Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

British Thoracic Society guidelines for the investigation and management of pulmonary nodules.

Bibliographic Source(s)

Callister ME, Baldwin DR, Akram AR, Barnard S, Cane P, Draffan J, Franks K, Gleeson F, Graham R, Malhotra P, Prokop M, Rodger K, Subesinghe M, Waller D, Woolhouse I, British Thoracic Society Pulmonary Nodule Guideline Development Group, British Thoracic Society Standards of Care Committee. British Thoracic Society guidelines for the investigation and management of pulmonary nodules. Thorax. 2015 Aug;70 Suppl 2:ii1-ii54. [359 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4), grades of recommendations (A-D), good practice points (GPPs) and recommendations for further research (RR) are defined at the end of the "Major Recommendations" field.

Route of Detection of Pulmonary Nodules

- Use the same diagnostic approach for nodules detected incidentally as those detected through screening. (D)
- Consider using the presence of previous malignancy as a factor in the risk assessment for further investigation. (D)
- Do not prioritise management of pulmonary nodules according to the route of presentation. (D)
- Evaluate coexistent lung nodules detected in patients with known lung cancer otherwise suitable for radical treatment in their own right; they should not be assumed to be malignant. (D)

Initial Assessment of the Probability of Malignancy in Pulmonary Nodules

- Do not offer nodule follow-up or further investigation for people with nodules with diffuse, central, laminated or popcorn pattern of calcï¬cation or macroscopic fat. (C)
- Do not offer nodule follow-up or further investigation for people with periï¬ssural or subpleural nodules (homogeneous, smooth, solid nodules with a lentiform or triangular shape either within 1 cm of a ï¬ssure or the pleural surface and <10 mm). (C)
- Consider follow-up of larger intrapulmonary lymph nodes, especially in the presence of a known extrapulmonary primary cancer. (D)

- Do not offer nodule follow-up for people with nodules <5 mm in maximum diameter or <80 mm^3 volume. (C)
- Offer computed tomography (CT) surveillance to people with nodules ≥5 mm to <8 mm maximum diameter or ≥80 mm^3 to <300 mm^3. (C)
- Use composite prediction models based on clinical and radiological factors to estimate the probability that a pulmonary nodule (≥8 mm or ≥300 mm^3) is malignant. (C)
- Use the Brock model (full, with spiculation) for initial risk assessment of pulmonary nodules (≥8 mm or ≥300 mm^3) at presentation in people aged ≥50 who are smokers or former smokers. (C)
- Consider the Brock model (full, with spiculation) for initial risk assessment of pulmonary nodules (≥8 mm or ≥300 mm^3) in all patients at presentation. (D)
- Base the risk assessment of people with multiple pulmonary nodules on that of the largest nodule. (C)
- Nodule malignancy risk prediction models should be validated in patients with known extrapulmonary cancer. (RR)
- Further analysis of variation in volumetry measurements by different software packages should be undertaken and methods developed for standardisation. (RR)

Imaging Follow-up

- Where initial risk stratification assigns a nodule a chance of malignancy of <10%, assess growth rate using interval CT with capability for automated volumetric analysis. (C)
- Assess growth for nodules ≥80 mm^3 or ≥6 mm maximum diameter by calculating volume doubling time (VDT) by repeat CT at 3 months and 1 year. (C)
- Use a ≥25% volume change to define significant growth. (C)
- Assess growth for nodules of ≥5 to <6 mm maximum diameter by calculating VDT by repeat CT at 1 year. (C)
- Offer further diagnostic investigation (biopsy, imaging or resection) for patients with nodules showing clear growth or a VDT of <400 days (assessed after 3 months, and 1 year). (C)
- Discharge patients with solid nodules that show stability (<25% change in volume) on CT after 1 year. (C)
- If two-dimensional diameter measurements are used to assess growth, follow-up with CT for a total of 2 years. (D)
- Consider ongoing yearly surveillance or biopsy for people with nodules that have a VDT of 400–600 days, according to patient preference. (C)
- Consider discharge or ongoing CT surveillance for people who have nodules with a VDT of >600 days, taking into account patient preference and clinical factors such as fitness and age. (C)
- Where nodules are detected in association with an extrapulmonary primary cancer, consider the growth rate in the context of the primary and any treatment thereof. (D)

