide consistent terminology to allow communication and benchmarking between centres. Such items may comprise mandatory fields in centres where electronic reporting is standard, however it is not expected that all items be recorded for all cases at all centres. Reporting templates should be developed for individual institutions following consideration of local factors including patient profiles (e.g., proportion of diagnostic vs. staging EBUS) and local resource constraints.

Key to the success of these indicators is that they are practical to measure and have clear connection to clinically meaningful outcomes. As noted above, having a performance measure (quality indicator) does not result in improved health outcomes *per se*: in order to improve quality, it is essential to measure local performance regularly against this benchmark. It is equally important that this mechanism not be used to 'punish' those not meeting minimum performance criteria. Instead, internal audit is encouraged to ensure optimal performance is being achieved and where outcomes are not consistent with published literature, internal review may allow identification of opportunities for quality improvement in EBUS.

In conclusion, this statement is intended to provide a framework for individual proceduralists to assess the quality of EBUS they provide their patients through identification of clinically relevant, feasible quality measures. We hope that routine measurement of quality indicators and standardization of reporting will improve the overall care of patients undergoing EBUS. Quality improvement is an ongoing iterative process and as such we expect this document to also evolve over time as future studies identify other valuable markers of high-quality care.

ACKNOWLEDGEMENTS

Ms. Smaro Lazarakis—support in completion of electronic medical database search strategy. Mr. Michael Mendoza—support in coordination of taskforce meetings, execution and collation of anonymous e-voting.

FUNDING INFORMATION

DPS supported in part by NHMRC Investigator Grant.

CONFLICT OF INTEREST STATEMENT

None declared.

ORCID

Daniel P. Steinfort https://orcid.org/0000-0002-8998-2949
Karan Madan https://orcid.org/0000-0002-5330-6391
Calvin Sidhu https://orcid.org/0000-0002-4574-8157
Erik H. F. M. Van Der Heijden https://orcid.org/0000-0003-3596-518X

