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British Thoracic Society quality standards for the investigation and management of pulmonary nodules

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ABSTRACT

Introduction The purpose of the quality standards document is to provide healthcare professionals, commissioners, service providers and patients with a guide to standards of care that should be met for the investigation and management of pulmonary nodules in the UK, together with measurable markers of good practice.

Methods Development of British Thoracic Society (BTS) Quality Standards follows the BTS process of quality standard production based on the National Institute for Health and Care Excellence process manual for the development of quality standards.

Results 7 quality statements have been developed, each describing a key marker of high-quality, cost-effective care for the investigation and management of pulmonary nodules, and each statement is supported by quality measures that aim to improve the structure, process and outcomes of healthcare.

Discussion BTS Quality Standards for the investigation and management of pulmonary nodules form a key part of the range of supporting materials that the Society produces to assist in the dissemination and implementation of guideline recommendations.

INTRODUCTION

The British Thoracic Society (BTS) has been at the forefront of the production of guidelines for best clinical practice in respiratory medicine since the Society was established over 30 years ago. The Society's guideline production process is accredited by National Institute for Health and Care Excellence (NICE) Accreditation (November 2011, renewed in 2017), and the Society's Guideline Production Manual[1] setting out the detailed methodology and policy for the production of guidelines is reviewed annually by the BTS Standards of Care Committee (SOCC).

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.

The purpose of the quality standards document is to provide commissioners, healthcare professionals, planners and patients with a guide to standards of care that should be met for pulmonary nodule investigation and management in the UK, together with measurable markers of good practice.

BTS quality standards are intended for:

- healthcare professionals to allow decisions to be made about care based on the latest evidence and best practice
- people with pulmonary nodules undergoing investigation and treatment to enable understanding of what services they should expect from their healthcare 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.

NICE Quality Standards and the NICE Quality Standards Process Guide[2] were used as a model for the development of BTS Quality Standards.

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.

The rationale for these quality standards is drawn from evidence and recommendations summarised in the BTS Guidelines for the Investigation and Management of Pulmonary Nodules.[3]

Each quality standard includes the following:

Table 1 Quality Standards Working Group members

Name	To represent:	Location
Professor David Baldwin	Co-chair	Respiratory medicine, Nottingham
Dr Matthew Callister	Co-chair	Respiratory medicine, Leeds
Dr Ian Woolhouse	RCP London representative	Respiratory medicine, Birmingham
Professor Fergus Gleeson	RCR representative	Radiology, Oxford
Dr Kevin Franks		Clinical oncology, Leeds
Dr Paul Cane		Pathology, London
Jeanette Draffan	National Lung Cancer Forum for Nurses representative	Macmillan Lung Cancer Nurse Specialist, North Tees & Hartlepool
Mr David Waller	SCTS representative	Surgery, London
Dr Richard Graham	BNMS representative	Radiology, Bath
Dr Ahsan Akram		Respiratory medicine, Edinburgh
Dr Puneet Malhotra		Respiratory medicine, St Helens and Knowsley
Dr Manil Subesinghe		Radiology, London
Dr Philip Pearson	BTS Quality Improvement Committee representative	Respiratory medicine, Northampton

BNMS, British Nuclear Medicine Society; BTS, British Thoracic Society; RCP, Royal College of Physicians; RCR, Royal College of Radiologists; SCTS, Society of Cardiothoracic Surgeons.

- A quality statement, which describes a key marker of high-quality, cost-effective care for this condition.
- Quality measures, which aim to improve the structure, process and outcomes of healthcare.

The quality measures are not intended to be new sets of targets or mandatory indicators for performance management that need to be collected. The quality measures are specified in the form of a numerator and a denominator, which define a proportion or ratio (numerator/denominator). It is assumed that the numerator is a subset of the denominator population. The suggested numerator and denominator are provided to allow healthcare 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 condition, 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 main source references for these quality standards are:

- BTS Guidelines for the Investigation and Management of Pulmonary Nodules, 2015.[3]
- NICE Clinical Guideline Lung Cancer: diagnosis and management, 2011.[4]

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

METHOD OF WORKING

A Quality Standards Working Group was convened in February 2016 and met in May 2016. Membership is given in table 1.

