British Thoracic Society

Quality Standards

for Diagnostic Flexible Bronchoscopy in Adults

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BTS Quality Standards for Flexible Bronchoscopy in Adults should be read alongside the BTS Diagnostic Flexible Bronchoscopy in Adults guideline (www.brit-thoracic.org.uk)

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Quality Standards for Diagnostic Flexible Bronchoscopy in Adults

The British Thoracic Society has been at the forefront of the production of Guidelines for best clinical practice in respiratory medicine since the Society was established over 25 years ago. Over the past 5 years especially, the methodology for the production of evidence-based Guidelines has evolved considerably and a manual setting out the detailed policy for the production of BTS Guidelines was approved in July 2010[1] and is reviewed annually.

A statement on quality standards based on each BTS Guideline is a key part of the range of supporting materials that the Society produces to assist in the dissemination and implementation of a Guideline's recommendations.

A quality standard is a set of specific, concise statements that:

- act as markers of high-quality, cost-effective patient care across a pathway or clinical area, covering treatment or prevention.
- are derived from the best available evidence and are produced collaboratively with the NHS along with their partners and service users.

NICE Quality Standards were used as a model for the development of BTS Quality Standards and further information on the NICE Quality Standards process [2] is available here:

http://www.nice.org.uk/standards-and-indicators

This document contains Quality Standards for diagnostic flexible bronchoscopy in adults. The Quality Standards do not apply to children.

The Quality Standards are based on the BTS Guideline on diagnostic flexible bronchoscopy in adults published in 2013[3] (http://www.brit-thoracic.org.uk/guidelines-and-quality-standards).

The Quality Standards also include the use of endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) in relation to lung cancer, supported by the BTS Guideline for advanced diagnostic and therapeutic flexible bronchoscopy in adults (2011)[4].

The purpose of the Quality Standards document is to provide commissioners, planners and patients with a guide to standards of care that should be met for flexible bronchoscopy procedures in the UK, together with measurable markers of good practice.

BTS quality standards are intended for:

Health care professionals to allow decisions to be made about care based on the latest evidence and best practice.

People undergoing a diagnostic flexible bronchoscopy and their families and carers, to enable understanding of what services they should expect from their health and social care provider.

Service providers to be able to quickly and easily examine the clinical performance of their organisation and assess the standards of care they provide.

Commissioners so that they can be confident that the services they are purchasing are high quality and cost effective.

Method of Working

A Quality Standards Working Group was convened in September 2013, with the following membership:

Dr Ingrid Du Rand	Co-Chair Consultant respiratory physician Hereford
Dr M Munavvar	Co-Chair Consultant respiratory physician Preston
Dr Jonathan Bennett	Consultant respiratory physician Leicester
Dr John Blaikley	Senior lecturer and Honorary consultant respiratory physician Manchester
Dr Richard Booton	Consultant respiratory physician Manchester
Dr Nazia Chaudhuri	Consultant respiratory physician Manchester
Dr James Finnerty	Consultant respiratory physician Chester
Dr Vandana Gupta	Specialist registrar in respiratory medicine Manchester
Dr Saifudin Khalid	Consultant respiratory physician Blackburn
Dr Swapna Mandal	Specialist registrar in respiratory medicine London
Ms Julie Martin	Respiratory nurse consultant Manchester
Mrs Anne McCloy	Lay representative
Ms Janet Mills	Respiratory nurse Preston
Dr Neal Navani	Consultant respiratory physician London
Dr Najib Rahman	Consultant respiratory physician Oxford
Dr John Wrightson	Consultant respiratory physician Oxford

Members of the Quality Standards Group submitted Declaration of Interest forms in line with the BTS Policy and copies of forms are available online via the BTS website or on request from BTS Head Office. The BTS Standards of Care Committee considered the draft document in detail in November 2013 and June 2014. Following revision, the BTS Professional and Organisational Standards Committee considered the document in June 2014. The BTS Public Liaison Committee was consulted.

The document was made available on the BTS website for public consultation for the period from July 2014 to the end of August 2014.

Following further revision the document was submitted for approval to the BTS Standards of Care Committee in October 2014.

The Quality Standards document will be reviewed in 2018 or following the publication of a revised Guideline, whichever is the sooner.

Each Quality Standard includes the following:

A quality statement, which describes a key marker of high quality, cost-effective care for this condition.

Quality measures aimed at improving the structure, process and outcomes of health care.

The quality measures are not intended to be read as a new set of targets or a set of mandatory indicators for performance management that need to be collected.

The quality measures are specified in the form of a numerator and a denominator, defining a proportion (numerator/denominator). It is assumed that the numerator is a subset of the denominator population. The suggested numerator and denominator are provided to allow health care professionals and service providers to examine their clinical performance in relation to each quality standard. It is recognised that no national quality indicators will be available for this procedure, and institutions will need to agree locally what information is required for the denominator to be used in each case, and what the expected level of achievement should be given local circumstances. A brief description about the quality standard in relation to each audience is given.

The BTS Guideline for diagnostic flexible bronchoscopy in adults (2013)[3] and the BTS Guideline for advanced diagnostic and therapeutic flexible bronchoscopy in adults (2011)[4] are the main references for the Quality Standards.

There is no specific order of priority associated with the list of quality standards.

Summary of Quality Statements

Quality Statements for Flexible Bronchoscopy in Adults
Access
1a) All patients requiring urgent bronchoscopy and patients with suspected lung cancer be offered a procedure within 7 working days of decision to perform bronchoscopy.
Safety
2a) All units collect appropriate data to enable them to continuously assess and maintain safe unit and operator performance, with protocols in place to ensure appropriate management of serious adverse events.
2b) All units have a clearly defined safety checklist which is applied for each procedure.
2c) All trusts have a multi-disciplinary sedation policy and all patients having bronchoscopy have their level of sedation monitored and recorded.
2d) All units performing bronchoscopy are staffed safely with an appropriate skill mix.
2e) All services providing bronchoscopy ensure effective decontamination of bronchoscopes and accessories.
Outcome measures
3a) Each unit achieves a minimum diagnostic sensitivity rate of 85% for visible mucosal endobronchial tumour. Diagnostic samples contain sufficient material for molecular testing required to direct treatment.
3b) All patients with suspected lung malignancy undergo an appropriate staging CT scan prior to a bronchoscopy procedure that is accessible during the bronchoscopy procedure.
Patient experience
4a) All bronchoscopists provide patients (and carers) with clear and appropriate information about the procedure. Competent staff complete patient consent.
4b) All units collect regular (at least once yearly) patient feedback on the bronchoscopy, the consent procedure and the written information.
EBUS - TBNA
5a) All units achieve a diagnostic sensitivity for staging lung cancer of at least 88%. Operators ensure that sufficient diagnostic material is obtained to allow phenotyping and genotyping of tumours where appropriate.
5b) EBUS-TBNA complication rates are recorded and audited to be <1%.