REFERENCES

1. Kurimoto N, Miyazawa T, Okimasa S, Maeda A, Oiwa H, Miyazu Y, et al. Endobronchial ultrasonography using a guide sheath increases the ability to diagnose peripheral pulmonary lesions endoscopically. Chest. 2004;126(3):959–65.
2. Yasufuku K, Chiyo M, Sekine Y, Chhajed PN, Shibuya K, Iizasa T, et al. Real-time endobronchial ultrasound-guided transbronchial needle aspiration of mediastinal and hilar lymph nodes. Chest. 2004; 126(1):122–8.
3. Silvestri GA, Gonzalez AV, Jantz MA, Margolis ML, Gould MK, Tanoue LT, et al. Methods for staging non-small cell lung cancer: diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. Chest. 2013;143(Suppl 5):e211S–e250S.
4. Vilmann P, Clementsen PF, Colella S, Siemsen M, De Leyn P, Dumonceau JM, et al. Combined endobronchial and oesophageal endosonography for the diagnosis and staging of lung cancer. European Society of Gastrointestinal Endoscopy (ESGE) Guideline, in cooperation with the European Respiratory Society (ERS) and the European Society of Thoracic Surgeons (ESTS). Eur Respir J. 2015; 46(1):40–60.
5. Maconachie R, Mercer T, Navani N, McVeigh G, Guideline C. Lung cancer: diagnosis and management: summary of updated NICE guidance. BMJ. 2019;364:l1049.
6. Langendam MW, Piggott T, Nothacker M, Agarwal A, Armstrong D, Baldeh T, et al. Approaches of integrating the development of guidelines and quality indicators: a systematic review. BMC Health Serv Res. 2020;20(1):875.
7. Chassin MR, Galvin RW. The urgent need to improve health care quality. Institute of Medicine National Roundtable on Health Care Quality. Jama. 1998;280(11):1000–5.
8. Barnett ML, Olenski AR, Jena AB. Patient mortality during unannounced accreditation surveys at US hospitals. JAMA Intern Med. 2017;177(5):693–700.
9. Rutter MD, Senore C, Bisschops R, Domagk D, Valori R, Kaminski MF, et al. The European Society of Gastrointestinal Endoscopy Quality Improvement Initiative: developing performance measures. Endoscopy. 2016;48(1):81–9.
10. Welsh RC, MacFarlane K, Quraishi AUR, Canadian Cardiovascular Society Percutaneous Coronary Intervention Quality Working Group. Canadian Cardiovascular Society and Canadian Institute of Health Information Public Reporting of Percutaneous Coronary Intervention Quality Indicators. Can J Cardiol. 2018;34(12):1539–40.
11. Wani S, Wallace MB, Cohen J, Pike IM, Adler DG, Kochman ML, et al. Quality indicators for EUS. Am J Gastroenterol. 2015;110(1): 102–13.
12. Hudson J, Semenkovich T, Puri V. Oncologic quality indicators in thoracic surgery. Thorac Surg Clin. 2017;27(3):227–44.
13. Harden SV, Chiew KL, Millar J, Vinod SK. Quality indicators for radiation oncology. J Med Imaging Radiat Oncol. 2022;66(2):249–57.
14. Slade MG, Rahman NM, Stanton AE, Curry L, Slade GC, Clelland CA, et al. Improving standards in flexible bronchoscopy for lung cancer. Eur Respir J. 2011;37(4):895–901.
15. Ost DE, Niu J, Zhao H, Grosu HB, Giordano SH. Quality gaps and comparative effectiveness in lung cancer staging and diagnosis. Chest. 2020;157(5):1322–45.
16. Evison M, Crosbie P, Martin J, Shah R, Doran H, Borrill Z, et al. EBUS-guided mediastinal lung cancer staging: monitoring of quality standards improves performance. Thorax. 2016;71(8):762–3.
17. ISFU System. National Quality Measures Clearinghouse (NQMC). http://www.qualitymeasures.ahrq.gov
18. Du Rand IMM. Quality standards for diagnostic flexible bronchoscopy in adults. Br Thorac Soc Rep. 2014;6(5).
19. Rizk MK, Sawhney MS, Cohen J, Pike IM, Adler DG, Dominitz JA, et al. Quality indicators common to all GI endoscopic procedures. Gastrointest Endosc. 2015;81(1):3–16.
20. Mazzone PJ, Vachani A, Chang A, Detterbeck F, Cooke D, Howington J, et al. Quality indicators for the evaluation of patients with lung cancer. Chest. 2014;146(3):659–69.
21. Murphy MK, Black NA, Lamping DL, McKee CM, Sanderson CF, Askham J, et al. Consensus development methods, and their use in clinical guideline development. Health Technol Assess. 1998;2(3):1–88.
22. Eapen GA, Shah AM, Lei X, Jimenez CA, Morice RC, Yarmus L, et al. Complications, consequences, and practice patterns of endobronchial ultrasound-guided transbronchial needle aspiration: results of the AQuIRE registry. Chest. 2013;143(4):1044–53.
23. Asano F, Aoe M, Ohsaki Y, Okada Y, Sasada S, Sato S, et al. Complications associated with endobronchial ultrasound-guided transbronchial needle aspiration: a nationwide survey by the Japan Society for Respiratory Endoscopy. Respir Res. 2013;14(1):50.
24. Ali MS, Trick W, Mba BI, Mohananey D, Sethi J, Musani AI. Radial endobronchial ultrasound for the diagnosis of peripheral pulmonary lesions: a systematic review and meta-analysis. Respirology. 2017; 22(3):443–53.
25. Ost DE, Ernst A, Lei X, Kovitz KL, Benzaquen S, Diaz-Mendoza J, et al. Diagnostic yield and complications of bronchoscopy for peripheral lung lesions. Results of the AQuIRE Registry. Am J Respir Crit Care Med. 2016;193(1):68–77.
26. Chandra S, Nehra M, Agarwal D, Mohan A. Diagnostic accuracy of endobronchial ultrasound-guided transbronchial needle biopsy in mediastinal lymphadenopathy: a systematic review and meta-analysis. Respir Care. 2012;57(3):384–91.
27. Yan JH, Pan L, Chen XL, Chen JW, Yan LM, Liu B, et al. Endobronchial ultrasound versus conventional transbronchial needle aspiration in the diagnosis of mediastinal lymphadenopathy: a meta-analysis. Springerplus. 2016;5(1):1716.
28. Kuijvenhoven JC, Leoncini F, Crombag LC, Spijker R, Bonta PI, Korevaar DA, et al. Endobronchial ultrasound for the diagnosis of centrally located lung tumors: a systematic review and meta-analysis. Respiration. 2020;99(5):441–50.
29. Kassirian S, Hinton SN, Iansavitchene A, Amjadi K, Chee A, Dhaliwal I, et al. Effect of needle size on diagnosis of sarcoidosis with endobronchial ultrasound-guided transbronchial needle aspiration: systematic review and meta-analysis. Ann Am Thorac Soc. 2022; 19(2):279–90.
30. Crombag LMM, Mooij-Kalverda K, Szlubowski A, Gnass M, Tournoy KG, Sun J, et al. EBUS versus EUS-B for diagnosing sarcoidosis: the International Sarcoidosis Assessment (ISA) randomized clinical trial. Respirology. 2022;27(2):152–60.
31. Lim CE, Steinfort DP, Irving LB. Diagnostic performance of 19-gauge endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) in suspected lymphoma: a prospective cohort study. Clin Respir J. 2020;14(9):800–5.
32. Labarca G, Sierra-Ruiz M, Kheir F, Folch E, Majid A, Mehta HJ, et al. Diagnostic accuracy of endobronchial ultrasound transbronchial needle aspiration in lymphoma. A systematic review and meta-analysis. Ann Am Thorac Soc. 2019;16(11):1432–9.
33. Kheir F, Itani A, Assasa O, Alraiyes AH. The utility of endobronchial ultrasound-transbronchial needle aspiration in lymphoma. Endosc Ultrasound. 2016;5(1):43–8.
34. Geake J, Hammerschlag G, Nguyen P, Wallbridge P, Jenkin GA, Korman TM, et al. Utility of EBUS-TBNA for diagnosis of mediastinal tuberculous lymphadenitis: a multicentre Australian experience. J Thorac Dis. 2015;7(3):439–48.
35. Madan K, Mohan A, Ayub II, Jain D, Hadda V, Khilnani GC, et al. Initial experience with endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) from a tuberculosis endemic population. J Bronchol Interv Pulmonol. 2014;21(3):208–14.
36. Li W, Zhang T, Chen Y, Liu C, Peng W. Diagnostic value of convex probe endobronchial ultrasound-guided transbronchial needle aspiration in mediastinal tuberculous lymphadenitis: a systematic review and meta-analysis. Med Sci Monit. 2015;21:2064–72.