Management of Sub-solid Nodules (SSNs)

- Do not follow-up SSNs that are <5 mm in maximum diameter at baseline. (C)
- Reassess all SSNs with a repeat thin-section CT at 3 months. (D)
- Use the Brock risk prediction tool to calculate risk of malignancy in SSNs ≥5 mm that are unchanged at 3 months. (C)
- Consider using other factors to further refine the estimate of risk of malignancy, including smoking status, peripheral eosinophilia, history of lung cancer, size of solid component, bubble-like appearance and pleural indentation. (D)
- Offer repeat low-dose, thin-section CT at 1, 2 and 4 years from baseline where the risk of malignancy is approximately <10%. (D)
- Discuss the options of observation with repeat CT, CT-guided biopsy, or resection/non-surgical treatment with the patient where the risk of malignancy is approximately >10%; consider factors such as age, comorbidities and risk of surgery. (D)
- Consider using changes in mass of SSNs to accurately assess growth. (D)
- Consider resection/non-surgical treatment or observation for pure ground-glass nodules (pGGNs) that enlarge ≥2 mm in maximum diameter; if observed, repeat CT after a maximum of 6 months. Take into account patient choice, age, comorbidities and risk of surgery. (D)
- Favour resection/non-surgical treatment over observation for part-solid nodules (PSNs) that show enlargement of the solid component, or for pGGNs that develop a solid component. Take into account patient choice, age, comorbidities and risk of surgery. (D)
- Favour resection/non-surgical treatment over observation where malignancy is pathologically proven. Take into account patient choice, age, comorbidities and risk of surgery. (D)

Further Imaging in Management of Pulmonary Nodules

- Offer a positron emission tomography–computed tomography (PET-CT) scan to patients with a pulmonary nodule with an initial risk of malignancy of >10% (Brock model) where the nodule size is greater than the local PET-CT detection threshold. (B)

- Ensure that PET-CT reports include the method of analysis. (D)
- Use qualitative assessment with an ordinal scale to deï¬ne fluoro-deoxy-glucose (FDG) uptake as absent, faint, moderate or high using the following guide:
  - 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 (D)
- Reassess risk after PET-CT using the Herder prediction tool. (B)
- After reassessment of risk:
  - Consider CT surveillance for people who have nodules with a chance of malignancy of <10%.
  - Consider image-guided biopsy where the risk of malignancy is assessed to be between 10% and 70%; other options are excision biopsy or CT surveillance guided by individual risk and patient preference.
  - Offer people surgical resection as the favoured option where the risk that the nodule is malignant is >70%; consider non-surgical treatment for people who are not ï¬t for surgery. (C)
- Do not use magnetic resonance imaging (MRI), single photon emission CT (SPECT) or dynamic contrast-enhanced CT to determine whether a nodule is malignant where PET-CT is an available alternative. (D)
- Further research is needed into the most effective follow-up pathway in low to medium risk patients and for those with pGGNs. (RR)
- Further research should be undertaken into the use of PET-CT in the evaluation of pGGNs using lower standardised uptake value (SUV) cut-off values. (RR)

Non-imaging Tests and Non-surgical Biopsy

- Do not use biomarkers in the assessment of pulmonary nodules. (D)
- Consider bronchoscopy in the evaluation of pulmonary nodules with bronchus sign present on CT. (D)
- Consider augmenting yield from bronchoscopy using either radial endobronchial ultrasound, ï¬,uoroscopy or electromagnetic navigation. (D)
- Offer percutaneous lung biopsy in cases where the result will alter the management plan. (C)
- Consider the use of other imaging techniques such as C-arm cone beam CT and multiplanar reconstruction to improve diagnostic accuracy. (D)
- Consider the risk of pneumothorax when deciding on a transthoracic needle biopsy. (C)
- Interpret negative lung biopsies in the context of the pre-test probability of malignancy. (D)
- Consider repeating percutaneous lung biopsies where the probability of malignancy is high. (D)
- Undertake research into the application of new and existing biomarkers in the evaluation of pulmonary nodules. (RR)