Quality Statement

Quality Statement 1a	**All patients requiring urgent bronchoscopy and patients with suspected lung cancer be offered a procedure within 7 working days of the decision to perform bronchoscopy.**
Rationale	Urgent bronchoscopy is defined as a patient with suspected mycobacterial disease, immunocompromised patients with chest symptoms or radiological changes, patients with refractory consolidation, patients with significant frank haemoptysis (>100ml). Competition for slots for bronchoscopy often exists on current endoscopy suites, especially where the majority of work is gastro-intestinal. No clinically significant waiting list can be allowed to develop where bronchoscopy is indicated, and that this applies both to cancer and non-cancer work.
Quality measure	**Structure:** • Evidence of local arrangements to ensure that a place on a bronchoscopy list can be offered within 7 working days of the decision to perform bronchoscopy. • Evidence of a bronchoscopy referral system to include triage of referrals, allocation of slots on bronchoscopy lists and communication with patients to attend procedures. **Process:** • Proportion of adults with suspected lung cancer or requiring an urgent bronchoscopy, having bronchoscopy within 7 working days of the decision to perform bronchoscopy. **Numerator:** • The number of urgent procedures done within 7 working days of the decision to perform bronchoscopy. **Denominator:** • The number of urgent bronchoscopies referred and performed in the unit.

Description of what the quality statement means for each audience	**Service Provider:** • Ensure that the time between the decision to perform bronchoscopy and bronchoscopy is recorded for all adults undergoing the procedure. • Ensure an effective referral system for bronchoscopy is in place. • Ensure there is the appropriate number of bronchoscopy lists to meet demand for the procedure within 7 working days of decision to perform. **Healthcare Professional:** • Ensure that an offer of bronchoscopy within 7 working days of the decision to perform the urgent procedure is always made. • Ensure appropriate triage of referrals to available bronchoscopy lists. • Ensure communication with patients and bronchoscopists to utilise spaces on bronchoscopy lists. **Commissioners:** • Ensure that sufficient capacity exists to allow bronchoscopy within 7 working days of the decision to perform the procedure. **People undergoing bronchoscopy:** • Where appropriate, have an offer of bronchoscopy to take place within 7 working days of the decision to perform procedure by their chest physician.
Relevant existing indicators	Lung Cancer waiting times (http://www.england.nhs.uk/statistics/wp-content/uploads/sites/2/2013/05/Cancer-Waiting-Times-commentary-Q4-2012-13-provider-based-data.pdf)[5]. Lechtzin (2002) patient satisfaction with bronchoscopy. Am J Resp. Crit Care Med. 166:1326-1331[6]
Other possible national data sources	National Cancer waiting times[5] National Cancer Intelligence Network (NCIN)[7]
Source reference	Nil

Quality Statement

Quality Statement 2a	**All units collect appropriate data to enable them to continuously assess and maintain safe unit and operator performance, with protocols in place to ensure appropriate management of serious adverse events.**
Rationale	This standard will enable a prospective evaluation of complications at diagnostic bronchoscopy (see Appendix 1), and taken together with additional standards relating to efficacy, safe sedation and patient experience will provide much needed information on the quality of bronchoscopy services in the UK. In time, these data may prove useful in setting appropriate targets for audit/quality
Quality measure	**Structure:** • Evidence of local arrangements to ensure that performance data are collected and reviewed annually. • Evidence that local protocols exist for the management of serious adverse events. **Process:** • Proportion of adults undergoing bronchoscopy who suffer a serious adverse event, and the proportion managed according to local protocol. **Numerator:** • Number of adults undergoing bronchoscopy who suffer a serious adverse event. **Denominator:** • The total number of adults undergoing bronchoscopy.
Description of what the quality statement means for each audience	**Service providers:** • Ensure systems are in place to monitor and record safe practice. **Healthcare professionals:** • Ensure that optimal patient assessment prior to bronchoscopy minimises the risk of adverse events. • Ensure that unit data is collected and discussed at respiratory departmental meetings. • Ensure protocols are in place to ensure serious adverse events are managed appropriately. **Commissioners:** • Ensure that safe bronchoscopy services are available. **People undergoing bronchoscopy:** • Should be confident that the unit has safe operating practices.
Relevant existing indicators	None
Other possible national data sources	Royal College of Anaesthetists. Safe Sedation Practice for Healthcare Procedures: Standards and Guidance[8] RCA document- http://www.rcoa.ac.uk/node/15182
Source reference	British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults[3]