37. Yang B, Li F, Shi W, Liu H, Sun S, Zhang G, et al. Endobronchial ultrasound-guided transbronchial needle biopsy for the diagnosis of intrathoracic lymph node metastases from extrathoracic malignancies: a meta-analysis and systematic review. Respirology. 2014;19(6): 834–41.
38. Steinfort DP, Khor YH, Manser RL, Irving LB. Radial probe endobronchial ultrasound for the diagnosis of peripheral lung cancer: systematic review and meta-analysis. Eur Respir J. 2011;37(4):902–10.
39. Lee J, Song JU. Diagnostic yield of radial probe endobronchial ultrasonography-guided transbronchial biopsy without fluoroscopy in peripheral pulmonary lesions: a systematic review and meta-analysis. Thorac Cancer. 2022;14:195–205.
40. Ost DE, Ernst A, Lei X, Feller-Kopman D, Eapen GA, Kovitz KL, et al. Diagnostic yield of endobronchial ultrasound-guided transbronchial needle aspiration: results of the AQuIRE Bronchoscopy Registry. Chest. 2011;140(6):1557–66.
41. Stather DR, MacEachern P, Chee A, Dumoulin E, Tremblay A. Trainee impact on procedural complications: an analysis of 967 consecutive flexible bronchoscopy procedures in an interventional pulmonology practice. Respiration. 2013;85(5):422–8.
42. Nguyen S, Ferland N, Beaudoin S, Martel S, Simon M, Laberge F, et al. Influence of trainee involvement on procedural characteristics for linear endobronchial ultrasound. Thorac Cancer. 2017;8(5): 517–22.
43. Gu P, Zhao YZ, Jiang LY, Zhang W, Xin Y, Han BH. Endobronchial ultrasound-guided transbronchial needle aspiration for staging of lung cancer: a systematic review and meta-analysis. Eur J Cancer. 2009; 45(8):1389–96.
44. Leong TL, Loveland PM, Gorelik A, Irving L, Steinfort DP. Preoperative staging by EBUS in cN0/N1 lung cancer: systematic review and meta-analysis. J Bronchol Interv Pulmonol. 2019;26(3):155–65.
45. Tay JH, Irving L, Antippa P, Steinfort DP. Radial probe endobronchial ultrasound: factors influencing visualization yield of peripheral pulmonary lesions. Respirology. 2013;18(1):185–90.
46. Hong KS, Lee KH, Chung JH, Shin KC, Jin HJ, Jang JG, et al. Utility of radial probe endobronchial ultrasound guided transbronchial lung biopsy in bronchus sign negative peripheral pulmonary lesions. J Korean Med Sci. 2021;36(24):e176.
47. Jacomelli M, Demarzo SE, Cardoso PF, Palomino AL, Figueiredo VR. Radial-probe EBUS for the diagnosis of peripheral pulmonary lesions. J Bras Pneumol. 2016;42(4):248–53.
48. Izumo T, Matsumoto Y, Sasada S, Chavez C, Nakai T, Tsuchida T. Utility of rapid on-site cytologic evaluation during endobronchial ultrasound with a guide sheath for peripheral pulmonary lesions. Jpn J Clin Oncol. 2017;47(3):221–5.
49. Fujiwara T, Yasufuku K, Nakajima T, Chiyo M, Yoshida S, Suzuki M, et al. The utility of sonographic features during endobronchial ultrasound-guided transbronchial needle aspiration for lymph node staging in patients with lung cancer: a standard endobronchial ultrasound image classification system. Chest. 2010;138(3):641–7.
50. Sullivan KA, Farrokhyar F, Leontiadis GI, Patel YS, Churchill IF, Hylton DA, et al. Routine systematic sampling versus targeted sampling during endobronchial ultrasound: a randomized feasibility trial. J Thorac Cardiovasc Surg. 2022;164(1):254–61 e1.
51. Hylton DA, Turner S, Kidane B, Spicer J, Xie F, Farrokhyar F, et al. The Canada lymph node score for prediction of malignancy in mediastinal lymph nodes during endobronchial ultrasound. J Thorac Cardiovasc Surg. 2020;159(6):2499–507 e3.
52. Verhoeven RLJ, Leoncini F, Slotman J, de Korte C, Trisolini R, van der Heijden E, et al. Accuracy and reproducibility of endoscopic ultrasound B-mode features for observer-based lymph nodal malignancy prediction. Respiration. 2021;100(11):1088–96.
53. Sehgal IS, Dhooria S, Aggarwal AN, Agarwal R. Impact of rapid onsite cytological evaluation (ROSE) on the diagnostic yield of transbronchial needle aspiration during mediastinal lymph node sampling: systematic review and meta-analysis. Chest. 2018;153(4):929–38.