Surgical Excision Biopsy

- Surgical resection of pulmonary nodules should preferentially be by video-assisted thoracoscopic surgery (VATS) rather than by an open approach. (C)
- Offer lobectomy (to patients ï¬t enough to undergo the procedure) as deï¬nitive management of a pulmonary nodule conï¬rmed as lung cancer preoperatively or after wedge resection and intraoperative frozen section analysis during the same anesthetic procedure. (C)
- Consider anatomical segmentectomy where preservation of functioning lung tissue may reduce the operative risk and improve physiological outcome. (D)
- Consider a diagnostic anatomical segmentectomy for nodules <2 cm in diameter without nodal disease when there has been no pathological conï¬rmation and frozen section analysis is not possible. (D)
- Use localisation techniques depending on local availability and expertise to facilitate limited resection of pulmonary nodules. (D)
- Consider sublobar resection for pGGNs deemed to require surgical resection owing to the excellent long-term prognosis and low risk of local relapse. (D)
- Prospective trials should compare complications and oncological outcomes from lobectomy versus anatomical segmentectomy in appropriately selected patients. (RR)

Non-surgical Treatment without Pathological Conï¬rmation of Malignancy

- Consider people who are unï¬t for surgery who have pulmonary nodule(s) with high probability of malignancy, where biopsy is non-diagnostic or not possible, for treatment with stereotactic ablative body radiotherapy (SABR) or radiofrequency ablation (RFA) if technically suitable. (C)
- Consider people who are unï¬t for surgery who have pulmonary nodule(s) with high probability of malignancy, where biopsy is non-diagnostic or not possible, for treatment with conventional radical radiotherapy if not suitable for SABR or RFA. (D)

- Do not use inhaled corticosteroids in the management of indeterminate pulmonary nodules. (B)
- Do not use antibiotics in the management of indeterminate pulmonary nodules. (D)
- Consider prospective randomised trials of local treatments for pathologically proven or clinically diagnosed early-stage lung cancer and pulmonary oligometastases. (RR)
- Prospective randomised trials of interventions for pathologically proven or clinically diagnosed early-stage lung cancer should include assessment of harms. (RR)

Information and Support

- Offer accurate and understandable information to patients and carers about the probability of malignancy of the pulmonary nodule. (D)
- Ensure patients have the opportunity to discuss concerns about lung cancer and surveillance regimens. (D)
- Offer patients the choice of seeing a lung cancer nurse specialist where the probability of malignancy is high or when patients are anxious about the possibility of having lung cancer. (D)
- Ensure that clear written and verbal information is available on follow-up schedules and the number of repeat CT scans required. (D)
- Explain the risks and benefits of investigations and treatment. Where appropriate, offer a choice of management. (D)
- Inform patients who remain at high risk of developing malignancy about the warning symptoms of lung cancer at the start of observation and at discharge from follow-up. (D)
- Emphasise to patients the importance of smoking cessation and offer referral to smoking cessation services. (D)

Technical Aspects of the Imaging of Pulmonary Nodules

- Where CT scans are performed that include the chest where nodule detection is of potential importance, use a maximum section thickness of 1.25 mm. (C)
- Use low radiation dose CT with a maximum section thickness of 1.25 mm in follow-up imaging. (C)
- Use maximum intensity projection (MIP) or volume rendering (VR) to improve nodule detection and characterisation. (C)
- Use diameter measurements where volumetry is not possible or where there is clear evidence of marked growth. (D)
- When reporting on growth, take into account factors that may reduce accuracy such as nodule shape and position and interval between scans. (D)
- Ensure a radiologist or radiographer checks that the nodule has been accurately segmented. (D)

Definitions

Key to Evidence Statements

Grade	Evidence
1++	High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews or RCTs, or RCTs with a high risk of bias
2++	High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk of confounding, bias or chance, and a high probability that the relationship is causal
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance, and a moderate probability that the relationship is causal
2-	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal
3	Non-analytic studies—for example, case reports, case series
4	Expert opinion

Grades of Recommendations

Grade	Type of Evidence
A	At least one meta-analysis, systematic review, or randomised controlled trial (RCT) rated as 1++ and directly applicable to the target population *or*