Members of the Quality Standards Working Group submitted Declaration of Interest forms in line with the BTS Policy, and copies of forms are available on request from BTS head office.

The draft document was considered in detail by the BTS Standards of Care Committee initially in October 2016 and the BTS Quality Improvement Committee in March 2017.

The document was made available on the BTS website for public consultation for the period from 13 March to 10 April 2017.

Following further revision, the document was submitted for approval to the BTS Standards of Care Committee in October 2017.

The Quality Standards document will be reviewed in 5 years from the date of publication or following the publication of a revised Guideline whichever is sooner.

LIST OF QUALITY STATEMENTS

1. People with non-calcified pulmonary nodules confirmed on CT have their nodule(s) assessed for risk of malignancy.
2. People with solid pulmonary nodules have their nodules assessed by semi-automated volumetry in preference to manual diameter measurements where possible and appropriate (eg, for smaller nodules and for measuring doubling time, when growth not obvious).
3. Positron emission tomography (PET)-CT examinations undertaken for assessment of solid pulmonary nodules are reported using qualitative assessment with an ordinal scale to define fluorodeoxyglucose (FDG) uptake as absent, faint, moderate or intense, in relation to background lung tissue and mediastinal blood pool, to facilitate use of the Herder risk prediction model.
4. People with pulmonary nodules confirmed on CT are offered discharge, further surveillance, further work up or treatment according to BTS guidelines (see for specific recommendations).
5. People with pulmonary nodules considered for definitive treatment and suitable for surgical intervention are offered lobectomy with pathological confirmation of malignancy by frozen section, if not previously confirmed, or anatomical segmentectomy if unfit for lobectomy.
6. People with pulmonary nodules considered for definitive treatment but who decline or who are unsuitable for surgery are offered ablative non-surgical treatment where safe.
7. People with pulmonary nodules confirmed on CT are offered verbal and written information that allows them to make an informed choice about their management.

Quality statement 1	**People with non-calcified pulmonary nodules confirmed on CT have their nodule(s) assessed for risk of malignancy.**
Rationale	To ensure patients with non-calcified pulmonary nodules on CT have their nodule(s) assessed for risk of malignancy to guide appropriate use of interval imaging and recommendation for further workup.
Quality measure	**Structure**: ► Evidence of local arrangements and written clinical protocols to ensure that people with non-calcified pulmonary nodules confirmed on CT have their nodule(s) assessed for risk of malignancy. **Process:** ► Proportion of people with non-calcified pulmonary nodules confirmed on CT who have their nodule(s) assessed for risk of malignancy. ► Numerator: the number of people with non-calcified pulmonary nodules confirmed on CT who have their nodule(s) assessed for risk of malignancy. ► Denominator: the number of people with non-calcified pulmonary nodules confirmed on CT.
Description of what the quality statement means for each audience	**Service providers:** ► Ensure there are systems in place for people with non-calcified pulmonary nodules confirmed on CT to have their nodule(s) assessed for risk of malignancy and managed according to the latest recommendations. **Healthcare professionals:** ► Refer people with non-calcified pulmonary nodules confirmed on CT to services where their nodule(s) are assessed for risk of malignancy and are managed according to the latest recommendations. **Commissioners**: ► Ensure they commission services for people with non-calcified pulmonary nodules confirmed on CT to have their nodule(s) assessed for risk of malignancy and be managed according to the latest recommendations. **People with non-calcified pulmonary nodules confirmed on CT:** ► Have their nodule(s) assessed for risk of malignancy and are managed according to the latest recommendations.
Relevant existing indicators	Local multidisciplinary team (MDT) minutes/database/audit
National data sources	National Lung Cancer Audit, Society for Cardiothoracic Surgery Thoracic Registry
Source references	BTS Guidelines for the Investigation and Management of Pulmonary Nodules, 2015[3]; NICE Lung Cancer: Diagnosis and Management Guideline, 2011[4]
Other information	► BTS Pulmonary Nodule Risk Prediction Calculator https://www.brit-thoracic.org.uk/standards-of-care/guidelines/bts-guidelines-for-the-investigation-and-management-of-pulmonary-nodules/bts-pulmonary-nodule-risk-prediction-calculator/ (to be read in conjunction with the relevant sections of the above guideline). ► NHS England Service Specification for Thoracic Surgical Services https://www.england.nhs.uk/publication/thoracic-surgery-adults/ ► NHS England Commissioning Guidance for the Whole Lung Cancer Pathway: https://www.brit-thoracic.org.uk/media/396232/Clinical-Advice-for-the-Provision-of-Lung-Cancer-Services-Aug-2017.pdf https://www.brit-thoracic.org.uk/media/382380/National-Optimal-LUNG-Pathway-Aug-2017.pdf ► NLCFN Patient Information: https://www.nlcfn.org.uk/patient-information