54. Yarmus LB, Akulian J, Lechtzin N, Yasin F, Kamdar B, Ernst A, et al. Comparison of 21-gauge and 22-gauge aspiration needle in endobronchial ultrasound-guided transbronchial needle aspiration: results of the American College of Chest Physicians Quality Improvement Registry, education, and evaluation registry. Chest. 2013;143(4): 1036–43.
55. Dooms C, Vander Borght S, Yserbyt J, Testelmans D, Wauters E, Nackaerts K, et al. A randomized clinical trial of flex 19G needles versus 22G needles for endobronchial ultrasonography in suspected lung cancer. Respiration. 2018;96(3):275–82.
56. Manley CJ, Kumar R, Gong Y, Huang M, Wei SS, Nagarathinam R, et al. Prospective randomized trial to compare the safety, diagnostic yield and utility of 22-gauge and 19-gauge endobronchial ultrasound transbronchial needle aspirates and processing technique by cytology and histopathology. J Am Soc Cytopathol. 2022;11(2):114–21.
57. Romatowski NPJ, Gillson AM, Stollery D, Dumoulin E, Vakil E, Dhaliwal I, et al. Endobronchial ultrasound transbronchial needle aspiration with a 19-gauge needle vs 21- and 22-gauge needles for mediastinal lymphadenopathy. Chest. 2022;162(3):712–20.
58. Yu Lee-Mateus A, Garcia-Saucedo JC, Abia-Trujillo D, Labarca G, Patel NM, Pascual JM, et al. Comparing diagnostic sensitivity of different needle sizes for lymph nodes suspected of lung cancer in endobronchial ultrasound transbronchial needle aspiration: systematic review and meta-analysis. Clin Respir J. 2021;15(12):1328–36.
59. Sanz-Santos J, Serra M, Gallego M, Monton C, Cosio B, Sauleda J, et al. Determinants of false-negative results in non-small-cell lung cancer staging by endobronchial ultrasound-guided needle aspiration. Eur J Cardiothorac Surg. 2015;47(4):642–7.
60. Wahidi MM, Herth F, Yasufuku K, Shepherd RW, Yarmus L, Chawla M, et al. Technical aspects of endobronchial ultrasound-guided transbronchial needle aspiration: CHEST Guideline and expert panel report. Chest. 2016;149(3):816–35.
61. Sainz Zuniga PV, Vakil E, Molina S, Bassett RL Jr, Ost DE. Sensitivity of radial endobronchial ultrasound-guided bronchoscopy for lung cancer in patients with peripheral pulmonary lesions: an updated meta-analysis. Chest. 2020;157(4):994–1011.
62. Steinfort DP, Leong TL, Laska IF, Beaty A, Tsui A, Irving LB. Diagnostic utility and accuracy of rapid on-site evaluation of bronchoscopic brushings. Eur Respir J. 2015;45(6):1653–60.
63. Yamada N, Yamazaki K, Kurimoto N, Asahina H, Kikuchi E, Shinagawa N, et al. Factors related to diagnostic yield of transbronchial biopsy using endobronchial ultrasonography with a guide sheath in small peripheral pulmonary lesions. Chest. 2007 Aug;132(2):603–8.
64. Leong P, Deshpande S, Irving LB, Bardin PG, Farmer MW, Jennings BR, et al. Endoscopic ultrasound fine-needle aspiration by experienced pulmonologists: a cusum analysis. Eur Respir J. 2017; 50(5):1701102.
65. Korevaar DA, Crombag LM, Cohen JF, Spijker R, Bossuyt PM, Annema JT. Added value of combined endobronchial and oesophageal endosonography for mediastinal nodal staging in lung cancer: a systematic review and meta-analysis. Lancet Respir Med. 2016;4(12):960–8.
66. Inomata M, Kuse N, Awano N, Tone M, Yoshimura H, Jo T, et al. Utility of radial endobronchial ultrasonography combined with transbronchial lung cryobiopsy in patients with diffuse parenchymal lung diseases: a multicentre prospective study. BMJ Open Respir Res. 2021; 8(1):e000826.
67. Abdelghani R, Thakore S, Kaphle U, Lasky JA, Kheir F. Radial endobronchial ultrasound-guided transbronchial cryobiopsy. J Bronchol Interv Pulmonol. 2019;26(4):245–9.
68. Vaidya PJ, Munavvar M, Leuppi JD, Mehta AC, Chhajed PN. Endobronchial ultrasound-guided transbronchial needle aspiration: safe as it sounds. Respirology. 2017;22(6):1093–101.
69. Wahidi MM, Hulett C, Pastis N, Shepherd RW, Shofer SL, Mahmood K, et al. Learning experience of linear endobronchial ultrasound among pulmonary trainees. Chest. 2014;145(3):574–8.
70. Kemp SV, El Batrawy SH, Harrison RN, Skwarski K, Munavvar M, Rosell A, et al. Learning curves for endobronchial ultrasound using cusum analysis. Thorax. 2010;65(6):534–8.
71. Bolliger CT, Mathur PN, Beamis JF, Becker HD, Cavaliere S, Colt H, et al. ERS/ATS statement on interventional pulmonology. European