Quality Statement

Quality Statement 2b	**All units have a clearly defined safety checklist which is applied for each procedure.**
Rationale	In 2009 the National Patient Safety Agency published an alert for healthcare organisations to use the World Health Organisation (WHO) Surgical Safety Checklist in any operating theatre environment. In June 2008, WHO launched a second Global Patient Safety Challenge, 'Safe Surgery Saves Lives', to reduce the number of surgical deaths across the world. The safety checklist is part of this initiative. The checklist divides the procedure into two phases, each corresponding to a specific time period in the normal flow of a procedure; - The period before the procedure starts or sedation is given. - The period during or immediately after the procedure is completed, but before taking the patient out of the procedure room. Nearly all the steps are checked verbally (by the bronchoscopist/nurse in charge) with the appropriate personnel to ensure that key actions have been performed and are indicated on the checklist. The checklist co-ordinator (bronchoscopist) and nurse in charge both take responsibility to ensure the checklist is completed in full before the patient moves to the recovery area. Endoscopy teams should seek to incorporate use of the checklist into their work with maximum efficiency and minimum disruption, while aiming to accomplish the steps in a timely and effective manner. Organisations are required to: • Ensure an executive and a clinical lead is identified in order to implement the safety checklist within the organisation. • Ensure the checklist is completed for every patient undergoing a surgical procedure, including procedures under sedation and local anaesthesia. • Ensure that a registered member of the team enters the checklist in the clinical notes or electronic record of each patient.
Quality measure	**Structure:** • Evidence of a safety checklist completed for each procedure as a standard, scheduled feature to ensure that safety checks are done at an appropriate time. • Evidence that a checklist is implemented to reinforce accepted safety practices and foster better communication and teamwork during bronchoscopy procedures. Checklists are not intended as a regulatory device; they are tools for use by bronchoscopists and nursing staff to improve the safety of the procedure and reduce the number of unnecessary or avoidable complications. The aim is to ensure that the safety checks are a standard, scheduled feature of each bronchoscopy list and they are allocated the appropriate time. **Process:** • Proportion of bronchoscopy procedures performed with a completed safety checklist. **Numerator:** • The number of safety checklists completed. **Denominator:** • The number of procedures done.

Description of what the quality statement means for each audience	**Service Provider:** • Ensure a standardised safety checklist is available and time is allocated to support staff performing necessary safety checks before, during and after each procedure. **Healthcare Professional:** • Ensure a safety checklist is implemented before the procedure is started or sedation is given and completed before the patient leaves the procedure room. • Becomes familiar with the steps of the checklist. • Integrates the checks into familiar work patterns with minimal disruption and ensure comprehensive safety check. **Commissioners:** • Ensure a safe and high standard of care for patients having a bronchoscopy. **People undergoing bronchoscopy:** • Assurance that safety checks are performed and appropriate steps are taken to prevent complications and near miss events.
Relevant existing indicators	British Thoracic Society Guideline for diagnostic flexible bronchoscopy in adults. (2013)[3] Appendix 5: BTS Flexible Bronchoscopy Safety Checklist WHO surgical safety checklist (2008) available online (https://www.brit-thoracic.org.uk/document-library/clinical-information/bronchoscopy/flexible-bronchoscopy/appendix-5-diagnostic-flexible-bronchoscopy-in-adults-guideline-2013/) (See Appendix 2).
Other possible national data sources	The Joint Advisory Group on Gastrointestinal Endoscopy (JAG)[9] BSG Quality and Safety Indicators for Endoscopy (2007)[10] Jean-Francois Rey (2011). Quality Control in Endoscopy Unit: Safety Considerations for the Patient, Applications and Experiences of Quality Control, Prof. Ognyan Ivanov (Ed.), ISBN: 978-953-307-236-4, InTech, Available from: http://www.intechopen.com/books/applications-and-experiences-of-quality- control/quality-control-in-endoscopy-unit-safety-considerations-for-the-patient[11]
Source reference	British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults. (2013)[3

Quality Statement

Quality Statement 2c	**All trusts have a multi-disciplinary sedation policy and all patients having bronchoscopy have their level of sedation monitored and recorded.**
Rationale	In 2008 the National Patient Safety Agency published a Rapid Response Report[12] to address concerns and make recommendations to reduce sedation related adverse events. More recently the Department of Health has identified overdose of midazolam during conscious sedation as one of the top ten "Never Events" for 2012/2013[13]. (See Appendix 3) The Francis Report[14] defines an integrated hierarchy of fundamental standards that all health care trusts and workers should implement and practice to ensure the safety and wellbeing of all patients.
Quality measure	**Structure:** • Evidence of local arrangement of a multi-disciplinary sedation policy that supports the delivery of audit, education and training. **Process:** • The proportion of patients who are managed according to the trust's sedation policy and have their levels of sedation monitored and recorded. **Numerator:** • The number of patients having a bronchoscopy that are managed according to a safe sedation policy. **Denominator:** • The number of bronchoscopy procedures performed.
Description of what the quality statement means for each audience	**Service Provider:** • Ensure systems are in place to support staff with the development and implementation of sedation policies and audit of adverse events. • Ensure education and competency based training in the safe and appropriate administration of sedation for all bronchoscopy unit staff. **Healthcare Professional:** • Ensure safe sedation policies are developed and implemented, ensure monitoring and recording levels of sedation for all patients having a flexible bronchoscopy (see Appendix 4). • Audit their practice and report adverse events and maintain their competence in safe sedation strategies. • Auditable outcomes to measure relating to safe sedation practice 1. Number of procedures performed by each operator. 2. Use of flumazenil. 3. Use of naloxone. **Commissioners:** • Ensure that a high standard of sedation care is in place. **People undergoing bronchoscopy:** • Patients have confidence that safe sedation practices are in place.

Relevant existing indicators	None
Other possible national data sources	The Department of Health "Never Events" list 2012/2013. (www.gov.uk/government/publications/the-never-events-list-for-2012-13)[13] Reducing risk of overdose with midazolam injection in adults. Rapid response Report.National Patient Safety Agency 2008.www.nlrs.npsa.nhs.uk.[12] BSG Quality and Safety Indicators for Endoscopy (2007)[10]
Source reference	British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults[3] Academy of Medical Royal Colleges. Safe sedation practice for healthcare procedures (2013) http://www.aomrc.org.uk/doc_view/9737-safe-sedation-practice-for-healthcare-procedures-standards-and-guidance[15]

Quality Statement

Quality Statement 2d	**All units performing bronchoscopy are staffed safely with an appropriate skill mix.**
Rationale	Staff numbers and skill mix in endoscopy are influenced by health care provider demands and changes, variation in patient complexity, and changes in sedation practices. The number of patients, patient acuity, and physical layout of the unit, available technology, and staff education, experience and competency must be considered in determining appropriate staffing levels. A high quality, patient-centred endoscopy service depends on staff who are properly trained, adequately supported, have balanced skill mix and are recognised and rewarded for a job done well.
Quality measure	**Structure:** • Evidence of a safe staffing levels policy for the appropriate number of staff in attendance during bronchoscopy, with reference to the safe sedation policy. • Evidence of appropriate levels of competency of staff in bronchoscopy units. • Evidence of appropriate skill mix to support each bronchoscopy list. **Process:** • Proportion of bronchoscopies done with the appropriate number, skill mix and competence of staff. **Numerator** • Number of procedures carried out with the appropriate staffing level, skill mix and competency. **Denominator** • Number of procedures carried out.