Quality statement 2	**People with solid pulmonary nodules have their nodules assessed by semi-automated volumetry in preference to manual diameter measurements where possible and appropriate (eg, for smaller nodules and for measuring doubling time, when growth not obvious).**
Rationale	To ensure patients with solid pulmonary nodules on CT have their nodule(s) assessed by the most accurate method, where possible to guide appropriate use of interval imaging and recommendation for further workup.
Quality measure	**Structure**: ► Evidence of local arrangements and written clinical protocols to ensure that people with solid pulmonary nodules have their nodules assessed by semi-automated volumetry in preference to manual diameter measurements where possible and appropriate (smaller nodules and for measuring doubling time, when growth not obvious).

	Process: ► Proportion of people with solid pulmonary nodules who have their nodule(s) assessed by semi-automated volumetry in preference to manual diameter measurements where possible and appropriate (smaller nodules and for measuring doubling time, when growth not obvious). ► Numerator: the number of people with solid pulmonary nodules who have their nodules assessed by semi-automated volumetry in preference to manual diameter measurements where possible and appropriate (smaller nodules and for measuring doubling time when growth not obvious). ► Denominator: the number of people with solid pulmonary nodules confirmed on CT where volumetry is preferable to manual measurements and is possible and appropriate.
Description of what the quality statement means for each audience	**Service providers:** ► Ensure there are systems in place that provide nodule assessment by semi-automated volumetry. **Healthcare professionals:** ► Refer people with solid pulmonary nodules confirmed on CT to services where they can have their nodules assessed by semi-automated volumetry in preference to manual diameter measurements where possible and appropriate. **Commissioners**: ► Ensure they commission services for people with solid pulmonary nodules confirmed on CT to have their nodule(s) assessed by semi-automated volumetry in preference to manual diameter measurements where possible and appropriate. **People with solid pulmonary nodules confirmed on CT** ► Have their nodule(s) assessed by semi-automated volumetry in preference to manual diameter measurements where possible and appropriate.
Relevant existing indicators	Local MDT minutes/database/audit
National data sources	National Lung Cancer Audit, Society for Cardiothoracic Surgery Thoracic Registry.
Source references	BTS Guidelines for the Investigation and Management of Pulmonary Nodules, 2015[3]; NICE Lung Cancer: Diagnosis and Management Guideline, 2011[4] **Note:** To ensure accuracy of comparative measurements, serial volumetry should be measured using the same CT settings, same software and release version.
Other information	► BTS Pulmonary Nodule Risk Prediction Calculator https://www.brit-thoracic.org.uk/standards-of-care/guidelines/bts-guidelines-for-the-investigation-and-management-of-pulmonary-nodules/bts-pulmonary-nodule-risk-prediction-calculator/ (to be read in conjunction with the relevant sections of the above guideline). ► NHS England Service Specification for Thoracic Surgical Services https://www.england.nhs.uk/publication/thoracic-surgery-adults/ ► NHS England Commissioning Guidance for the Whole Lung Cancer Pathway: https://www.brit-thoracic.org.uk/media/396232/Clinical-Advice-for-the-Provision-of-Lung-Cancer-Services-Aug-2017.pdf https://www.brit-thoracic.org.uk/media/382380/National-Optimal-LUNG-Pathway-Aug-2017.pdf ► NLCFN Patient Information: https://www.nlcfn.orwg.uk/patient-information