Respiratory Society/American Thoracic Society. Eur Respir J. 2002; 19(2):356–73.
72. Fielding D. Simulation and assessment tools in EBUS TBNA training: what are we waiting for? Respirology. 2017;22(8):1483–4.
73. Ridgers A, Li J, Coles-Black J, Jiang M, Chen G, Chuen J, et al. Teaching radial endobronchial ultrasound with a three-dimensional-printed radial ultrasound model. ATS Sch. 2021;2(4):606–19.
74. Steinfort DP, Irving LB. Patient satisfaction during endobronchial ultrasound-guided transbronchial needle aspiration performed under conscious sedation. Respir Care. 2010;55(6):702–6.
75. Casal RF, Lazarus DR, Kuhl K, Nogueras-González G, Perusich S, Green LK, et al. Randomized trial of endobronchial ultrasound-guided transbronchial needle aspiration under general anesthesia versus moderate sedation. Am J Respir Crit Care Med. 2015;191(7):796–803.
76. Maffucci R, Maccari U, Guidelli L, Benedetti L, Fabbroni R, Piccoli B, et al. Pulmonologist-administered balanced propofol analgosedation during interventional procedures: an Italian real-life study on comfort and safety. Int J Clin Pract. 2022;2022:3368077.
77. Chrissian AA, Bedi H. Bronchoscopist-directed continuous propofol infusion for targeting moderate sedation during endobronchial ultrasound bronchoscopy: a practical and effective protocol. J Bronchol Interv Pulmonol. 2015;22(3):226–36.
78. Khemasuwan D, Teerapuncharoen K, Griffin DC. Diagnostic yield and safety of bronchoscopist-directed moderate sedation with a bolus dose administration of propofol during endobronchial ultrasound bronchoscopy. J Bronchol Interv Pulmonol. 2018;25(3):181–8.
79. Huang CT, Ho CC, Tsai YJ, Yu CJ, Yang PC. Factors influencing visibility and diagnostic yield of transbronchial biopsy using endobronchial ultrasound in peripheral pulmonary lesions. Respirology. 2009;14(6):859–64.
80. Douglas N, Ng I, Nazeem F, Lee K, Mezzavia P, Krieser R, et al. A randomised controlled trial comparing high-flow nasal oxygen with standard management for conscious sedation during bronchoscopy. Anaesthesia. 2018;73(2):169–76.
81. Evison M, Morris J, Martin J, Shah R, Barber PV, Booton R, et al. Nodal staging in lung cancer: a risk stratification model for lymph nodes classified as negative by EBUS-TBNA. J Thorac Oncol. 2015; 10(1):126–33.
82. Hylton DA, Kidane B, Spicer J, Turner S, Churchill I, Sullivan K, et al. Endobronchial ultrasound staging of operable non-small cell lung cancer: do triple-normal lymph nodes require routine biopsy? Chest. 2021;159(6):2470–6.
83. Madan K, Madan M, Iyer H, Mittal S, Madan NK, Rathi V, et al. Utility of elastography for differentiating malignant and benign lymph nodes during EBUS-TBNA: a systematic review and meta-analysis. J Bronchol Interv Pulmonol. 2022;29(1):18–33.
84. NICE. Lung cancer: diagnosis and management NICE guideline [NG122]. NICE Clinical Guideline. 2019.
85. De Leyn P, Dooms C, Kuzdzal J, Lardinois D, Passlick B, Rami-Porta R, et al. Revised ESTS guidelines for preoperative mediastinal lymph node staging for non-small-cell lung cancer. Eur J Cardiothorac Surg. 2014;45(5):787–98.
86. Steinfort DP, Siva S, Leong TL, Rose M, Herath D, Antippa P, et al. Systematic endobronchial ultrasound-guided mediastinal staging versus positron emission tomography for comprehensive mediastinal staging in NSCLC before radical radiotherapy of non-small cell lung cancer: a pilot study. Medicine. 2016;95(8):e2488.
87. Cole AJ, Hardcastle N, Turgeon GA, Thomas R, Irving LB, Jennings BR, et al. Systematic endobronchial ultrasound-guided transbronchial needle aspiration improves radiotherapy planning in non-small cell lung cancer. ERJ Open Res. 2019;5(3):00004-02019.
88. Forde PM, Spicer J, Lu S, Provencio M, Mitsudomi T, Awad MM, et al. Neoadjuvant nivolumab plus chemotherapy in resectable lung cancer. N Engl J Med. 2022 May 26;386(21):1973–85.
89. Crombag LMM, Dooms C, Stigt JA, Tournoy KG, Schuurbiers OCJ, Ninaber MK, et al. Systematic and combined endosonographic staging of lung cancer (SCORE study). Eur Respir J. 2019;53(2):1800800.