Grade	Type of Evidence
	A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+ directly applicable to the target population and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++ directly applicable to the target population and demonstrating overall consistency of results *or* Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results *or* Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4 *or* Extrapolated evidence from studies rated as 2+
GPP (Good Practice Point)	Important practical points for which there is no research evidence, nor is there likely to be any research evidence. The Guideline Committee wishes to emphasise these as Good Practice Points.
RR	Recommendations for further research are designated RR

Clinical Algorithm(s)

The following algorithms are provided in the original guideline document:

- An example of a pulmonary nodule service pathway
- Initial approach to solid pulmonary nodules
- Solid pulmonary nodule surveillance algorithm
- Sub-solid pulmonary nodules algorithm
- Pulmonary nodule treatment algorithm

Scope

Disease/Condition(s)

Pulmonary nodules

Guideline Category

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Family Practice

Nuclear Medicine

Nursing

Oncology

Pathology

Pulmonary Medicine

Radiation Oncology

Radiology

Thoracic Surgery

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Hospitals

Nurses

Physician Assistants

Physicians

Respiratory Care Practitioners

Guideline Objective(s)

To provide comprehensive recommendations for the management of pulmonary nodules in the United Kingdom according to the dei¬nitions given in the original guideline document

Target Population

- Adults (≥18 years) with pulmonary nodules
- Adults with single and multiple pulmonary nodules
- Adults with nodules that are detected in the context of current or previously treated malignancy (either pulmonary or extrapulmonary)
- Adults with nodules detected in routine clinical practice, as part of radiological surveillance after a previous malignancy, or by computed tomography (CT) screening for lung cancer
- Adults with nodules of different morphologies including pure ground-glass nodules (pGGNs) and part-solid nodules (PSNs)

Note: Groups not covered:

- Children (younger than 18) with pulmonary nodules
- Adults where the nodule in question has been pathologically shown to represent lung cancer or a pulmonary metastasis from another cancer

Interventions and Practices Considered

1. Route of detection of pulmonary nodules (diagnostic approach)
2. Initial assessment of the probability of malignancy in pulmonary nodules
    - When to offer nodule follow-up or further investigation
    - When to offer computed tomography (CT) surveillance
    - Use of prediction models (e.g., Brock model)
    - Other risk assessment

3. Imaging follow-up (CT)
4. Management of sub-solid nodules
    - Resection/non-surgical treatment
    - Observation with repeat CT
    - CT-guided biopsy
5. Further imaging in management of pulmonary nodules
    - Positron emission tomography-computed tomography (PET-CT) scan
    - CT surveillance
    - Magnetic resonance imaging (MRI), single photon emission CT (SPECT) or dynamic contrast-enhanced CT (not recommended)
6. Non-imaging tests and non-surgical biopsy
    - Biomarkers (not recommended)
    - Bronchoscopy
    - Radial endobronchial ultrasound
    - Fluoroscopy
    - Electromagnetic navigation
    - Percutaneous lung biopsy
    - Other imaging techniques such as C-arm cone beam CT and multiplanar reconstruction
7. Surgical excision biopsy
    - Video-assisted thoracoscopic surgery (VATS)
    - Lobectomy
    - Anatomical segmentectomy
    - Sublobar resection
8. Non-surgical treatment without pathological confirmation of malignancy
    - Stereotactic ablative body radiotherapy (SABR)
    - Radiofrequency ablation (RFA)
    - Inhaled corticosteroids and antibiotics (not recommended)
9. Offering information and support to patients
10. Technical aspects of the imaging of pulmonary nodules

Major Outcomes Considered

- Prevalence and aetiology of lung nodules in different contexts
- Clinical and radiological characteristics of nodules in relation to probability of malignancy
- Growth rates of pulmonary nodules subsequently diagnosed as lung cancer
- Histopathological correlates of sub-solid nodules (SSNs)
- Utility, sensitivity, specificity, and accuracy of imaging studies in management of pulmonary nodules
- Utility, sensitivity, specificity, and accuracy of non-surgical biopsy/non-imaging tests in nodule evaluation
- Diagnostic outcomes of excision biopsies
- Rates of conversion to thoracotomy
- Morbidity
- Respiratory complications
- Length of hospital stay
- Disease progression
- Mortality
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Clinical Questions and Literature Search

Clinical questions were structured in the PICO (Patient, Intervention, Control, Outcome) format, to deï¬ne the scope of the guideline and inform the literature search (see supplementary appendix 1 [see the "Availability of Companion Documents" field]).