Quality statement 3	**PET-CT examinations undertaken for assessment of solid pulmonary nodules are reported using qualitative assessment with an ordinal scale to define FDG uptake as absent, faint, moderate or intense, in relation to background lung tissue and mediastinal blood pool, to facilitate use of the Herder risk prediction model.**
Rationale	The Herder risk prediction model is the most accurate at predicting malignancy in solid pulmonary nodules and has been validated in a UK population. It uses clinical and radiological factors in conjunction with FDG uptake within the pulmonary nodule to determine the risk of malignancy. The incorporation of FDG uptake has a synergistic effect on the predictive accuracy of clinicoradiological prediction models but is dependent on the accurate classification of FDG uptake within solid pulmonary nodules using qualitative assessment with an ordinal scale. The standardisation of reporting of FDG uptake within solid pulmonary nodules on PET-CT facilitates reliable reproducibility of the Herder risk prediction model in clinical practice.

Quality measure	**Structure**: ► Evidence that PET-CT reports for characterisation of solid pulmonary nodules are reported using qualitative assessment with an ordinal scale to define FDG uptake with nodules. **Process:** ► Proportion of patients undergoing PET-CT for characterisation of solid pulmonary nodules with FDG uptake within nodules categorised using qualitative assessment with an ordinal scale. ► Numerator: number of patients undergoing PET-CTs performed for characterisation of solid pulmonary nodules with FDG uptake within the nodules categorised using qualitative assessment with an ordinal scale. ► Denominator: number of patients undergoing PET-CTs performed for characterisation of solid pulmonary nodules.
Description of what the quality statement means for each audience	**Service providers:** ► Ensure that patients have timely access to PET-CT for characterisation of solid pulmonary nodules. **Healthcare professionals who report PET-CT** ► Ensure standardisation of reporting of FDG uptake within solid pulmonary nodules on PET-CT using qualitative assessment with an ordinal scale. **Commissioners**: ► Commission PET-CT for the characterisation of solid pulmonary nodules. **People having PET-CT undertaken for assessment of solid pulmonary nodules** ► Have their scans reported to facilitate the use of the Herder risk prediction model, one of the most accurate models in predicting malignancy in solid pulmonary nodules.
Relevant existing indicators	Local MDT minutes/database/audit
National data sources	National Lung Cancer Audit, Society for Cardiothoracic Surgery Thoracic Registry
Source references	BTS Guidelines for the Investigation and Management of Pulmonary Nodules, 2015[3]; NICE Lung Cancer: Diagnosis and Management Guideline, 2011[4]; RCP/RCR Evidence-based indications for the use of PET-CT in the United Kingdom, 2016[5]
Other information	► BTS Pulmonary Nodule Risk Prediction Calculator https://www.brit-thoracic.org.uk/standards-of-care/guidelines/bts-guidelines-for-the-investigation-and-management-of-pulmonary-nodules/bts-pulmonary-nodule-risk-prediction-calculator/ (to be read in conjunction with the relevant sections of the above guideline). ► NHS England Service Specification for Thoracic Surgical Services https://www.england.nhs.uk/publication/thoracic-surgery-adults/ ► NHS England Commissioning Guidance for the Whole Lung Cancer Pathway: https://www.brit-thoracic.org.uk/media/396232/Clinical-Advice-for-the-Provision-of-Lung-Cancer-Services-Aug-2017.pdf https://www.brit-thoracic.org.uk/media/382380/National-Optimal-LUNG-Pathway-Aug-2017.pdf ► NLCFN Patient Information: https://www.nlcfn.org.uk/patient-information
Definitions	**BTS qualitative ordinal scale for classification of solid pulmonary nodules with FDG PET-CT** **Absent:** uptake indiscernible from background lung tissue. **Faint:** uptake less than or equal to mediastinal blood pool. **Moderate:** uptake greater than mediastinal blood pool. **Intense:** uptake markedly greater than mediastinal blood pool.