Description of what the quality statement means for each audience	**Service Provider:** Minimum staffing levels during bronchoscopy procedures include: - • A suitably trained and competent bronchoscopist to consent the patient, co-ordinate the safety checklist, administer sedation and perform the required procedure. • A minimum of two suitably trained and competent endoscopy assistants, of whom at least one is a qualified nurse, to be present at endoscopy. o One assistant is dedicated to assisting the bronchoscopist during the procedure. o One assistant is dedicated to patient care, to monitor the patient's safety, comfort and well-being and to communicate significant changes to the bronchoscopist. • An additional endoscopy assistant to assist the team during more advanced bronchoscopic procedures, such as EBUS or cryoBx/ /diathermy etc. • A suitably trained and competent health care professional available to perform pre-procedure care, assessment and IV cannulation prior to bronchoscopy. • A suitably trained and competent health care professional available to monitor and assess the patient during the recovery period. • A suitably trained and competent person available to adequately clean and decontaminate bronchoscopy equipment. **Healthcare Professional:** • All patients undergoing bronchoscopy procedures will be cared for by an appropriate team of the appropriate size, skill mix and competence. **Commissioners:** • All patients undergoing bronchoscopy procedures will be cared for by a safe, competent team with the appropriate skill mix and expertise to manage and minimise the complications. **People undergoing bronchoscopy:** • Competent staff are caring for patients having a bronchoscopy.
Relevant existing indicators	BSG Quality & Safety indicators for Endoscopy (2007)[10]
Other possible national data sources	Academy of Medical Royal Colleges. Safe sedation practice for healthcare procedures (2013)[15]
Source reference	British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults. (2013)[3] British Thoracic Society guideline for advanced diagnostic and therapeutic flexible bronchoscopy in adults. (2011)[4]

Quality Statement

Quality Statement 2e	**All services providing bronchoscopy ensure effective decontamination of bronchoscopes and accessories.**
Rationale	Flexible bronchoscopes represent a valuable diagnostic and therapeutic tool in modern medicine and the incidence of infection associated with their use reportedly is very low. However, healthcare–associated infection outbreaks have been linked to contaminated endoscopes more than to any other medical device. Failure to remove or destroy microorganisms, tissue deposits, mucus, blood, and other body fluids from bronchoscopes may result in subsequent infection, instrument malfunction, and misdiagnosis. Flexible bronchoscopes are heat labile, complex, and difficult to clean. If they become damaged during use they may become even more difficult to decontaminate. Rigorous adherence to sterilisation and disinfection procedures and a common sense approach to protecting the uninfected patients and bronchoscopy personnel from infected patients and instruments will prevent the risk of propagating infection through the bronchoscope.
Quality measure	**Structure:** • Evidence of a decontamination policy. • Records of staff training and staff competence in decontaminating bronchoscopy equipment. • Evidence of a robust system for tracking the decontamination processes of bronchoscopes and accessories. • Evidence of the decontamination process in patient records. • Evidence of Automated Endoscope Reprocessor maintenance and service. **Process:** • Proportion of procedures performed with a tracked flexible bronchoscope and accessories with an adequate and correct decontamination. **Numerator:** • Number of procedures with evidence of correct decontamination. • Number of procedures performed with adequate tracking of bronchoscope and accessories. **Denominator:** • Number of bronchoscopy procedures performed. • Number of bronchoscopy procedures performed.

Description of what the quality statement means for each audience	**Service Provider:** • Ensure nominated decontamination lead reports are available to Trust decontamination lead. • Ensure a written decontamination policy is available and up-to-date. • Ensure suitable facilities are in place in order that appropriate decontamination can take place. • Ensure all healthcare professionals undertaking decontamination are trained and hold appropriate competencies. • Ensure robust tracking system available for bronchoscopy equipment and accessories. • Ensure regular maintenance and servicing of Automated Endoscope Reprocessors. **Healthcare Professional:** • Ensure that decontamination processes are followed. • Ensure healthcare professionals are appropriately trained and competent in decontaminating and tracking bronchoscopes and accessories. • Ensure Automated Endoscope Reprocessors are regularly maintained and serviced. **Commissioners:** • Ensure that training for healthcare professionals is accessible. • Ensure all bronchoscopes and accessories are fully traceable. • Confident there is no cross-contamination / infections post bronchoscopy in their client group. **People undergoing bronchoscopy:** • Risk of contamination with infection is minimised.
Relevant existing indicators	Joint Advisory Group in Gastrointestinal Endoscopy (JAG)[9]
Other possible national data sources	Management and decontamination of flexible endoscopes (CFPP01-06) Department of Health (2013) https://www.gov.uk/government/publications/management-and-decontamination-of-flexible-endoscopes[16] Medical Devices Agency Device Bulletin. Decontamination of endoscopes. (July 2002) MDA DB2002 (05)[17] DB 2006(04) Single-use Medical Devices: Implications and Consequences of Reuse. Medicines and Healthcare products Regulatory Agency, October 2006.[18] NHS Estates (1997) Health Technical Memorandum HTM 2030, Washer Disinfectors. HMSO.[19]
Source reference	British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults. (2013)[3] British Thoracic Society guideline for advanced diagnostic and therapeutic flexible bronchoscopy in adults. (2011)[4]