90. Sanz-Santos J, Serra P, Torky M, Andreo F, Centeno C, Mendiluce L, et al. Systematic compared with targeted staging with endobronchial ultrasound in patients with lung cancer. Ann Thorac Surg. 2018; 106(2):398–403.
91. DePew ZS, Edell ES, Midthun DE, Mullon JJ, Bungum AO, Decker PA, et al. Endobronchial ultrasound-guided transbronchial needle aspiration: determinants of sampling adequacy. J Bronchology Interv Pulmonol. 2012;19(4):271–6.
92. Karsenti D, Palazzo L, Perrot B, Zago J, Lemaistre AI, Cros J, et al. 22G acquire vs. 20G Procore needle for endoscopic ultrasound-guided biopsy of pancreatic masses: a randomized study comparing histologic sample quantity and diagnostic accuracy. Endoscopy. 2020;52(9): 747–53.
93. Evison M, Crosbie PA, Morris J, Martin J, Barber PV, Booton R. Can computed tomography characteristics predict outcomes in patients undergoing radial endobronchial ultrasound-guided biopsy of peripheral lung lesions? J Thorac Oncol. 2014;9(9):1393–7.
94. Durakovic A, Andersen H, Christiansen A, Hammen I. Retrospective analysis of radial EBUS outcome for the diagnosis of peripheral pulmonary lesion: sensitivity and complications. Eur Clin Respir J. 2015; 2:28947.
95. McGuire AL, Myers R, Grant K, Lam S, Yee J. The diagnostic accuracy and sensitivity for malignancy of radial-endobronchial ultrasound and electromagnetic navigation bronchoscopy for sampling of peripheral pulmonary lesions: systematic review and meta-analysis. J Bronchology Interv Pulmonol. 2020;27(2):106–21.
96. Asano F, Eberhardt R, Herth FJ. Virtual bronchoscopic navigation for peripheral pulmonary lesions. Respiration. 2014;88(5):430–40.
97. Ishida T, Asano F, Yamazaki K, Shinagawa N, Oizumi S, Moriya H, et al. Virtual bronchoscopic navigation combined with endobronchial ultrasound to diagnose small peripheral pulmonary lesions: a randomised trial. Thorax. 2011;66(12):1072–7.
98. Asano F, Shinagawa N, Ishida T, Shindoh J, Anzai M, Tsuzuku A, et al. Virtual bronchoscopic navigation combined with ultrathin bronchoscopy. A randomized clinical trial. Am J Respir Crit Care Med. 2013;188(3):327–33.
99. Zheng X, Cao L, Zhang Y, Xie F, Yang H, Liu J, et al. A novel electromagnetic navigation bronchoscopy system for the diagnosis of peripheral pulmonary nodules: a randomized clinical trial. Ann Am Thorac Soc. 2022;19(10):1730–9.
100. Anantham D, Feller-Kopman D, Shanmugham LN, Berman SM, DeCamp MM, Gangadharan SP, et al. Electromagnetic navigation bronchoscopy-guided fiducial placement for robotic stereotactic radiosurgery of lung tumors: a feasibility study. Chest. 2007;132(3):930–5.
101. Steinfort DP, Bonney A, See K, Irving LB. Sequential multimodality bronchoscopic investigation of peripheral pulmonary lesions. Eur Respir J. 2016;47(2):607–14.
102. Verhoeven RLJ, Vos S, van der Heijden E. Multi-modal tissue sampling in cone beam CT guided navigation bronchoscopy: comparative accuracy of different sampling tools and rapid on-site evaluation of cytopathology. J Thorac Dis. 2021;13(7):4396–406.
103. Fielding DIK, Bashirzadeh F, Son JH, Todman M, Chin A, Tan L, et al. First human use of a new robotic-assisted fiber optic sensing navigation system for small peripheral pulmonary nodules. Respiration. 2019;98(2):142–50.
104. Reisenauer J, Duke JD, Kern R, Fernandez-Bussy S, Edell E. Combining shape-sensing robotic bronchoscopy with mobile three-dimensional imaging to verify tool-in-lesion and overcome divergence: a pilot study. Mayo Clin Proc Innov Qual Outcomes. 2022;6(3):177–85.
105. Verhoeven RLJ, van der Sterren W, Kong W, Langereis S, van der Tol P, van der Heijden E. Cone-beam CT and augmented fluoroscopy-guided navigation bronchoscopy: radiation exposure and diagnostic accuracy learning curves. J Bronchol Interv Pulmonol. 2021;28(4):262–71.
106. von Bartheld MB, van Breda A, Annema JT. Complication rate of endosonography (endobronchial and endoscopic ultrasound): a systematic review. Respiration. 2014;87(4):343–51.
107. Folch EE, Mahajan AK, Oberg CL, Maldonado F, Toloza E, Krimsky WS, et al. Standardized definitions of bleeding after transbronchial lung biopsy: a Delphi Consensus Statement from the Nashville Working Group. Chest. 2020;158(1):393–400.