Quality statement 4	**People with pulmonary nodules confirmed on CT are offered discharge, further surveillance, further workup or treatment according to BTS Guidelines** (see Box 1 for specific recommendations)
Rationale	To ensure that patients are not followed up inappropriately where the risk of follow-up is likely to outweigh the benefit. To ensure that patients with larger nodules are managed according to assessment of risk of malignancy by further surveillance, further workup or treatment.
Quality measure	**Structure**: ► Evidence that local arrangements are in place to apply BTS guidelines to patients with pulmonary nodules to ensure they are offered discharge, further surveillance, further workup or treatment appropriately.

	Process: ▶ Proportion of patients with pulmonary nodules who are offered discharge, further surveillance, further work up or treatment according to BTS guidelines as a proportion of all nodules under follow-up. ▶ Numerator 1: number of patients discharged. ▶ Denominator: number of patients with pulmonary nodules who meet the criteria for discharge. ▶ Numerator 2: number of patients offered surveillance, further work up or treatment. ▶ Denominator 2: number of patients with pulmonary nodules who meet the criteria for surveillance, further work up or treatment.
Description of what the quality statement means for each audience	**Service providers:** ▶ Ensure patients are managed within a system in accordance with the latest and available evidence to allow safe discharge, further surveillance, further work up or treatment of patients with pulmonary nodules according to BTS guidelines. **Healthcare professionals:** ▶ Ensure they have a structure where they can safely discharge, or offer further surveillance, workup or treatment to patients with pulmonary nodules according to BTS guidelines. **Commissioners**: ▶ Ensure that adequate resource exists to allow for initial assessment of a nodule (including semi-automated volumetric analysis) to enable the calculation of risk of malignancy, offer further imaging surveillance with volumetric CT, further workup with PET-CT and other investigations or definitive treatment. **People with pulmonary nodules confirmed on CT** ▶ Are offered discharge, further surveillance, further workup or treatment according to BTS guidelines.
Relevant existing indicators	Local MDT minutes/database/audit
National data sources	National Lung Cancer Audit, Society for Cardiothoracic Surgery Thoracic Registry
Source references	BTS Guidelines for the Investigation and Management of Pulmonary Nodules, 2015[3]; NICE Lung Cancer: Diagnosis and Management Guideline, 2011[4]; Walter, J E *et al*. *Occurrence and lung cancer probability of new solid nodules at incidence screening with low-dose CT: analysis of data from the randomised, controlled NELSON trial*, 2016[6]

Quality statement 5	**People with pulmonary nodules considered for definitive treatment and suitable for surgical intervention are offered lobectomy with pathological confirmation of malignancy by frozen section, if not previously confirmed, or anatomical segmentectomy if unfit for lobectomy.**
Rationale	To maximise the surgical resection rate for early stage lung cancer and to allow geographical and temporal comparison of resection rates to instruct service development. To ensure an appropriate surgical strategy for resection that minimises lobectomy for benign disease, ensures anatomical resection for all pulmonary nodules confirmed as lung cancer and that, where appropriate, a completion lobectomy occurs during the same anaesthetic.
Quality measure	**Structure**: ▶ Evidence of local arrangements and written clinical protocols that ensure people with pulmonary nodules considered for definitive treatment and suitable for surgical intervention are offered lobectomy with pathological confirmation of malignancy by frozen section, if not previously confirmed, or anatomical segmentectomy if unfit for lobectomy. **Process:** ▶ Overall proportion of patients who have pulmonary nodules with pathological confirmation of malignancy that undergo surgical resection. ▶ Proportion of patients undergoing lobar or segmental resection of malignant pulmonary nodules as one definitive procedure. ▶ Proportion of patients undergoing wedge or segmental resection of pulmonary nodules with eventual benign diagnosis. **Numerator 1:** ▶ Number of patients who have pulmonary nodules with pathological confirmation of malignancy that undergo surgical resection.