Quality Statement

Quality Statement 3a	**Each unit achieves a minimum diagnostic sensitivity rate of 85% for visible mucosal endobronchial tumour. Diagnostic samples contain sufficient material for molecular testing required to direct treatment.**
Rationale	Patients with a visible mucosal endobronchial lesion described by the bronchoscopist as a definite tumour on the basis of macroscopic appearance should have a diagnosis made using bronchoscopic techniques. The requirement for repeat bronchoscopy for diagnostic purpose should be limited. In units where this is not achieved, investigation into local training and practices will be required.
Quality measure	**Structure:** • Evidence of individual and departmental audit of the diagnostic sensitivity rate for procedures where a definite visible endobronchial tumour was seen during bronchoscopy. • A record of repeat bronchoscopies performed either to make a diagnosis where a diagnosis is not made after the first attempt, or refine a diagnosis where insufficient sample was obtained for additional testing. **Process:** • Proportion of patients who have definite endobronchial tumours seen during bronchoscopy diagnosed as cancerous by the procedure (wash, brush and biopsy). **Numerator:** • The number of patients with a definite visible endobronchial tumour correctly diagnosed during bronchoscopy tissue sampling (histology and or cytology specimens). • The number of patients diagnosed with malignancy where sufficient tissue was obtained for genetic profiling / all tissue sent for profiling. **Denominator:** • The number of patients with a definite visible endobronchial tumour at bronchoscopy. • The number of patients diagnosed with malignacy where tissue was obtained.

Description of what the quality statement means for each audience	**Service Provider:** • Ensures that resources are provided and local arrangements are made for individual practitioners to audit their bronchoscopy practice. **Healthcare Professional:** • Ensures individual bronchoscopists audit their practice and diagnostic sensitivity and make improvements where necessary. • Record the number of repeat bronchoscopies performed to obtain diagnosis for a definite visible endobronchial tumour. • Record the number of repeat bronchoscopies to obtain sufficient sample for molecular testing to direct treatment. **Commissioners:** • Ensures patients are referred to centres that have excellent diagnostic rates (those with audited evidence of diagnostic rates >85% endobronchial biopsy and low rate of adverse events). **Patients undergoing bronchoscopy:** • Ensures that patients with endobronchial tumours are likely to have a diagnosis achieved requiring a single procedure and additional tests are performed on samples to direct treatment where appropriate.
Relevant existing indicators	None identified
Other possible national data sources	None identified
Source reference	British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults (2013)[3]

Quality Statement

Quality Statement 3b	**All patients with suspected lung malignancy undergo an appropriate staging CT scan prior to bronchoscopy procedure that is accessible during the bronchoscopy procedure.**
Rationale	Bronchoscopic sampling in suspected lung malignancy should be directed by the findings of CT scanning which gives greater anatomical information than is possible from plain radiography, and may suggest alternative diagnoses. This is particularly important in suspected lung cancer, and is frequently also true in other indications for bronchoscopy.
Quality measure	**Structure:** • Evidence of local arrangements to ensure that patients have CT scans and health care professionals have access to CT reports on patients with suspected lung malignancy before bronchoscopy is undertaken in those patients. **Process:** • Proportion of adults with suspected lung malignancy having CT scans reported prior to bronchoscopy. **Numerator:** • Number of patients having CT reported prior to bronchoscopy for suspected lung malignancy. **Denominator:** • Number of patients having bronchoscopy for suspected lung malignancy.
Description of what the quality statement means for each audience	**Service Provider:** • Ensures systems are in place to record whether CT reporting occurred prior to bronchoscopy in patients with suspected lung malignancy. **Healthcare Professional:** • Ensures that CT scan has been reviewed prior to bronchoscopy to determine the optimum histological sampling technique, to maximise the chance of a positive tissue diagnosis and give staging information if possible and, where possible, decide on whether EBUS bronchoscopy should be the procedure of first choice. **Commissioners:** • Ensure that sufficient CT service capacity exists to permit CT scanning and reporting prior to bronchoscopy in all patients with suspected lung malignancy. **People with suspected lung malignancy:** • An appropriate, contrast enhanced, staging CT scan is performed prior to bronchoscopy to direct sampling during the procedure.
Relevant existing indicators	National Lung Cancer Audit data. [20]
Other possible national data sources	None
Source reference	British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults (2013)[3] BTS guidelines on the radical management of patients with lung cancer, 2010.[21] NICE clinical guidelines 121: the diagnosis and treatment of lung cancer, 2011.[22]

Quality Statement

Quality Statement 4a	**All bronchoscopists provide patients (and carers) with clear and appropriate information about the procedure. Competent staff completes patient consent.**
Rationale	It is against UK law to perform a procedure on someone without his or her consent. The person obtaining consent should impart enough information to the patient to allow them to make an informed decision regarding bronchoscopy without duress. The process for this has been outlined in the GMC document "Patients and Doctors making decisions together" (2008).[23]
Quality measure	**Structure:** • Evidence of local arrangements to ensure that consent is taken and recorded according to local and national policies. **Process:** • Proportion of adults undergoing bronchoscopy where consent was taken and recorded in the clinical record. **Numerator:** • The number of bronchoscopies where the patient's clinical record shows consent was taken. **Denominator:** • The total number of bronchoscopies performed.
Description of what the quality statement means for each audience	**Service Provider:** • Ensures written information and where appropriate the translation of information leaflets, is available to all patients having a bronchoscopy and their carers. • Ensures systems are in place to record consent for bronchoscopy and adequate training is provided for people taking consent. **Healthcare Professional:** • Ensures that consent is obtained and recorded, according to national and local policies. • Ensures consent is recorded in the patient's clinical record prior to bronchoscopy. **Commissioners:** • Ensure services report the proportion of patients receiving consent prior to bronchoscopy. **People undergoing bronchoscopy:** • Ensures they are asked for their informed consent, provided with sufficient information and give their consent prior to having a bronchoscopy.
Relevant existing indicators	None
Other possible national data sources	None
Source reference	Example of Info for patient leaflet in Guideline British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults (2013)[3] GMC 2008 Consent: patients and doctors making decisions together[23]