Systematic electronic database searches were conducted to identify potentially relevant studies for inclusion in the guideline. For each topic area the following databases were searched: Ovid MEDLINE (including MEDLINE In-Process), Ovid EMBASE and the Cochrane Library (including the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects) from 1980.

The searches were ï¬rst run in November 2012 and updated in June 2014 (see supplementary appendix 2 for search strategy [see the "Availability of Companion Documents" field]). Searches included a combination of indexed terms and free text terms and were limited to English language publications only. The initial search identiï¬ed 6819 potential abstracts and the second search 2739.

Appraisal of Literature

Appraisal was performed to be compliant with the Appraisal of Guidelines for Research and Evaluation (AGREE) collaboration. Two individuals read the title and abstract of each article retrieved by the literature searches and decided whether the paper was deï¬nitely relevant, possibly relevant or not relevant to the project. Criteria formulated for categorizing the abstracts into these three groups were:

- Whether the study dealt with the clinical question
- Whether the appropriate study type was used to produce the best evidence to answer the clinical question
- Review articles were excluded
- Abstract was in English
- Abstracts were reviewed irrespective of the journal of publication, country in which the research was performed or published and the date of publication

The full paper was obtained for all relevant or possibly relevant abstracts and allocated to the relevant section(s) of the guideline.

The ï¬rst screening process identiï¬ed 2021 of the initial 6819 reference abstracts to be deï¬nitely or possibly relevant to the guideline.

The second literature search in June 2014 yielded 2739 abstracts of which 1611 were possibly or deï¬nitely relevant. Four members of the group sorted the references into subject groups and these were forwarded to the pairs of reviewers for each group.

Number of Source Documents

- The first screening process in November 2012 identified 2021 of the initial 6819 reference abstracts to be definitely or possibly relevant to the guideline.
- The second literature search in June 2014 yielded 2739 abstracts of which 1611 were possibly or deï¬nitely relevant.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Key to Evidence Statements

Grade	Evidence
1++	High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews or RCTs, or RCTs with a high risk of bias
2++	High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk

Grade	Evidence
	of confounding, bias or chance, and a high probability that the relationship is causal
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance, and a moderate probability that the relationship is causal
2-	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal
3	Non-analytic studies—for example, case reports, case series
4	Expert opinion

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Two guideline reviewers for each section independently reviewed the abstracts to identify papers to be appraised for the guideline. The two reviewers for each section then independently appraised each paper assigned to them using the Scottish Intercollegiate Guidelines Network (SIGN) critical appraisal checklists. The reliability of the evidence in each individual study was graded using the SIGN critical appraisal check lists. The body of evidence for each recommendation was summarised into evidence statements and graded using the SIGN grading system (see the "Rating Scheme for the Strength of the Evidence" field). Disagreements were resolved by discussion with the section partner.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This guideline is based on the best available evidence. The methodology used to write the guideline adheres strictly to the criteria as set out by the Appraisal of Guidelines for Research and Evaluation (AGREE) collaboration, which is available online (http://www.agreetrust.org/resource-centre/agree-ii/). The British Thoracic Society Standards of Care Committee guideline production manual is available at https://www.brit-thoracic.org.uk/guidelines-and-quality-standards/ .

Considered Judgement and Grading of Evidence

The Guideline Development Group (GDG) used the evidence tables to judge the body of evidence and grade recommendations for this guideline. Evidence tables are available in supplementary appendix 3 (see the "Availability of Companion Documents" field). Where evidence was lacking to answer the formulated clinical questions, expert opinions were obtained through consensus. The following were considered in grading of the recommendations:

- The available volume of the body of evidence
- How applicable the obtained evidence was in making recommendations for the defined target audience of this guideline
- Whether the evidence was generalisable to the target population for the guideline
- Whether there was clear consistency in the evidence obtained to support recommendations
- What the implications of recommendations would be on clinical practice in terms of resources and skilled expertise
- Cost-effectiveness was not reviewed in detail as in-depth economic analysis of recommendations fell beyond the scope of this guideline

Recommendations were graded from A to D according to the strength of the evidence as shown in the "Rating Scheme for the Strength of the Recommendations" field. In line with Scottish Intercollegiate Guidelines Network (SIGN) guidance, 'minus' evidence was considered in context but in the absence of other 'plus' supporting evidence, it was discussed by the GDG and any recommendation hence made was grade D. Important practical points lacking any research evidence, and not likely to be obtained by research evidence were highlighted as 'good practice points'. Recommendations for further research are designated 'RR'.