	Denominator 1: ► Total number of patients who have pulmonary nodules with pathological confirmation of malignancy. **Numerator 2:** ► Number of patients undergoing lobectomy with intraoperative frozen section analysis, or undergoing anatomic segmentectomy where not fit for lobectomy. **Denominator 2:** ► Number of patients undergoing resection of pulmonary nodules without a preoperative diagnosis who are subsequently confirmed malignant. **Numerator 3:** ► Number of patients undergoing resection of pulmonary nodules with an eventual benign diagnosis who undergo lobectomy. **Denominator 3:** ► Number of patients undergoing surgical resection of pulmonary nodules by lobectomy. (This fraction should be equivalent to 10% or less)
Description of what the quality statement means for each audience	**Service providers:** ► Ensure services are provided that ensure people with pulmonary nodules considered for definitive treatment and suitable for surgical intervention are offered lobectomy with pathological confirmation of malignancy by frozen section, if not previously confirmed, or anatomical segmentectomy, if unfit for lobectomy. **Healthcare professionals** ► Ensure surgical involvement in MDT discussion of pulmonary nodules, and ensure that surgical strategy is appropriate for the clinical situation. **Commissioners:** ► Commission specialist thoracic surgical services that offer lobectomy with pathological confirmation of malignancy by frozen section, if not previously confirmed, or anatomical segmentectomy, if unfit for lobectomy. Services will be supported by an expert lung cancer MDT. **People with pulmonary nodules considered for definitive treatment and suitable for surgical intervention** ► Should be treated at specialist centres with adequate provision for preoperative assessment, and intraoperative management for both diagnosis and resection.
Relevant existing indicators	Local MDT minutes/database/audit
National data sources	National Lung Cancer Audit, Society for Cardiothoracic Surgery Thoracic Registry
Source references	BTS Guidelines for the Investigation and Management of Pulmonary Nodules, 2015[3]; NICE Lung Cancer: Diagnosis and Management Guideline, 2011[4]; BTS Guidelines on the Radical Management of Patients with Lung Cancer, 2010[7]
Other information	► BTS Pulmonary Nodule Risk Prediction Calculator https://www.brit-thoracic.org.uk/standards-of-care/guidelines/bts-guidelines-for-the-investigation-and-management-of-pulmonary-nodules/bts-pulmonary-nodule-risk-prediction-calculator/ (to be read in conjunction with the relevant sections of the above guideline). ► NHS England Service Specification for Thoracic Surgical Services https://www.england.nhs.uk/publication/thoracic-surgery-adults/ ► NHS England Commissioning Guidance for the Whole Lung Cancer Pathway: https://www.brit-thoracic.org.uk/media/396232/Clinical-Advice-for-the-Provision-of-Lung-Cancer-Services-Aug-2017.pdf https://www.brit-thoracic.org.uk/media/382380/National-Optimal-LUNG-Pathway-Aug-2017.pdf ► NLCFN Patient Information: https://www.nlcfn.org.uk/patient-information

Quality statement 6	**People with pulmonary nodules considered for definitive treatment but who decline or who are unsuitable for surgery are offered ablative* non-surgical treatment where safe.**
Rationale	People who are unfit or decline surgery still stand to gain a lot from having early-stage lung cancer treated with curative intent. Such patients should therefore be offered alternative treatment with curative intent. The outcome of treatment is similar whether in biopsy confirmed malignancy or where unconfirmed. **Structure:** ► Evidence of local arrangements and written clinical protocols to ensure that people with pulmonary nodules considered for definitive treatment but who decline or who are unsuitable for surgery are offered ablative non-surgical treatment where safe.