Quality Statement

Quality Statement 4b	**All units should collect regular (at least once yearly) patient feedback on the bronchoscopy service, the consent procedure and the written information.**
Rationale	This standard will enable the prospective and regular evaluation of the quality of the procedure; consent process and written information in bronchoscopy from the patient perspective. This standard should help to identify inadequacies in local sedation information/procedure arrangements and facilitate local change to improve standards.
Quality measure	**Structure:** • Evidence of local arrangements to ensure that patient feedback on the bronchoscopy service, written information and consent is collected and reviewed at least once annually. • Evidence that review of these data is considered to improve the written information and consent procedures. **Process:** • At least once yearly patient feedback should be sought. The feedback should include information on the procedure, the consent process and the written information. A sample tool is available on the BTS website which can be adapted for use locally. • This should include at least 20 completed surveys from patients, and where more than one operator conducts bronchoscopy, should be for more than one operator. • Patient comfort during procedure should be recorded by the assisting nurse during all procedures in this period while observations are taken. **Numerator:** • Number of completed surveys. **Denominator:** • Number of patients having a flexible bronchoscopy in the unit per year.
Description of what the quality statement means for each audience	**Service Provider:** • Ensure systems are in place to assess patient feedback on the bronchoscopy procedure, written information and consent on a one yearly basis. **Healthcare Professional:** • Ensure that patient views are taken in to account in planning and changing written information and consent processes, and ensure patient experience is captured regularly. • Ensure this information is reviewed yearly by the respiratory team and discussed at departmental meetings. **Commissioners:** • Ensure that bronchoscopy services are regularly assessed from the patient perspective. **People undergoing bronchoscopy:** • Patients requiring bronchoscopy should be confident that patient feedback is regularly collected and reflected in local practice.

Relevant existing indicators	None
Other possible national data sources	None
Source reference	British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults (2013)[3]

Quality Statement for EBUS-TBNA

Quality Statement 5a	**All units achieve a diagnostic sensitivity for staging lung cancer of at least 88%. Operators ensure that sufficient diagnostic material is obtained to allow phenotyping and genotyping of tumours where appropriate.**
Rationale	To achieve high diagnostic standards for EBUS-TBNA practice and adequate sampling to direct treatment where appropriate.
Quality measure	**Structure:** Evidence of individual and departmental audit of sensitivity in the diagnosis of intra-thoracic lymphadenopathy. **Process:** Proportion of patients with suspected lung cancer who have pathological intra-thoracic lymphadenopathy correctly diagnosed or staged by EBUS-TBNA. A final diagnosis in patients with a negative EBUS-TBNA should be recorded after surgical sampling or at least 6 months clinical follow-up. **Numerator:** • The number of patients diagnosed and accurately staged by EBUS-TBNA sampling. • The number of EBUS-TBNA samples where sufficient tissue for genotyping were obtained. • The number of patients with non-small cell lung cancer, not otherwise specified (NSCLC NOS) diagnosed from EBUS sampling. **Denominator:** • The number of patients with confirmed diagnosis of lung cancer who underwent EBUS-TBNA sampling for diagnosis/staging. • The number of patients with confirmed lung cancer where genotyping was appropriately requested from EBUS sampling. • The total number of patients with non small cell lung cancer diagnosis confirmed from EBUS sampling.
Description of what the quality statement means for each audience	**Service Provider:** • Ensures that arrangements are made for individual practitioners to audit their EBUS-TBNA practice. **Healthcare Professional:** • Ensures EBUS-TBNA practitioners audit practice, learn from negative results, obtain adequate samples and make improvements where necessary. • Records the number of EBUS procedures repeated to obtain adequate sample for diagnostic purpose. • Ensures integration of findings into appropriate multidisciplinary team meetings. **Commissioners:** • Ensures that patients are informed about and encouraged to attend centres with excellent diagnostic rates. **People undergoing bronchoscopy:** • Ensures that patients with intra-thoracic lymphadenopathy are likely to have a diagnosis achieved without undergoing multiple procedures.

Relevant existing indicators	None
Other possible national data sources	National Lung Cancer Audit captures whether a patient with lung cancer has had an EBUS[20] Cancer Outcomes and Services Dataset (COSD) record mediastinum staging and diagnostic rates for audit purposes [24]
Source reference	British Thoracic Society guideline for advanced diagnostic and therapeutic flexible bronchoscopy in adults (2011)[4] 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 [published online ahead of print January 3, 3009]. Eur J Cancer 2009; 45:1389–1396[25] 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 [published online ahead of print May 18, 2009]. Thorax 2009; 64:757–762[26]

Quality Statement for EBUS-TBNA

Quality Statement 5b	**EBUS-TBNA Complication rates be recorded and audited to be <1%**
Rationale	To provide a safe EBUS-TBNA service.
Quality measure	**Structure:** Evidence that recorded complication rates are <1%. Procedure related complications include pneumothorax, pneumo-mediastinum, moderate or severe airway bleeding (as defined in table 1 Appendix 1), haemomediastinum, airway laceration, needle breakage and post FNA infection. (sedation related complications as for flexible bronchoscopy). **Process:** Proportion of patients who had EBUS-TBNA sampling and suffer a complication as result of the procedure. **Numerator:** The number of patients with recorded complications. **Denominator:** The number of EBUS-TBNA procedures performed.
Description of what the quality statement means for each audience	**Service Provider:** • Ensure that arrangements are made for individual practitioners to audit their EBUS-TBNA practice. • Ensure systems are in place to monitor and record safe practice. **Healthcare professionals:** • Ensure optimal patient assessment prior to EBUS to minimise the risk of adverse events. • Ensure that unit data is collected and discussed at departmental meetings. • Ensure protocols are in place to ensure serious adverse events are managed appropriately. **Commissioners:** • Ensure that safe EBUS services are available. **People undergoing EBUS:** • Should be confident that the unit has safe operating practices.
Relevant existing indicators	None identified
Other possible national data sources	None identified
Source reference	British Thoracic Society guideline for advanced diagnostic and therapeutic flexible bronchoscopy in adults (2011)[4] Asano et al (2013). Complications associated with endobronchial ultrasound guided transnbronchial needle aspiration. Respiratory Research, 14:50[27] http://respiratory-research.com/content/14/1/50 Eapen et al Complications, consequences and practice patterns of endobronchial ultrasound guided transnbronchial needle aspiration CHEST; 143 (4) APRIL 2013 1044-1053[28] (http://publications.chestnet.org/data/Journals/CHEST/926623/chest_143_4_1044.pdf)