108. Serra Mitja P, Dos Santos G, Carvalho F, Garcia Olive I, Sanz Santos J, Jimenez Lopez J, et al. Incidence and risk factors for infectious complications of EBUS-TBNA: prospective multicenter study. Arch Bronconeumol. 2022;59:84–9.
109. Wallbridge PD, Hannan LM, Joosten SA, Irving LB, Steinfort DP. Clinical utility of sequential venous blood gas measurement in the assessment of ventilatory status during physiological stress. Intern Med J. 2013;43(10):1075–80.
110. Bergbower EAS, Hong C, Gibbons M, Sachdeva A, Rock P, Anders MG. A retrospective analysis of respiratory complications under general anesthesia during EBUS-TBNA. J Community Hosp Intern Med Perspect. 2022;12(1):19–27.
111. Georgiou HD, Taverner J, Irving LB, Steinfort DP. Safety and efficacy of radial EBUS for the investigation of peripheral pulmonary lesions in patients with advanced COPD. J Bronchol Interv Pulmonol. 2016; 23(3):192–8.
112. Steinfort DP, Herth FJ, Eberhardt R, Irving LB. Potentially fatal arrhythmia complicating endobronchial epinephrine for control of iatrogenic bleeding. Am J Respir Crit Care Med. 2012;185(9):1028–30.
113. Jeffus SK, Joiner AK, Siegel ER, Massoll NA, Meena N, Chen C, et al. Rapid on-site evaluation of EBUS-TBNA specimens of lymph nodes: comparative analysis and recommendations for standardization. Cancer Cytopathol. 2015;123(6):362–72.
114. Giri S, Pathak R, Yarlagadda V, Karmacharya P, Aryal MR, Martin MG. Meta-analysis of 21- versus 22-G aspiration needle during endobronchial ultrasound-guided transbronchial needle aspiration. J Bronchol Interv Pulmonol. 2015;22(2):107–13.
115. Lung Cancer Clinical Expert Group. Endobronchial ultrasound service specifications. https://www.roycastle.org/app/uploads/2020/12/Appendices-1-4-EBUS-service-specification-final-to-NHSE.pdf
116. Liu X, Yang K, Guo W, Ye M, Liu S. Mediastinal nodal staging performance of combined endobronchial and esophageal endosonography in lung cancer cases: a systematic review and meta-analysis. Front Surg. 2022;9:890993.
117. Figueiredo VR, Cardoso PFG, Jacomelli M, Santos LM, Minata M, Terra RM. EBUS-TBNA versus surgical mediastinoscopy for mediastinal lymph node staging in potentially operable non-small cell lung cancer: a systematic review and meta-analysis. J Bras Pneumol. 2020; 46(6):e20190221.
118. Ge X, Guan W, Han F, Guo X, Jin Z. Comparison of endobronchial ultrasound-guided fine needle aspiration and video-assisted mediastinoscopy for mediastinal staging of lung cancer. Lung. 2015;193(5):757–66.
119. Dong X, Qiu X, Liu Q, Jia J. Endobronchial ultrasound-guided transbronchial needle aspiration in the mediastinal staging of non-small cell lung cancer: a meta-analysis. Ann Thorac Surg. 2013;96(4):1502–7.
120. Adams K, Shah PL, Edmonds L, Lim E. Test performance of endobronchial ultrasound and transbronchial needle aspiration biopsy for mediastinal staging in patients with lung cancer: systematic review and meta-analysis. Thorax. 2009;64(9):757–62.
121. Punjabi A, Al-Najjar H, Teng B, Borrill Z, Brown L, Nagarajan T, et al. Performance monitoring of EBUS for the staging and diagnosis of lung cancer: auditing the greater Manchester EBUS service against new national standards. BMJ Open Respir Res. 2021;8(1):e000777.
122. Edwards T, Al-Najjar H, Crosbie P, Martin J, Booton R, Evison M. 85P: performance of EBUS-TBNA in NSCLC mediastinal staging stratified according to ACCP radiographic groups on CT. J Thorac Oncol. 2016;11(4):S92.
123. Trisolini R, Lazzari Agli L, Tinelli C, De Silvestri A, Scotti V, Patelli M. Endobronchial ultrasound-guided transbronchial needle aspiration for diagnosis of sarcoidosis in clinically unselected study populations. Respirology. 2015;20(2):226–34.
124. Hu LX, Chen RX, Huang H, Shao C, Wang P, Liu YZ, et al. Endobronchial ultrasound-guided transbronchial needle aspiration versus standard bronchoscopic modalities for diagnosis of sarcoidosis: a meta-analysis. Chin Med J. 2016;129(13):1607–15.
125. Mohapatra PR, Janmeja AK. Tuberculous lymphadenitis. J Assoc Physicians India. 2009;57:585–90.
126. Ye W, Zhang R, Xu X, Liu Y, Ying K. Diagnostic efficacy and safety of endobronchial ultrasound-guided transbronchial needle aspiration in intrathoracic tuberculosis: a meta-analysis. J Ultrasound Med. 2015; 34(9):1645–50.
127. Li P, Zheng W, Zhao L. Convex probe endobronchial ultrasound: applications beyond conventional indications. J Thorac Dis. 2015;7(9):E289–97.
128. Aisner DL, Riely GJ. Non–small cell lung cancer: recommendations for biomarker testing and treatment. J Natl Compr Canc Netw. 2021; 19(5.5):610–3.
129. Kang YR, Park HY, Jeon K, Koh WJ, Suh GY, Chung MP, et al. EGFR and KRAS mutation analyses from specimens obtained by bronchoscopy and EBUS-TBNA. Thorac Cancer. 2013;4(3):264–72.
130. Labarca G, Folch E, Jantz M, Mehta HJ, Majid A, Fernandez-Bussy S. Adequacy of samples obtained by endobronchial ultrasound with transbronchial needle aspiration for molecular analysis in patients with non-small cell lung cancer. Systematic review and meta-analysis. Ann Am Thorac Soc. 2018;15(10):1205–16.
131. Perrotta F, Nankivell M, Adizie JB, Maqsood U, Elshafi M, Jafri S, et al. Endobronchial ultrasound-guided transbronchial needle aspiration for PD-L1 testing in non-small cell lung cancer. Chest. 2020; 158(3):1230–9.
132. Hendry S, Byrne DJ, Christie M, Steinfort DP, Irving LB, Wagner CA, et al. Adequate tumour cellularity is essential for accurate PD-L1 immunohistochemistry assessment on cytology cell-block specimens. Cytopathology. 2020;31(2):90–5.
133. Wahidi MM, Davidson K, Shofer S, Mahmood K, Cheng G, Giovacchini C, et al. Pilot study of the performance of 19-G needle in endobronchial ultrasound-guided transbronchial aspiration for the diagnosis and testing of molecular markers in lung cancer. J Bronchology Interv Pulmonol. 2021;28(3):209–14.