Quality measure	**Process:** ▶ Proportion of people with pulmonary nodules with a > 70% likelihood of malignancy or pathological confirmation of lung cancer who decline or are unsuitable for surgery, who are offered ablative non-surgical treatment where safe. **Numerator:** ▶ The number of people with pulmonary nodules with a >70% likelihood of malignancy or pathological confirmation of lung cancer who decline or are unsuitable for surgery and who are offered ablative non-surgical treatment where safe. **Denominator:** ▶ The number of people with pulmonary nodules with a >70% likelihood of malignancy or pathological confirmation of lung cancer who decline or are unsuitable for surgery.
Description of what the quality statement means for each audience	**Service providers:** ▶ Ensure there are systems and services in place for people with pulmonary nodules who decline or who are unsuitable for surgery to be offered ablative non-surgical treatment where safe. **Healthcare professionals:** ▶ Offer referral to people with pulmonary nodules who decline or who are unsuitable for surgery for ablative non-surgical treatment where safe. **Commissioners:** ▶ Ensure they commission services for people with pulmonary nodules who decline or who are unsuitable for surgery so that they can be offered ablative non-surgical treatment where safe. **People with pulmonary nodules who decline or who are considered unsuitable for surgery** ▶ Are offered ablative non-surgical treatment where safe.
Relevant existing indicators	Local MDT minutes/database/audit
National data sources	National Lung Cancer Audit, Society for Cardiothoracic Surgery Thoracic Registry
Source references	BTS Guidelines for the Investigation and Management of Pulmonary Nodules, 2015[3]; NICE Lung Cancer: Diagnosis and Management Guideline, 2011[4]; BTS Guidelines on the Radical Management of Patients with Lung Cancer, 2010[7]
Other information	*Ablative treatment refers to stereotactic ablative body radiotherapy, radiofrequency ablation or microwave ablation. ▶ BTS Pulmonary Nodule Risk Prediction Calculator https://www.brit-thoracic.org.uk/standards-of-care/guidelines/bts-guidelines-for-the-investigation-and-management-of-pulmonary-nodules/bts-pulmonary-nodule-risk-prediction-calculator/ (to be read in conjunction with the relevant sections of the above guideline). ▶ NHS England Service Specification for Thoracic Surgical Services https://www.england.nhs.uk/publication/thoracic-surgery-adults/ ▶ NHS England Commissioning Guidance for the Whole Lung Cancer Pathway: https://www.brit-thoracic.org.uk/media/396232/Clinical-Advice-for-the-Provision-of-Lung-Cancer-Services-Aug-2017.pdf https://www.brit-thoracic.org.uk/media/382380/National-Optimal-LUNG-Pathway-Aug-2017.pdf ▶ NLCFN Patient Information: https://www.nlcfn.org.uk/patient-information

Quality statement 7	**People with pulmonary nodules confirmed on CT are offered verbal and written information that allows them to make an informed choice about their management.**
Rationale	People with pulmonary nodules confirmed on CT should be provided with verbal and written information that allows them to make an informed choice about their management.
Quality measure	**Structure**: ▶ Evidence of local arrangements and written clinical protocols to ensure that people with pulmonary nodules confirmed on CT are offered verbal and written information that allows them to make an informed choice about their management. **Process:** ▶ Proportion of people with pulmonary nodules confirmed on CT who are offered verbal and written information that allows them to make an informed choice about their management. **Numerator:** ▶ The number of people with pulmonary nodules confirmed on CT who are offered verbal and written information that allows them to make an informed choice about their management. **Denominator:** ▶ The number of people with pulmonary nodules confirmed on CT excluding nodules with obvious benign features.

Description of what the quality statement means for each audience	**Service providers:** ► Ensure there are systems in place to ensure people with pulmonary nodules confirmed on CT are offered verbal and written information that allows them to make an informed choice about their management. **Healthcare professionals:** ► Offer people with pulmonary nodules confirmed on CT verbal and written information that allows them to make an informed choice about their management. **Commissioners:** ► Ensure they commission services where people with pulmonary nodules confirmed on CT are offered verbal and written information that allows them to make an informed choice about their management. **People with pulmonary nodules confirmed on CT** ► Are offered verbal and written information that allows them to make an informed choice about their management. This provides patients (and their carers) with the opportunity to ask questions and make comments in connection with the proposed management and about their care in general. They should be able to appreciate the balance of benefits and risks concerning nodule management.
Relevant existing indicators	Local MDT minutes/database/audit
National data sources	National Lung Cancer Audit, Society for Cardiothoracic Surgery Thoracic Registry
Source references	BTS Guidelines for the Investigation and Management of Pulmonary Nodules, 2015[3]; NICE Lung Cancer: Diagnosis and Management Guideline, 2011[4]
Other information	► BTS Pulmonary Nodule Risk Prediction Calculator https://www.brit-thoracic.org.uk/standards-of-care/guidelines/bts-guidelines-for-the-investigation-and-management-of-pulmonary-nodules/bts-pulmonary-nodule-risk-prediction-calculator/ (to be read in conjunction with the relevant sections of the above guideline). ► NHS England Service Specification for Thoracic Surgical Services https://www.england.nhs.uk/publication/thoracic-surgery-adults/ ► NHS England Commissioning Guidance for the Whole Lung Cancer Pathway: https://www.brit-thoracic.org.uk/media/396232/Clinical-Advice-for-the-Provision-of-Lung-Cancer-Services-Aug-2017.pdf https://www.brit-thoracic.org.uk/media/382380/National-Optimal-LUNG-Pathway-Aug-2017.pdf ► NLCFN Patient Information: https://www.nlcfn.org.uk/patient-information