Appendices

Appendix 1 - Classification of bleeding

Appendix 2 - BTS flexible bronchoscopy safety checklist

Appendix 3 - Drugs used in bronchoscopy

Appendix 4 - Levels of sedation

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Appendix 1

Classification of bleeding during bronchoscopy

Suggested serious adverse events
• Severe bleeding (see table 1 below)
• Cardiac arrhythmia requiring treatment
• Seizures
• Myocardial infarction/pulmonary oedema
• Pneumothorax requiring aspiration/intercostal drain
• Oversedation requiring ventilatory support or reversal
• Hospitalisation
• Admission to intensive care unit
• Death

Table 1: Classification of bleeding during bronchoscopy.

No bleeding	**Traces of blood with no need for continuous suctioning bleeding stops spontaneously**
Mild bleeding	**Continued suctioning of blood from the airways bleeding stops spontaneously**
Moderate bleeding	**Intubation of the biopsied segment with the bronchoscope into the wedge position** **Use of adrenaline or cold saline to stop bleeding**
Severe bleeding	**Placement of bronchus blocker or catheter, applying fibrin sealant** **Resuscitation, blood transfusion, admission to critical care unit or death**

Ernst A, Eberhardt R, Wahidi M, et al. Effect of routine clopidogrel use on bleeding complications after transbronchial biopsy in humans. Chest 2006;129:734–7

Appendix 2

BTS Flexible Bronchoscopy Safety Checklist (adapted from the WHO Surgical Safety Checklist)

Before the procedure
Registered Practitioner verbally confirms with the team
☐ Have all team members introduced themselves by name and role?
☐ Has the patient confirmed his/her identity, procedure and consent?
☐ Is the monitoring equipment and medication check complete?
Does the patient have a known allergy? ☐ Yes ☐ No
Is the patient taking any anticoagulation or antiplatelet agent? ☐ Yes ☐ No

Before sedation is given / procedure starts
Bronchoscopist:
☐ Has essential imaging been reviewed and displayed?
☐ Have blood results where appropriate been reviewed?
☐ Are there any critical or unexpected steps you want the team to know about?
Nurse in Charge:
☐ Has the sterility of the instrumentation been confirmed (including indicator results)?
☐ Are there any equipment issues or concerns?

After the procedure
Registered Practitioner verbally confirms with the team
☐ Have the details of the procedure been recorded?
☐ Have all instruments and controlled drugs been accounted for?
☐ Have the specimens been labeled (including patient name)?
☐ Have any equipment problems been identified that need to be addressed?
☐ Have the key concerns for recovery and management of this patient been recorded and communicated to appropriate staff?

PATIENT DETAILS/LABEL	
Last name:	
First name:	
Date of birth:	
NHS Number:	
Hospital Number:	

BRONCHOSCOPIST 1	
Name:	
Signature of Registered Practitioner:	
BRONCHOSCOPIST 2	
Name:	
Signature of Registered Practitioner:	

NURSE IN CHARGE	
Name:	
Signature of Registered Practitioner:	

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

Appendix 3

Drugs used in bronchoscopy. All tables are for guidance only; for up to date information on doses, side effects and interactions, refer to the British National Formulary.

Drug	Dose	Speed of Onset / Duration of Action / Half-life	Common / Serious Side Effects	Comments
Midazolam	Slow IV injection – maximum rate 2 mg/min • Initial dose: 2 mg-2.5 mg (0.5-1 mg in the frail or elderly) given 5-10 mins before procedure • Supplemental doses, if required: 1 mg (0.5-1 mg in frail or elderly), at 2-10 mins intervals • Usual maximum total dose: 3.5-7 mg (3.5 mg in frail or elderly) for standard bronchoscopic procedures. May be higher in longer procedures (e.g. EBUS)	Onset of Sedation • Within 2 mins, with maximum effect at 5-10 mins. (May be longer in frail or elderly or those with chronic illnesses) Duration of Action • Variable, but typical range is 30-120 mins Approximate half-life • 1.5-2.5 hours	Respiratory depression, apnoea, bronchospasm, laryngospasm, hypotension, heart rate alterations, cardiac arrest. Life-threatening side effects and prolonged sedation are more likely in the elderly and those with impaired respiratory or cardiovascular status, hepatic impairment, renal impairment, myasthenia gravis, and with rapid IV injection.	Enhanced sedation and increased risk of respiratory depression when combined with opioids. When combined sedation is used, opioids should always be administered prior to midazolam. To prevent risk of accidental overdose, only 1 mg/mL vials should be available in bronchoscopy suites. 2 mg/mL or 5 mg/mL vials should not be available unless a formal risk assessment has been undertaken.
Fentanyl	Slow IV injection – usually over 1-3 mins • Initial dose: 25 micrograms • Supplemental doses, if required: 25 micrograms • Usual maximum total dose: 50 micrograms	Onset of Sedation • Almost immediate, with maximum effect at 5 mins • Duration of Action • Variable, but typical range is 30-60 mins • Approximate half-life • 2-7 hours	Nausea, vomiting and other GI upset, myoclonic movements, respiratory depression, apnoea, bronchospasm, laryngospasm, hypo/hypertension, arrhythmia, cardiac arrest. Significant respiratory depression common above 200 micrograms. Caution in elderly patients and those with impaired respiratory or cardiovascular status, hepatic impairment and myasthenia gravis.	Enhanced sedation and respiratory depression when given with benzodiazepines. When combined sedation is used, opioids should always be administered prior to midazolam.