How to cite this article: Steinfort DP, Evison M, Witt A, Tsaknis G, Kheir F, Manners D, et al. Proposed quality indicators and recommended standard reporting items in performance of EBUS bronchoscopy: An official World Association for Bronchology and Interventional Pulmonology Expert Panel consensus statement. Respirology. 2023;28(8): 722–43. https://doi.org/10.1111/resp.14549

APPENDIX A

TABLE A1 Outcome of voting Delphi round 1.

Quality indicator Domain: PRE-PROCEDURE INDICATORS	Type of measure	%½ agree or strongly agree[a]	Outcome of round
1. Frequency with which indication for EBUS is documented in the procedure report	Process	**90**	Accept
2. Frequency with which consent is obtained, including specific discussions of risks associated with EBUS, and fully documented	Process	**80**	Discuss → reword and new voting round
3. Frequency with which EBUS examinations are performed/supervised by trained Interventional Pulmonologists	Process	**80**	Discuss → reword and new voting round
4. Frequency with which a sedation plan is documented	Process	**60**	Discuss → reword and new voting round
5. Frequency with which imaging is available from within 4 weeks of date of procedure		**50**	Discuss → reword and new voting round
Domain: INTRA-PROCEDURE INDICATORS			
6. Frequency with which anaesthetic management is recorded	Process	**80**	Discuss → accept
7. Frequency with which the appearance of relevant structures, specific to the indication for the EBUS, is recorded	Process	**80**	Discuss → combined with QI #8 for new voting round
8. Frequency with which photo-documentation of sites/lesions of interest is included in procedure report	Process	**60**	Discuss → combined with QI #7 for new voting round
9. Number of lymph nodes sampled per procedure	Process	**90**	Accept
10. Frequency with which patients with ACCP radiographic group B and C (cN1/2/3) undergo systematic mediastinal LN staging.	Process	**90**	Accept
Domain: POST-PROCEDURAL INDICATORS			
11. Frequency with which immediate adverse events are observed.	Outcome	**90**	Accept
12. Frequency of unplanned admissions to hospital following procedure	Outcome	**60**	Discuss → reword and new voting round
13. Incidence of complications following EBUS (including individual complications)	Outcome	**80**	Discuss → accept
14. Frequency with which inadequate specimens are reported from an individual LN station	Outcome	**90**	Accept
15. Diagnostic accuracy and sensitivity for performance of EBUS-TBNA according to indication/ACCP radiographic group	Outcome	**100**	Accept
16. Frequency with which tissue/specimens are inadequate for required molecular testing	Outcome	**90**	Accept
17. Pathology pathway time (median—days) from biopsy to formal pathology report including molecular testing results	Process	**30**	Reject
18. Diagnostic yield and sensitivity of radial EBUS for diagnosis of peripheral pulmonary lesions	Outcome	**80**	Discuss → accept
19. Incidence of delayed complications[1]	Outcome	**20**	Reject
20. Measures of patient experience (?frequency with which patient satisfaction is recorded)		**40**	Reject

[a]10 taskforce members participated in the first Delphi round.

TABLE A2 Outcome of voting Delphi round 2.

Quality indicator **Domain: PRE-PROCEDURE INDICATORS**	Type of measure	Agreement	Final QI #
1. Frequency with which indication for EBUS is documented in the procedure report	Process	Accepted in round 1	1
2. Frequency with which consent is obtained, and fully documented, including specific discussions of risks associated with EBUS and sedation	Process	Accept	2
3. Frequency with which EBUS examinations are performed/supervised by trained EBUS operators	Process	Accept	3
4. Frequency with which a sedation plan is developed and documented based on clinical co-morbidities and anaesthetic/sedation risks	Process	Discuss (a) → accept	4
5. Frequency with which imaging is available from within 4 weeks of date of procedure for patients with suspected/known malignancy	Process	Reject (b)	
Domain: INTRA-PROCEDURE INDICATORS			
6. Frequency with which anaesthetic/sedation management is recorded	Process	Accepted in round 1	5
7. Frequency with which the appearance of relevant structures, specific to the indication for the EBUS, is recorded. ~~Photo-documentation should ideally be performed to aid review of results by colleagues/MDT~~	Process	Accept (with rejection of photo-documentation)	6
8. ~~Frequency with which photo-documentation of sites/lesions of interest is included in procedure report~~	Process	Reject (c)	
9. Number of lymph nodes sampled per procedure (for staging EBUS)	Process	Accepted in round 1[d]	
10. Frequency with which patients with ACCP radiographic group B and C (cN1/2/3) undergo systematic mediastinal LN staging	Process	Accepted in round 1	7
Domain: POST-PROCEDURAL INDICATORS			
11. Frequency with which immediate adverse events are observed.	Outcome	Accepted in round 1	8
12. ~~Frequency of unplanned admissions to hospital following procedure~~	Outcome	Reject	
13. Incidence of complications following EBUS (including individual complications)	Outcome	Accepted in round 1	9
14. Frequency with which inadequate specimens are reported from an individual LN station	Outcome	Accepted in round 1	10
15. Diagnostic accuracy and sensitivity for performance of EBUS-TBNA according to indication/ACCP radiographic group	Outcome	Accepted in round 1[e]	11a
16. Frequency with which tissue/specimens are inadequate for required molecular testing	Outcome	Accepted in round 1	12
17. ~~Pathology pathway time (median - days) from biopsy to formal pathology report including molecular testing results~~	Process	Rejected in round 1	
18. Diagnostic sensitivity for malignancy of radial EBUS for diagnosis of peripheral pulmonary lesions	Outcome	Accepted in round 1[e]	11b
19. ~~Incidence of delayed complications~~	Outcome	Rejected in round 1	
20. ~~Measures of patient experience (?frequency with which patient satisfaction is recorded)~~	Outcome	Rejected in round 1	

[a]Accepted following subsequent discussion.
[b]Rejected as a marker of quality. Recommended for consideration as standard reporting item.
[c]Re-worded for inclusion in the SRE's.
[d]Subsequently discussed as not a marker of quality, though should be examined in aggregate as a potential factor if the minimum target performance of EBUS-TBNA not met.
[e]Items 15 and 18 merged to form one quality item on diagnostic performance.