Box 1 Specific guideline recommendations in relation to quality statement 4.

Solid Pulmonary nodules

Offer discharge if:

1. the largest nodule is <80 mm^3 or 5 mm diameter, except where there is a history of previous malignancy or the nodule was not seen on a previous CT within 2 years.
2. there are obvious benign features (diffuse central laminated or popcorn pattern of calcification or macroscopic fat) or typical perifissural or sub-pleural nodules.
3. people with solid pulmonary nodules who are stable by semi-automated volumetry at one year, or at 2 years if by diameter measurement.

Offer imaging follow-up with low radiation dose CT (LDCT) and semi-automated volumetric analysis if:

4. nodule(s) are <300mm^3 or 8mm diameter, or have a calculated risk of malignancy of <10% Offer PET-CT to further assess risk of malignancy
5. nodule(s) that are ≥300mm^3 or ≥8mm diameter and have a >10% risk of malignancy. Offer biopsy (may also elect to have surveillance imaging or definitive treatment)
6. nodules that have a risk of malignancy of 10 to 70% after PET-CT.
7. Offer definitive treatment with or without prior biopsy
8. if nodule(s) have a risk of malignancy of >70% after PET-CT.

Sub-solid pulmonary nodules (SSN)

9. offer interval thin section LDCT at 3 months to people with sub-solid pulmonary nodules ≥5 mm diameter and subsequently manage them according to risk of malignancy with follow-up of persistent SSN for 4 years

Source references BTS Guidelines for the Investigation and Management of Pulmonary Nodules, 2015[3]; NICE Lung Cancer: Diagnosis and Management Guideline, 2011[4]; Walter, J. E *et al.* Occurrence and lung cancer probability of new solid nodules at incidence screening with low-dose CT: analysis of data from the randomised, controlled NELSON trial, 2016.[6]

Other information BTS Pulmonary Nodule Risk Prediction Calculator https://www.brit-thoracic.org.uk/standards-of-care/guidelines/bts-guidelines-for-the-investigation-and-management-of-pulmonary-nodules/bts-pulmonary-nodule-risk-prediction-calculator/ (to be read in conjunction with the relevant sections of the above Guideline).
NHS England Service Specification for Thoracic Surgical Services https://www.england.nhs.uk/publication/thoracic-surgery-adults/
NHS England Commissioning Guidance for The Whole Lung Cancer Pathway https://www.brit-thoracic.org.uk/media/396232/Clinical-Advice-for-the-Provision-of-Lung-Cancer-Services-Aug-2017.pdf https://www.brit-thoracic.org.uk/media/382380/National-Optimal-LUNG-Pathway-Aug-2017.pdf
NLCFN Patient Information: https://www.nlcfn.org.uk/patient-information

Note: Integration of nodule volumetry software with other radiology systems used for image management and reporting is important to reduce reporting times and ensure images are stored appropriately for future reference.

GLOSSARY OF TERMS

Definitive treatment: removal or ablation of the nodule with curative intent.

Ablative treatment: stereotactic ablative body radiotherapy, radiofrequency ablation or microwave ablation.

BTS Quality Standards for the investigation and management of pulmonary nodules are endorsed by: Royal College of Physicians (RCP), Royal College of Radiologists (RCR), National Lung Cancer Forum for Nurses (NLCFN), Society for Cardiothoracic Surgery (SCTS), British Nuclear Medicine Society (BNMS).

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