Drug	Dose	Speed of Onset / Duration of Action / Half-life	Common / Serious Side Effects	Comments
Alfentanil	Slow IV injection – usually over 30 secs • Initial dose: 250 micrograms • Supplemental doses, if required: 250 micrograms • Usual maximum total dose: 500 micrograms	Onset of Sedation • Almost immediate onset and maximum effect Duration of Action • Variable, but usually shorter than fentanyl Approximate half-life • 1-2 hours	See Fentanyl	See Fentanyl
Lidocaine	Intranasal • Lidocaine 2% gel: 6 mL (120 mg) Oropharnyx • Lidocaine 10% spray: 3 actuations (30 mg) Vocal cords, tracheobronchial tree • Lidocaine 1% solution: 2 mL boluses applied topically, as required Maximum total dose (see Table 3) • Use minimum dose to achieve effective cough suppression and patient comfort. Subjective symptoms of Lidocaine toxicity are common when ≥ 9.6 mg/kg is used; much lower doses are usually sufficient.	Onset of Action • 3 to 5 mins Duration of Action • Variable, but typical range is 60-90 mins Approximate half-life • 1.5-2 hours	CNS effects (confusion, blurred vision, dizziness, drowsiness, lightheadedness, myoclonus, nausea, nystagmus, paraesthesia, restlessness, tremulousness, coma, convulsions, respiratory failure) CVS effects (hypotension, bradycardia, arrhythmia, cardiac arrest). Methaemoglobinaemia (rare). Caution in those with hepatic and cardiac dysfunction, and with significant renal impairment.	
Adrenaline	Topical • Adrenaline 1:10,000: 2 to 10 mL		Hypertension, tachycardia, arrhythmia, tremor.	

Table 1. Commonly used drugs in bronchoscopy.

Adapted from 'Drugs in Bronchoscopy' (BTS Bronchoscopy eLearning Module available at: http://learninghub.brit-thoracic.org.uk/?bts=topic&param=3), with kind permission of Toby Capstick and Daniel G Peckham.

Drug	Dose	Speed of Onset / Duration of Action / Half-life	Common / Serious Side Effects	Comments
Flumazenil	• To reverse midazolam • Initial dose: 200 micrograms IV over 15 secs • Supplemental doses: 100 micrograms every 60 secs if inadequate response • Typical cumulative dose range: 300-600 micrograms • Maximum total dose: 1 mg	Onset of Action • 1 min Duration of Action • 1-4 hours Approximate half-life • 40-80 mins	Nausea, vomiting, anxiety, agitation, dizziness, hypertension, tachycardia. May lower seizure threshold. May cause withdrawal in chronic benzodiazepine users.	Flumazenil has a shorter duration of action than midazolam, and so patients should be observed long enough to ensure that sedation and cardiorespiratory depression does not recur once the effect of flumazenil ceases. Further doses may be required. Where combined sedation with midazolam and opioid has been used, it is recommended that flumazenil is administered first, unless a large dose of opioid has been given
Naloxone	To reverse opioids • Initial dose: 100-200 micrograms IV • Supplemental dose: 100 micrograms every 2 mins if inadequate response	Onset of Action • 2-3 mins Duration of Action • 45 mins to 4 hours Approximate half-life • 11.5 hours	Nausea, vomiting, dizziness, headache, tachycardia, hypo/hypertension. May cause withdrawal in chronic opioid users.	Naloxone has a shorter duration of action than many opioids, and so patients should be observed long enough to ensure that sedation and cardiorespiratory depression does not recur once its effect ceases. Further doses may be required.

Table 2. Antagonists available for sedative drugs used in bronchoscopy.

Adapted from 'Drugs in Bronchoscopy' (BTS Bronchoscopy eLearning Module available at: http://learninghub.brit-thoracic.org.uk/?bts=topic&param=3), with kind permission of Toby Capstick and Daniel G Peckham

Drug	Dose	Speed of Onset / Duration of Action / Half-life	Common / Serious Side Effects
Lidocaine 2% gel	20 mg/mL	Nasal	Gel preparation syringe typically contains 6 mL (120 mg)
Lidocaine 10% aerosol spray	10 mg/actuation	Oropharynx	3 actuations (30 mg) often sufficient
Lidocaine 1% solution	10 mg/mL	Vocal cords, trachea and bronchial tree	

Table 3. Doses and concentrations of lidocaine used for bronchoscopy.

Appendix 4

Levels of safe sedation

	Minimal Sedation/ Anxiolysis	Moderate Sedation/ Analgesia ('Conscious Sedation')	Deep Sedation/ Analgesia
Responsiveness	Normal response to verbal stimulation	Purposeful* response to verbal or tactile stimulation	Purposeful* response following repeated or painful stimulation
Airway	Unaffected	No intervention required	Intervention may be required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained
Escalation of required competencies			

* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response. Excerpted from Continuum of Depth of Sedation. Definition of General Anesthesia and Levels of Sedation/ Analgesia of the American Society of Anesthesiology. From the ASA, 520N, Northwest Highway, Park Ridge, Illinois, 60068-2573, USA.

Academy of Medical Royal Colleges. Safe sedation practice for healthcare procedures (2013) http://www.aomrc.org.uk/doc_view/9737-safe-sedation-practice-for-healthcare-procedures-standards-and-guidance

Ramsay Scale (RS)	
Level	**Response**
1	Anxious and agitated or restless
2	Cooperative, orientated and tranquil
3	Responds only to commands
4	Brisk response to light glabellar touch or loud noise
5	Sluggish response to light glabellar touch or loud noise
6	No response to light glabellar touch or loud noise

Ramsay MA, Savege TM, Simpson BR, Goodwin R. Controlled sedation with alphaxalone-alphadolone. Br Med J. 1974 Jun. 22;2(5920):656–9.

Modified Observer's Assessment of Alertness/Sedation (MOAAS) scale	
Level	**Response**
5	Responds readily to name spoken in normal tone
4	Lethargic response to name spoken in normal tone
3	Responds only after name is called loudly or repeatedly
2	Responds only after mild prodding or shaking
1	Does not respond to mild prodding or shaking
0	Does not respond to pain

Chernik DA, Gillings D, Laine H, Hendler J, Silver JM, Davidson AB, et al. Validity and reliability of the Observer's Assessment of Alertness/Sedation Scale: study with intravenous midazolam. J Clin Psychopharmacol. 1990 Aug.;10(4):244–51.

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