Drafting the Guideline

The GDG corresponded regularly by email, and meetings of the full group were held in February, May and November 2012, February, April, June and October 2013, February and June 2014.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendations

Grade	Type of Evidence
A	At least one meta-analysis, systematic review, or randomised controlled trial (RCT) rated as 1++ and directly applicable to the target population *or* A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+ directly applicable to the target population and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++ directly applicable to the target population and demonstrating overall consistency of results *or* Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results *or* Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4 *or* Extrapolated evidence from studies rated as 2+
GPP (Good Practice Point)	Important practical points for which there is no research evidence, nor is there likely to be any research evidence. The Guideline Committee wishes to emphasise these as Good Practice Points.
RR	Recommendations for further research are designated RR

Cost Analysis

The guideline developer reviewed published cost analyses. Cost-effectiveness was not reviewed in detail as in-depth economic analysis of recommendations fell beyond the scope of this guideline.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The British Thoracic Society (BTS) Standards of Care Committee (SOCC) reviewed the draft guideline in September 2014. The draft guideline was made available online in January 2015 for public consultation. A draft guideline document was circulated to all the relevant stakeholders for consultation in January 2015. The BTS SOCC re-reviewed the revised draft guideline and granted ï¬nal approval in March 2015.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Improved nodule detection and characterisation, anatomical localisation, and risk stratification
- In one study, the major benefit of knowing the computed tomography (CT)-guided biopsy result was a reduction in unnecessary surgery, especially when the clinical perception of pre-test probability of malignancy was intermediate.

Refer to the evidence statements in the original guideline document for a discussion of benefits of specific recommendations.

Potential Harms

- Risk of false-positive and false-negative imaging and biopsy results
- Lesion detection on positron emission tomography-computed tomography (PET-CT) scans is adversely affected by breathing artefact, particularly peripheral lesions and those just above the diaphragm, the latter additionally affected by scatter artefact from the liver.
- Pneumothorax is the most common complication of CT-guided biopsies; by far the largest study showed an incidence of 15%, with 6.6% of patients requiring an intercostal drain insertion. Consistent factors that increase the risk are lower forced expiratory volume in 1 second (FEV1) and presence of emphysema along the needle tract.
- The frequency of complications in case series of patients treated with radiofrequency ablation (RFA) was as follows: pneumothorax was the most commonly reported complication with rates varying from 9% to 54% in 19 case series. Other reported complications after RFA were bleeding (0.7%–26%), pleural effusion (1.8%–19%), pneumonia (1.8%–12%), pleuritis (0.6%–4.3%), lung abscess (0.3%–3.1%), haemothorax (3.0%), severe pain (2%), bronchopleural ï¬stula (1.5%–1.8%), acute respiratory distress syndrome (1.5%) and pericardial tamponade (0.9%). Procedure-related mortality varied from 0% to 0.9% in seven case series, although one series reported a 30-day procedure-related mortality of 2.6%.
- The main acute toxicities of stereotactic ablative body radiotherapy (SABR) are fatigue, chest pain, skin erythema and cough, but these side effects are almost always mild (<grade 3) and self-limiting. Severe radiation pneumonitis—that is, grade 3 (requiring oxygen, severe symptoms±limiting self-care), is uncommon (range 1%–2.8%) and grade 2 (symptomatic requiring medical intervention±limiting activities of daily living) or less ranges from 1% to 11%. The incidence of radiation pneumonitis does not appear to be higher in patients with poor pulmonary function. Rib fracture and chest wall pain are the main late side effects with varying incidence depending on the dose fractionation scheme used.
- The ï¬nding of a pulmonary nodule has an adverse impact on quality of life.
    - Patients commonly assume that the ï¬nding of a nodule means that they have cancer.
    - Patients may be frustrated if healthcare providers fail to deal with their concerns about cancer or potential adverse effects of surveillance.
    - Effective communication by the healthcare team can reduce the impact on quality of life after diagnosis of a pulmonary nodule.

Qualifying Statements

Qualifying Statements

Healthcare providers need to use clinical judgement, knowledge and expertise when deciding whether it is appropriate to apply recommendations for the management of patients. The recommendations cited here are a guide and may not be appropriate for use in all situations. The guidance provided does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient, in consultation with the patient and/or their guardian or carer.

Implementation of the Guideline

Description of Implementation Strategy

Appendix 3 in the original guideline document provides a description of service organization and an associated example of a pulmonary nodule service pathway to support implementation of the guideline recommendations.

Implementation Tools

Clinical Algorithm

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Callister ME, Baldwin DR, Akram AR, Barnard S, Cane P, Draffan J, Franks K, Gleeson F, Graham R, Malhotra P, Prokop M, Rodger K, Subesinghe M, Waller D, Woolhouse I, British Thoracic Society Pulmonary Nodule Guideline Development Group, British Thoracic Society Standards of Care Committee. British Thoracic Society guidelines for the investigation and management of pulmonary nodules. Thorax. 2015 Aug;70 Suppl 2:ii1-ii54. [359 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015 Aug

Guideline Developer(s)

British Thoracic Society - Medical Specialty Society

Source(s) of Funding

British Thoracic Society

Guideline Committee

British Thoracic Society Pulmonary Nodule Guideline Development Group

British Thoracic Society Standards of Care Committee

Composition of Group That Authored the Guideline

Guideline Development Group Members: M E J Callister (*Co-Chair*), Department of Respiratory Medicine, Leeds Teaching Hospitals, Leeds, UK; D R Baldwin (*Co-Chair*), Nottingham University Hospitals, Nottingham, UK; A R Akram, Royal Infirmary of Edinburgh, Edinburgh, UK; S Barnard, Department of Cardiothoracic Surgery, Freeman Hospital, Newcastle, UK; P Cane, Department of Histopathology, St Thomas' Hospital, London, UK; J Draffan, University Hospital of North Tees, Stockton on Tees, UK; K Franks, Clinical Oncology, St James's Institute of Oncology, Leeds, UK; F Gleeson, Department of Radiology, Oxford University Hospitals NHS Trust, Oxford, UK; R Graham, Royal United Hospital, Bath, UK; P Malhotra, St Helens and Knowsley Teaching Hospitals NHS Trust, UK; M Prokop, Department of Radiology and Nuclear Medicine, Radboud University Medical Center, Nijmegen, Netherlands; K A Rodger, Respiratory Medicine, St James's University Hospital, Leeds, UK; M Subesinghe, Department of Radiology, Churchill Hospital, Oxford, UK; D Waller, Department of Thoracic Surgery, Glenfield Hospital, Leicester, UK; I Woolhouse, Department of Respiratory Medicine, University Hospitals of Birmingham, Birmingham, UK; A Biagioli, Patient representative; C Paterson, Patient representative

Financial Disclosures/Conflicts of Interest

The Guideline Development Group (GDG) members adhered to the British Thoracic Society (BTS) policy for the Declaration of Interests (available on the BTS Web site or by contacting the BTS Head Office).

Competing interests: None.

Guideline Endorser(s)

British Nuclear Medicine Society - Medical Specialty Society

National Lung Cancer Forum For Nurses - Professional Association

Royal College of Physicians - Medical Specialty Society

Royal College of Radiologists - Medical Specialty Society

Society for Cardiothoracic Surgery in Great Britain and Ireland - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the British Thoracic Society (BTS) Web site .

Availability of Companion Documents

The following is available:

- British Thoracic Society Standards of Care Committee guideline production manual. London (UK): British Thoracic Society; 2014 Jul 1. 31 p. Available from the British Thoracic Society (BTS) Web site .
- Supplementary appendices are available from the BTS Web site .
- A pulmonary risk prediction calculator is available from the BTS Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on December 9, 2015. The information was verified by the guideline developer on January 5, 2016.

Copyright Statement

This summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouseâ„¢ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion-criteria.aspx.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.